

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	[AZITHROMYCIN,AZITHROMYCIN ANHYDROUS,AZITHROMYCIN DIHYDRATE,AZITHROMYCIN DIHYDROCHLORIDE,AZITHROMYCIN HEMIETHANOLATE MONOHYDRATE,AZITHROMYCIN MONOHYDRATE]			
Active Moiety:				
FDA Received Date:	From:	05-May-2015	To:	05-May-2020
MedDRA® Version* :	23.0			
Total Cases**:	10462			
Number of Pages:	3890			

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

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

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

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

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

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

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

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

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2015	11091174	NON-EXPEDITED			US-PFIZER INC-2015147999			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		250 Mg, Unk (Dose: 2; Qd X 4d)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2015	11091487	EXPEDITED (15-DAY)		DE	SI-TEVA-560152ISR		36 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Sumamed			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2015	11091988	EXPEDITED (15-DAY)		OT	US-BAXTER-2014BAX029677		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Decreased Appetite; Malaise; Nausea; Transaminases Increased; Weight Decreased	Fluconazole Injection, Usd			S	Unknown			Baxter	
	Tacrolimus			S	Unknown			Not Reported	
	Mycophenolate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Albendazole			S	Intravenous (not otherwise specified)			Not Reported	
	Pentamidine			S	Intravenous (not otherwise specified)			Not Reported	
	Miltefosine			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2015	11096082	EXPEDITED (15-DAY)		OT	2843179		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Drugs Affecting Foetus	Azithromycin			S	Transplacental		2 DAY	Not Reported
	Aciclovir			S	Transplacental			Not Reported
	Abacavir			S	Transplacental		2 DAY	Not Reported
	Bactrim			S	Transplacental			Not Reported
	Intelence			S	Transplacental		2 DAY	Not Reported
	Isentress			S			2 DAY	Not Reported
	Lamivudine			S	Transplacental		2 DAY	Not Reported
	Prezista			S	Transplacental		2 DAY	Not Reported
	Ritonavir			S			2 DAY	Not Reported
	Tenofovir			S	Transdermal		1 DAY	Not Reported
	Zidovudine			S	Transplacental		2 DAY	Not Reported
	Folic Acid			C				Not Reported
	Iron			C				Not Reported
	Magnesium Gluconate			C				Not Reported
	Prenatal Vitamins			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2015	11096169	EXPEDITED (15-DAY)	Y	DE	FK201502024		35 YR	Male	BGD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Azithromycin (Manufacturer Unknown) (Azithromycin)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2015	11096470	EXPEDITED (15-DAY)	Y	HO	FK201502025		50 YR	Male	BGD

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

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

Toxic Epidermal Necrolysis		Azithromycin (Manufacturer Unknown) (Azithromycin)		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	9647890	NON-EXPEDITED			US-PFIZER INC-2013300633			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	10633963	EXPEDITED (15-DAY)	Y	OT	ADR-2014-02266		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Device	Baclofen Intrathecal			S		22.928 Mcg/Day See B5		Not Reported	
Dislocation; Incorrect Route Of Product	Bupivacaine Intrathecal			S		3.668 Mg/Day See B5		Not Reported	
Administration; Kyphosis;	Morphine			S				Not Reported	
Lumbar Spinal Stenosis;	Dantrolene			S				Not Reported	
Medication Error; Muscle	Mirtazepine Teva			S				Not Reported	
Spasms; Rales; Spinal	Wellbutrin			S				Not Reported	
Compression Fracture;	Fluvoxamine			S				Not Reported	
Spinal Stenosis	Skelaxin			S				Not Reported	
	Robaxin			S				Not Reported	
	Gabapentin			S				Not Reported	
	Celebrex			S				Not Reported	
	Morphine			S				Not Reported	
	Baclofen			S				Not Reported	
	Bupivacaine			S				Not Reported	
	Alendronate (Fosamax)			S	Oral			Not Reported	
	Amoxicillin-Clavulanate (Augmentin)			S				Not Reported	
	Aspirin 81 Mg Ec			S	Oral			Not Reported	
	Atorvastatin (Lipitor)			S	Oral			Not Reported	
	Azithromycin (Zithromax)			S	Oral			Not Reported	
	Baclofen (Lioresal)			S	Oral			Not Reported	

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

Budesonide-Formoterol (Symbicort)	S	Respiratory (inhalation)	160-4.5 Mcg/Actuation Inhaler Inhale Two Puffs Into Lungs Two Times Daily	Not Reported
Bupropion (Wellbutrin)	S	Oral		Not Reported
Ca Citrate/Mgox/Vitd3/B6/Min (Calcium Citrate +D With Mag Oral)	S			Not Reported
Calcium	S	Oral		Not Reported
Celecoxib (Celebrex)	S	Oral		Not Reported
Dutasteride (Avodart)	S			Not Reported
Ergocalciferol (Vitamind)	S	Oral	50,000 Unit Oral Once Every Other Week	Not Reported
Fluvoxamine (Luvox)	S	Oral		Not Reported
Gabapentin (Neurontin) 300 Mg	S	Oral		Not Reported
Guaifenesin-Codeine (Guaifenesin Ac) 100-10mg/5ml Liquid Oral	S		5 MI Two Times Daily As Needed For Cough, One Half Teaspoon	Not Reported
Ipratropium Albuterol (Duoneb)	S	Respiratory (inhalation)	0.5 Mg-3mg (2.5 Mg Base) /3ml Neb Inhalation Solution Take 3 MI By Nebulization Twice Daily	Not Reported
Loratadine	S	Oral		Not Reported
Metaxalone (Skelaxin)	S	Oral		Not Reported
Methadone (Dolophine)	S	Oral		Not Reported
Mirtazapine (Remeron)	S	Oral		Not Reported
Mometasone (Nasonex)	S	Nasal	1.62 Percent (20.25 Mg/ 1.25 Gram) Gelpkt Place Onto Skin	Not Reported
Ondansetron (Zofran)	S	Oral		Not Reported
Pantoprazole (Protonix)	S	Oral		Not Reported
Sodium Chloride	S	Respiratory (inhalation)	Inhalation Solution 4 MI Nebulization Daily Inhale 4 MI One To Two Times Daily	Not Reported

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

Sterile Water (Pf) Solution	S			Not Reported
Morphine 100 Percent Pwd 2.2 Mg/Ml	S			Not Reported
Bupivacaine	S			Not Reported
Baclofen (Bulk) 100 Percent Pwd 75 Mcg/Ml	S			Not Reported
Basal Rate Morphine	S			Not Reported
Baclofen	S			Not Reported
Bupivacaine	S			Not Reported
Sucralfate (Carafate Oral)	S	Oral		Not Reported
Tamsulosin (Flomax) 0.4 Mg 24 Hour Capsule	S	Oral		Not Reported
Testosterone (Androgel) 1.62 Percent	S	Topical	(20.25 Mg/1.25 Gram) Gelpkt Place Onto Skin	Not Reported
Chlorzoxazone (Parafon Forte)	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	10953360	NON-EXPEDITED			US-PFIZER INC-2015102974			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Swelling; Urticaria	Azithromycin			S		Unk		Pfizer
	Tequin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	11059794	EXPEDITED (15-DAY)		OT	FR-SA-2015SA050513		61 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Neutropenia	Tavanic			S	Oral			Not Reported
	Lovenox			S	Unknown			Not Reported
	Lovenox			S	Subcutaneous			Not Reported
	Inexium			S	Oral			Not Reported
	Risperdal			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported

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

Spiramycin	C	Oral	9 Miu (3 Miu, 3 In 1 Day (S))	Not Reported
Erythromycin	C	Intravenous (not otherwise specified)		Not Reported
Levothyrox	C	Oral		Not Reported
Atarax	C	Oral		Not Reported
Lithium	C			Not Reported
Imurel	C			Not Reported
Teralithe Lp	C			Not Reported
Metformin	C			Not Reported
Rocephine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	11094662	NON-EXPEDITED			US-PFIZER INC-2015151293			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	11099582	EXPEDITED (15-DAY)		OT	2844077		21 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia Neonatal; Blood Lactic Acid Increased; Maternal Drugs Affecting Foetus	Azithromycin			S	Transplacental			Not Reported	
	Cefotaxime Sodium			S	Transplacental			Not Reported	
	Abacavir			S	Transplacental			Not Reported	
	Amlodipine			S	Transplacental			Not Reported	
	Intelence			S	Transplacental			Not Reported	
	Monopril			S	Transplacental			Not Reported	
	Prezista			S	Transplacental			Not Reported	
	Ritonavir			S	Transplacental			Not Reported	
	Tenofovir			S	Transplacental			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	11099596	EXPEDITED (15-DAY)	Y	OT	2844311		51 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity Vasculitis	Azithromycin			S		Not Reported, Unknown, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	11099605	EXPEDITED (15-DAY)		OT	2844340		56 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Foetal Exposure During Pregnancy	Azithromycin			S	Transplacental		2 DAY	Not Reported	
	Aciclovir			S	Transplacental			Not Reported	
	Abacavir			S	Transplacental		2 DAY	Not Reported	
	Bactrim			S	Transplacental			Not Reported	
	Intelence			S	Transplacental		2 DAY	Not Reported	
	Lamivudine			S	Transplacental		2 DAY	Not Reported	
	Prezista			S	Transplacental		2 DAY	Not Reported	
	Ritonavir			S			2 DAY	Not Reported	
	Tenofovir			S	Transplacental		1 DAY	Not Reported	
	Zidovudine			S	Transplacental		2 DAY	Not Reported	
	Folic Acid			C				Not Reported	
	Magnesium Gluconate			C				Not Reported	
	Iron			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2015	11099617	EXPEDITED (15-DAY)		OT	2844457		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Blood Thyroid Stimulating Hormone	Azithromycin			S				Not Reported	
	Amlodipine Besilate			S		2.5 Mg Milligram(S), 2 Day		Not Reported	

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

Decreased; Drug Interaction; Dyspnoea; Panic Reaction; Self-Injurious Ideation	Micardis	S	Oral	80 Mg Milligram(S), 1 Day	Not Reported
	Synthroid	S			Not Reported
	Hydrochlorothiazide	C			Not Reported
	W/Spirolactone				
	Warfarin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2015	9462424	EXPEDITED (15-DAY)		DE	PHHY2013NL087047		61 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Cardiac Arrest; Drug Ineffective; Neutropenia; Pyrexia	Azithromycin			S	Unknown			Novartis
	Thiamazole			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2015	11044259	NON-EXPEDITED			US-PFIZER INC-2015132753			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Macrobid			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2015	11097599	DIRECT		OT			25 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Palpitations	Azithromycin			S	Oral			Greenstone
	Benzonatate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2015	11098072	NON-EXPEDITED			US-PFIZER INC-2015154110			Female	USA

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

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

Drug Hypersensitivity	Flagyl	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer
	Midrin	S	Unk	Not Reported
	Acetaminophen	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2015	11088366	NON-EXPEDITED		OT	US-PFIZER INC-2015148182		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Syncope	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2015	11100253	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2015104609		24 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
	Zithromac			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2015	11101421	NON-EXPEDITED			US-PFIZER INC-2015152546			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2015	11101451	NON-EXPEDITED			US-PFIZER INC-2015154014			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	

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

Dilantin	S	Unk	Pfizer
Ibuprofen	S	Unk	Pfizer
Lasix	S	Unk	Not Reported
Naprosyn	S	Unk	Not Reported
Vioxx	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2015	11102329	EXPEDITED (15-DAY)		HO	FR-TEVA-561624ISR		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Not Reported	
	Lymecycline			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2015	11103862	EXPEDITED (15-DAY)		DS	GB-TEVA-561093ACC		18 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dizziness Postural; Faeces Pale; Rash	Azithromycin			S	Oral	4 Dosage Forms Daily;		Not Reported	
	Clarithromycin			C				Not Reported	
	Progesterone			C				Not Reported	
	Zapain			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	10990450	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015111486		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatinine Increased; Blood Urea Increased; Pain; Renal Failure	Bosulif			S	Oral	400 Mg (100mg 4 Tabs), Daily		Pfizer	
	Bosulif			S		400 Mg, Daily		Pfizer	
	Bosulif			S		400 Mg, Daily		Pfizer	
	Zithromax			S		Unk		Pfizer	

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

Valium	C	10 Mg, Unk	Not Reported
Valium	C	2 Mg, 4x/Day (As Needed)	Not Reported
Valium	C	10 Mg, 4x/Day	Not Reported
Amlodipine	C	2.5 Mg, 1x/Day	Not Reported
Humalog	C	Subcutaneous 30 Iu, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	11061440	NON-EXPEDITED			US-PFIZER INC-2015134983		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Disorder; Eyelid Ptosis; Headache; Impaired Driving Ability; Visual Impairment	Zithromax			S		1 Df, 2x/Day		Pfizer	
	Zithromax			S		1 Df, 1x/Day		Pfizer	
	Zithromax			S	Oral	1 Df, 4x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	11084059	EXPEDITED (15-DAY)		OT	PHHY2015BR051443		16 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Forced Expiratory Volume Decreased; Pseudomonas Infection; Staphylococcal Infection	Tobramycin			S	Unknown	Unk Unk, Qod		Not Reported	
	Azithromycin			S	Unknown			Novartis	
	Ursodeoxycholic Acid			S	Unknown			Not Reported	
	Dornase Alfa			S	Unknown			Not Reported	
	Pancreatic Enzymes			S	Unknown	Unk		Not Reported	
	Polivit/Vitamins Nos			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	11106456	EXPEDITED (15-DAY)		DS	GB-PFIZER INC-2015156496		18 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dizziness	Azithromycin			S	Oral	4 Df, 1x/Day		Pfizer	

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

Postural; Faeces Pale; Rash	Clarithromycin	C	Unk	Not Reported
	Progesterone	C	Unk	Not Reported
	Zapain	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	11176744	NON-EXPEDITED	Y		US-002967			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use	Miltefosine (Miltefosine) Capsule, 50mg			S				Not Reported
	Pentamidine			S				Not Reported
	Sulfadiazine			S				Not Reported
	Flucytosine			S				Not Reported
	Fluconazole (Fluconazole)			S				Not Reported
	Azithromycin (Azithromycin)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	11176765	NON-EXPEDITED	Y		US-I00037		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Off Label Use; Transaminases Increased	Miltefosine			S			155 DAY	Not Reported
	Azithromycin			S			162 DAY	Not Reported
	Albendazole			S	Oral		162 DAY	Not Reported
	Fluconazole			S	Oral		162 DAY	Not Reported
	Sulfadiazine			S	Oral		162 DAY	Not Reported
	Pentamidine			S	Intravenous (not otherwise specified)		7 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2015	11176809	NON-EXPEDITED	Y		US-002968			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use;	Miltefosine			S				Not Reported

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

Therapeutic Response	Pentamidine	S	Not Reported
Unexpected	Sulfadiazine	S	Not Reported
	Flucytosine	S	Not Reported
	Fluconazole (Fluconazole)	S	Not Reported
	Azithromycin (Azithromycin)	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2015	11031726	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2015125010		88 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression	Zithromac			S		500 Mg, Daily		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2015	11108875	NON-EXPEDITED		OT	GB-LUPIN PHARMACEUTICALS INC.-2015-01093		14 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness	Amikacin			S	Intravenous (not otherwise specified)	3 Courses		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftazidime			S	Intravenous (not otherwise specified)			Not Reported
	Flucloxacillin			S	Intravenous (not otherwise specified)			Not Reported
	Tobramycin			S	Unknown			Not Reported
	Gentamycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2015	11109876	NON-EXPEDITED			US-PFIZER INC-2015158066		75 YR	Female	USA

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

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

Diarrhoea	Azithromycin	S	Unk	Pfizer					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2015	11110648	EXPEDITED (15-DAY)		DS	PHHY2015GB055590		18 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dizziness	Azithromycin			S	Oral	4 Df, Qd		Novartis	
Postural; Faeces Pale;	Clarithromycin			C	Unknown			Not Reported	
Rash	Progesterone			C	Unknown			Not Reported	
	Zapain			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2015	11112652	DIRECT	Y	HO			14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2015	7232275	NON-EXPEDITED		OT	US-JNJFOC-20091204820		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Fungal Infection;	Levaquin			S	Oral	Course Completed		Not Reported	
Insomnia; Joint Swelling;	Levaquin			S	Oral			Not Reported	
Myalgia; Neuropathy	Levaquin			S	Oral			Not Reported	
Peripheral; Osteoarthritis;	Levaquin			S	Oral			Not Reported	
Psoriatic Arthropathy;	Levaquin			S	Oral			Not Reported	
Rheumatoid Arthritis;	Levaquin			S	Oral			Not Reported	
Tinnitus	Levaquin			S	Oral			Not Reported	
	Levaquin			S	Oral	Course Completed		Not Reported	
	Levaquin			S	Oral			Not Reported	
	Levaquin			S	Oral			Not Reported	

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

Levaquin	S	Oral	Course Completed	Not Reported
Cipro	S	Unknown		Not Reported
Cipro	S	Unknown		Not Reported
Zithromax	S	Unknown		Not Reported
Zithromax	S	Unknown		Not Reported
Prednisone	C	Oral		Not Reported
Naprosyn	C	Oral		Not Reported
Azulfidine	C	Oral		Not Reported
Allopurinol	C	Unknown		Not Reported
Acetaminophen\Hydrocodone Bitartrate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2015	10674414	NON-EXPEDITED			US-PFIZER INC-2014352115		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash; Varicella	Zithromax			S		Unk		Pfizer
	Zithromax			S				Pfizer
	Methotrexate			C		5 Mg, Monday, Wednesday And Friday		Not Reported
	Methotrexate			C		Unk		Not Reported
	Prednisone			C	Oral	5 Mg, 3x/Day		Not Reported
	Lisinopril W/Hydrochlorothiazide			C		20/25mg, Daily		Not Reported
	Acetaminophen W/Codeine			C		300-30mg, 3x/Day As Needed		Not Reported
	Gabapentin			C		100 Mg, 3x/Day, 7am, 3pm, 11pm		Not Reported
	Xeljanz			C		5 Mg, 1x/Day		Not Reported
	Lidocaine			C		2 Df, Daily 12 Hours On And 12 Hours Off		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2015	11111836	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015157549		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swollen Tongue	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Ceftriaxone			S	Oral	Unk		Not Reported	
	Humira			S		160 Mg, Unk		Not Reported	
	Humira			S		Unk		Not Reported	
	Humira			S		Unk		Not Reported	
	Humira			S		Unk		Not Reported	
	Lomotil			C		Unk		Not Reported	
	Hyoscyamine Sulfate			C		Unk		Not Reported	
	Iron			C		Unk		Not Reported	
	Iron			C				Not Reported	
	Multivitamins			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2015	11116426	DIRECT		OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin Tablets			S	Oral	6 Tablets, Taken 2 Then 1 Ea, 2 On Day 1, Then 1 A Day For 4 Days		Sandoz	
	Synthroid			C				Not Reported	
	Proair Hfa			C				Not Reported	
	Nasonex			C				Not Reported	
	Meloxicam			C				Not Reported	
	Fish Oil			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Allegra			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	10946995	EXPEDITED (15-DAY)		HO	CO-PFIZER INC-2015102589		14 YR	Male	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Dysbiosis; Off Label Use	Zitromax			S	Oral	500 Mg, 3x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	10948892	NON-EXPEDITED			US-PFIZER INC-2015098171		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Tums			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	10983383	NON-EXPEDITED			US-PFIZER INC-2015117766			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	11080773	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-96413		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Inappropriate Antidiuretic Hormone	Azithromycin			S	Unknown	Unk		Not Reported	
	Lymecycline			S	Unknown	Unk		Not Reported	

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

Secretion

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	11117014	NON-EXPEDITED			US-PFIZER INC-2015159446			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Zithromax			S		Unk		Pfizer	
	Victoza			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	11117048	NON-EXPEDITED			US-PFIZER INC-2015159678			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Erythema	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Avalox			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	11117083	NON-EXPEDITED			US-PFIZER INC-2015159396			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Reglan			S		Unk		Not Reported	
	Compazine			S		Unk		Not Reported	
	Nubain			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	11117098	NON-EXPEDITED			US-PFIZER INC-2015160529			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Tetracycline Hcl	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2015	11121569	EXPEDITED (15-DAY)	Y	OT	FK201502182		44 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Hepatitis; Jaundice Cholestatic	Azithromycin (Manufacturer Unknown) (Azithromycin)			S				Unknown
	Lymecycline (Lymecycline)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2015	11005104	NON-EXPEDITED			US-PFIZER INC-2015121564			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Levaquin			S	Oral	500 Mg, 1x/Day (X 10 Days)		Not Reported
	Codeine			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2015	11119202	NON-EXPEDITED			US-PFIZER INC-2015161330		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Dysphagia; Odynophagia; Oral Mucosal Exfoliation; Oral Pain; Oropharyngeal Pain	Azithromycin			S	Oral	1 G, Unk		Pfizer
	Zosyn			S	Oral	600 Mg, 2x/Day		Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	2 G In 500 Cc Over 4 Hours		Not Reported

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

Meropenem	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	80 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2015	11119861	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2015165058		22 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Anger; Concussion; Confusional State; Cyanosis; Disorganised Speech; Drug Hypersensitivity; Dysstasia; Eye Disorder; Fall; Gait Disturbance; Insomnia; Loss Of Consciousness; Mental Disorder; Muscle Disorder; Peripheral Coldness; Pulse Absent; Repetitive Speech; Restlessness	Azithromycin			S	Intramuscular	2000 Mg, Single		Pfizer
	Azithromycin			S				Pfizer
	Zithromax			S		500 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2015	11121936	DIRECT		OT			47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Urticaria	Azythromycin			S	Oral	6 Pills/5 Days		Not Reported
	Vit. C			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2015	11122490	DIRECT					44 YR	Female	USA

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

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

Cardiac Flutter; Eructation; Flatulence; Pruritus; Urticaria	Azithromycin 250 Mg Greenstone Llc Benadryl	S C	Oral	Greenstone Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	10956318	EXPEDITED (15-DAY)		HO	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-94589		82 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection	Amoxicillin			S	Unknown	500 Mg, Tid		Ranbaxy
	Azithromycin			S	Unknown	500 Mg, In The Morning		Not Reported
	Azithromycin			S	Oral	500 Mg, Stat		Not Reported
	Ciprofloxacin			S	Unknown	500 Mg, Unk		Ranbaxy
	Clarithromycin			S	Intravenous (not otherwise specified)	500 Mg, Bid		Not Reported
	Clarithromycin			S	Oral	500 Mg, Bid		Ranbaxy
	Doxycycline			S	Oral	200mg Stat, 100mg Daily		Ranbaxy
	Doxycycline			S	Oral	100 Mg, Qd		Ranbaxy
	Omeprazole			S	Oral	40 Mg, In The Morning		Astrazeneca
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, 3x1		Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	4.5 G, Tid		Not Reported
	Benzylpenicillin			S	Intravenous (not otherwise specified)	2.4 G, Qd		Not Reported
	Gentamicin			S	Intravenous drip	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	11102533	EXPEDITED (15-DAY)		DE	BD-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-97035		35 YR	Male	BGD

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

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

Toxic Epidermal Necrolysis		Azithromycin		S	Unknown		Unk	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	11102553	EXPEDITED (15-DAY)		OT	BD-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-97039		50 YR	Male	BGD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis		Azithromycin		S	Unknown		Unk	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	11122753	NON-EXPEDITED		OT	US-PFIZER INC- 2015165136			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Seizure		Zithromax		S	Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	11122757	NON-EXPEDITED			US-PFIZER INC- 2015162772			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ativan			S		Unk		Pfizer	
	Rapamune			S		Unk		Pfizer	
	Prednisone			S		Unk		Pfizer	
	Acyclovir			S		Unk		Not Reported	
	Pepcid			S		Unk		Not Reported	
	Dulera			S		Unk		Not Reported	
	Flexeril			S		Unk		Not Reported	
	Singulair			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	11123146	EXPEDITED (15-DAY)		DS	GB-MYLANLABS-2015M1015326			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dizziness Postural; Faeces Pale; Rash	Azithromycin			S	Oral	4 Df, Qd		Not Reported	
	Clarithromycin			C		Unk		Not Reported	
	Progesterone			C		Unk		Not Reported	
	Zapain			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2015	11124318	DIRECT		OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Colitis; Diarrhoea; Muscle Spasms; Vomiting; Vomiting	Azithromycin			S	Oral	6 Pills 2 Init, Then 1 Dai Taken By Mouth		Greenstone	
	Restasis			C				Not Reported	
	Dry Eye Omega Gelcaps			C				Not Reported	
	Multivitamin			C				Not Reported	
	Aspirin			C				Not Reported	
	Biotin			C				Not Reported	
	Vitamin D3			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	9015776	EXPEDITED (15-DAY)	Y	OT	2010JP003369		43 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Cough; Back Pain; Back Pain; Dental Caries; Diarrhoea; Drug Interaction; Dry Skin; Dyspepsia; Eczema; Enterocolitis Viral; Hypercholesterolaemia; Hyperlipidaemia;	Prograf			S	Oral	3 Mg, Unknown/D, Oral		Not Reported	
	Prednisolone			S	Oral			Not Reported	
					Oral				
					Oral	20-5 Mg, Alternately, Oral			
					Oral	17.5-5 Mg, Alternately, Oral			
					Oral	15-5 Mg, Alternately, Oral			

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

Intentional Product		Oral		
Misuse; Iron Deficiency		Oral		
Anaemia; Muscle Spasms;		Oral		
Nasopharyngitis;		Oral		
Oropharyngeal Pain; Pain		Oral		
In Extremity; Pruritus;		Oral	5-12.5 Mg, Alternately,	
Rash			Oral	
		Oral		
		Oral		
		Oral		
		Oral	17.5-5 Mg, Alternately,	
			Oral	
		Oral		
		Oral		
		Oral		
		Oral		
Flomox [Cefcapene Pivoxil	S	Oral	300 Mg, Unknown/D/, Oral	Not Reported
Hydrochloride]		Oral		
Zithromac	S	Oral	2 G, Unknown/D, Oral	Not Reported
Lipitor	S	Oral		Not Reported
Gaster (Famotidine)	C			Not Reported
Myser (Difluprednate)	C			Not Reported
Incremin (Ferric Pyrophosphate)	C			Not Reported
Restamin (Diphenhydramine)	C			Not Reported
PI (Non-Pyrine Cold Preparation)	C			Not Reported
Cocarl (Acetaminophen)	C			Not Reported
Biofermin R (Antibiotics-	C			Not Reported
Resistant Lactic Acid Bacteriae)				
Lac-B (Bifidobacterium)	C			Not Reported
Lopemin (Loperamide	C			Not Reported
Hydrochloride)				
Onon (Pranlukast Hydrate)	C			Not Reported
Buscopan (Scopolamine	C			Not Reported
Butylbromide)				
Propeto (White Petrolatum)	C			Not Reported
Epadel-S (Eicosapentaenoic	C			Not Reported
Acid Ethyl Ester)				

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

Edirol (Eldecalcitol) Capsule	C	Not Reported
Baktar (Sulfamethoxazole/Trimethoprim)	C	Not Reported
Alfarol (Alfacalcidol)	C	Not Reported
Persantin-L (Dipyridamole)	C	Not Reported
Modified-Release Capsule, Hard		
Isodine Gargle (Povidone Iodine)	C	Not Reported
Juvela (Tocopherol Acetate)	C	Not Reported
Lutoral (Chlormadinone Acetate)	C	Not Reported
Pariet (Sodium Rabeprazole)	C	Not Reported
Fosamac (Alendronate Sodium)	C	Not Reported
Glakay (Menatetrenone)	C	Not Reported
Premarin (Conjugated Estrogens)	C	Not Reported
Mevalotin (Pravastatin Sodium)	C	Not Reported
Imuran (Azathioprine)	C	Not Reported
Bredinin (Mizoribine)	C	Not Reported
Indometacin (Indometacin)	C	Not Reported
Zetia (Ezetimibe)	C	Not Reported
Loxonin (Loxoprofen Sodium)	C	Not Reported
Selbex (Teprenone)	C	Not Reported
Ferromia (Ferrous Sodium Citrate)	C	Not Reported
Juvela N (Tocopherol Nicotinate)	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	11031718	EXPEDITED (15-DAY)		DE	JP-PFIZER INC- 2015125091		76 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Drug Administration Rate; Lung Neoplasm Malignant	Zithromac			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer	
	Maxipime			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	11124920	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2015162830		71 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Peripheral Arterial Occlusive Disease; Peripheral Vascular Disorder; Skin Ulcer	Novatrex	S	Oral	20 Mg, Weekly	Pfizer
	Lyrica	S	Oral	150 Mg, 2x/Day	Pfizer
	Pravastatin Sodium	S	Oral	40 Mg, 1x/Day	Not Reported
	Plavix	S	Oral	75 Mg, 1x/Day	Not Reported
	Bisocor	S	Oral	1.25 Mg, 1x/Day	Not Reported
	Durogesic	S	Transdermal	1 Df (50 Mg/H [8.4 Mg/21 Cm^2]), Every 3 Days	Not Reported
	Actiskenan	S	Oral	25 Mg, 3x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	11125169	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015166731		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	11125441	NON-EXPEDITED			US-PFIZER INC-2015163898			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Lortab			S		Unk		Not Reported	
	Tylox			S		Unk		Not Reported	
	Novocaine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	11126621	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015162806		24 YR	Male	FRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Thrombocytopenia; Melaena	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Grisefuline			S	Oral	500 Mg, 1x/Day		Not Reported	
	Grisefuline			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2015	11127245	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Diarrhoea; Dysuria	Azithromycin			S	Oral	2 To Start - Then 1 Mouth		Greenstone	
	Coq10			C				Not Reported	
	D3			C				Not Reported	
	Probiotic			C				Not Reported	
	B12			C				Not Reported	
	Immune Booster			C				Not Reported	
	Air Bourn			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2015	11117086	NON-EXPEDITED			US-PFIZER INC-2015160984			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Inapsine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2015	11127930	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2015M1016265			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Oral Mucosal Exfoliation; Oral Pain; Oropharyngeal Pain	Vancomycin			S	Intravenous (not otherwise specified)	2 G In 500cc Over 4 Hrs		Mylan	

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

Zosyn	S	Oral	600 Mg, Bid	Not Reported
Azithromycin	S		1 G, Qd	Not Reported
Meropenem	S	Intravenous (not otherwise specified)	Unk, Q6h	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	80 Mg, Q12h, Iv Push	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2015	11129069	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2015166730		44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ammonia Increased; Haemodialysis; Nervous System Disorder; Pathogen Resistance	Azithromycin			S	Parenteral	500 Mg, Daily		Pfizer
	Azithromycin			S		Unk		Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer
	Vancomycin			S		Unk		Unknown
	Vancomycin			S				Unknown
	Cefepime			S		Unk		Not Reported
	Cefepime			S				Not Reported
	Voriconazole			S		Unk		Not Reported
	Valganciclovir			S		Unk		Not Reported
	Tacrolimus			C		Unk		Not Reported
	Mycophenolate Mofetil			C		1000 Mg, 2x/Day		Pfizer
	Prednisone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2015	11129232	NON-EXPEDITED			US-PFIZER INC-2015165746			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Condition Aggravated; Constipation; Decreased Appetite; Depression;	Azithromycin			S		Unk		Pfizer
	Iron			S				Not Reported

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

Diarrhoea; Faeces
Discoloured; Flatulence

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2015	11130606	DIRECT		HO, LT			27 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute; Pharyngitis; Pyrexia	Ibugesic Plus Azithromycin			S S	Oral			Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2015	11101175	EXPEDITED (15-DAY)			ID-PFIZER INC- 2015154330			Unknown	IDN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Lethargy; Vomiting	Zithromax			S	Oral	1 Df, Single		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2015	11133291	NON-EXPEDITED			US-009507513- 1505USA010748		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Multiple- Drug Resistance	Invanz Amikacin Azithromycin Ciprofloxacin Ethambutol Isoniazid Linezolid Meropenem Pyrazinamide Rifampin Tigecycline			S S S S S S S S S S S	Unknown			Merck Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2015	11135459	DIRECT					38 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Arthralgia; Constipation; Discomfort; Dizziness; Hyperhidrosis; Hypoaesthesia; No Reaction On Previous Exposure To Drug; Oropharyngeal Pain; Pharyngeal Swelling; Pyrexia	Azithromycin			S	Oral	6 Pills Once Daily Taken By Mouth		Greenstone	
	Adderall			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2015	11135586	DIRECT	Y	HO			32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Phosphokinase Increased; Dyspnoea; Fatigue; Muscular Weakness	Azithromycin 250mg			S	Oral	500mg Day 1; 250mg Days 2-5 Qd		Not Reported	
	Atorvastatin 40mg Watson			S	Oral			Not Reported	
	Amlodipine Besylate			C				Not Reported	
	Aspirin			C				Not Reported	
	Fosinopril			C				Not Reported	
	Hydrochlorothiazide			C				Not Reported	
	Metformin Hcl			C				Not Reported	
	Clotrimazole			C				Not Reported	
	Insulin			C				Not Reported	
Novolog Flexpen			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2015	11133642	NON-EXPEDITED			US-JNJFOC- 20150212760			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Decreased Appetite; Nausea; Off Label Use; Pyrexia	Sirturo			S	Oral	With Food For The First 2 Weeks		Not Reported	
	Sirturo			S	Oral	With Food For The First 2 Weeks		Not Reported	

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

Azithromycin	S	Unknown		Not Reported
Ethambutol	S	Unknown		Not Reported
Streptomycin	S	Intramuscular		Not Reported
Streptomycin	S	Intravenous (not otherwise specified)		Not Reported
Amikacin	S	Intravenous (not otherwise specified)		Not Reported
Rifabutin	S	Unknown	150-300 Mg	Not Reported
Amikacin	S	Respiratory (inhalation)	500 Mg Daily Or 3 Times A Week Via Pari Lc Nebulizer	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2015	10942524	NON-EXPEDITED			US-JNJFOC-20130909959		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Invokana			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	9436881	NON-EXPEDITED		OT	US-JNJFOC-20130306546			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Emotional Disorder; Exposure During Pregnancy	Topamax			S	Oral	25-50mg		Not Reported	
	Relpax			S	Oral			Not Reported	
	Omeprazole			S	Oral			Not Reported	
	Benadryl			S	Oral			Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	9436883	NON-EXPEDITED		CA, HO, OT	US-JNJFOC-20130306547		< 1 DAY	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aortic Valve Atresia; Atrial Septal Defect; Atrial Septal Defect; Emotional Disorder; Failure To Thrive; Foetal Exposure During Pregnancy;	Topamax			S	Transplacental			Not Reported	
Gastrooesophageal Reflux Disease; Hypoplastic Left Heart Syndrome;	Relpax			S	Transplacental			Not Reported	
Laryngomalacia; Mitral Valve Atresia; Patent Ductus Arteriosus	Omeprazole			S	Transplacental			Not Reported	
	Benadryl			S	Transplacental			Not Reported	
	Zithromax			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	9706526	NON-EXPEDITED		CA	US-JNJFOC-20131111629			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Attention Deficit Hyperactivity Disorder;	Topamax			S	Transplacental			Not Reported	
Cardiac Murmur; Cardiac Valve Disease; Cleft Lip;	Topamax			S	Transplacental	Maternal Dosing		Not Reported	
Cleft Palate; Ear Disorder; Emotional Disorder;	Topamax			S	Transplacental			Not Reported	
Eustachian Tube Dysfunction; Foetal Exposure During Pregnancy	Topamax			S	Transplacental	Maternal Dosing		Not Reported	
	Topamax			S	Transplacental			Not Reported	
	Topamax			S	Transplacental	Maternal Dosing		Not Reported	
	Topamax			S	Transplacental			Not Reported	
	Topamax			S	Transplacental	Maternal Dosing		Not Reported	
	Maxalt			S	Transplacental			Not Reported	
	Zoloft			S	Transplacental			Not Reported	
	Zoloft			S	Transplacental			Not Reported	
	Doxepin			S	Transplacental			Not Reported	
	Meclizine			S	Transplacental			Not Reported	
	Hydroxyzine Pamoate			S	Transplacental			Not Reported	
	Zithromax			S	Transplacental			Not Reported	

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

Zyrtec	Y	S	Transplacental	Not Reported
Zyrtec		S	Transplacental	Not Reported
Sulfamethoxazole/Trimethoprim		S	Transplacental	Not Reported
Amitriptyline Hcl		S	Transplacental	Not Reported
Primacare		S	Transplacental	Not Reported
Ery-Tab		S	Transplacental	Not Reported
Amoxicillin		S	Transplacental	Not Reported
Spirolactone		S	Transplacental	Not Reported
Ibuprofen		S	Transplacental	Not Reported
Phenazopyridine		S	Transplacental	Not Reported
Ferrous Sulfate		C	Transplacental	Not Reported
Iron		C	Transplacental	Not Reported
Prenatal Vitamins		C	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	10074696	NON-EXPEDITED		OT	US-JNJFOC-20131111626			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Emotional Disorder; Exposure During Pregnancy; Off Label Use; Pre-Eclampsia; Twin Pregnancy	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Zoloft			S	Oral			Not Reported
	Zoloft			S	Oral			Not Reported
	Doxepin			S	Oral			Not Reported

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

Meclizine		S	Oral	Not Reported
Hydroxyzine Pamoate		S	Oral	Not Reported
Zithromax		S	Unknown	Not Reported
Zyrtec	Y	S	Oral	Not Reported
Zyrtec		S	Oral	Not Reported
Sulfamethoxazole/Trimethoprim		S	Unknown	Not Reported
Amitriptyline Hcl		S	Unknown	Not Reported
Primacare		S	Unknown	Not Reported
Ery-Tab		S	Oral	Not Reported
Amoxicillin		S	Unknown	Not Reported
Spironolactone		S	Unknown	Not Reported
Ibuprofen		S	Unknown	Not Reported
Phenazopyridine		S	Oral	Not Reported
Maxalt		S	Oral	Not Reported
Ferrous Sulfate		C	Oral	Not Reported
Iron		C	Unknown	Not Reported
Prenatal Vitamins		C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	10310640	NON-EXPEDITED		CA, OT	US-JNJFOC-20130306581			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cleft Palate; Dental Caries; Foetal Exposure During Pregnancy	Topamax			S	Transplacental	Mother'S Dosing		Not Reported	
	Zithromax			S	Transplacental	Mother'S Dosing		Not Reported	
	Tessalon			S	Transplacental	Mother'S Dosing		Not Reported	
	Entex Pse			S	Transplacental	Mother'S Dosing		Not Reported	
	Anaplex			S	Transplacental	Mother'S Dosing		Not Reported	
	Robaxin			S	Transplacental	Mother'S Dosing		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	10937095	NON-EXPEDITED			US-JNJFOC-20130306579			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy	Topamax			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Tessalon			S	Oral			Not Reported	
	Entex Pse			S	Oral			Not Reported	
	Anaplex			S	Oral			Not Reported	
	Robaxin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019283	NON-EXPEDITED		DE, HO	US-JNJFOC-20110308427			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Levaquin			S	Oral			Not Reported	
	Levaquin			S	Oral			Not Reported	
	Levaquin			S	Oral			Not Reported	
	Levaquin			S	Oral			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019460	NON-EXPEDITED			US-JNJFOC-20130916847			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia	Levaquin			S	Unknown	On Day 1,Followed By 500mg/D		Not Reported	
	Ethambutol			S		25/Mg/Kg/D Up To Maximum Dosage Of 1200mg/D		Not Reported	

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

Azithromycin	S	500 Mg On Day 1, Followed By 250mg/D	Not Reported
Azithromycin	S		Not Reported
Rifampin	S	10mg/Kg/D Up To Maximum Dosage Of 300mg/D	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019488	NON-EXPEDITED			US-JNJFOC- 20130916846			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia	Levaquin			S	Unknown	Day 1		Not Reported
	Levaquin			S	Unknown			Not Reported
	Ethambutol			S	Unknown	Upto A Maximum Dosage Of 1200 Mg Per Day		Not Reported
	Azithromycin			S	Unknown	One Day 1		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Rifampin			S	Unknown	10mg/Kg/Day Upto a Maximum Dosage Of 300 Mg/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019571	NON-EXPEDITED			US-JNJFOC- 20130916425			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Levaquin			S	Unknown	Day 1		Not Reported
	Ethambutol			S	Unknown	Upto A Maximum Dosage Of 1200 Mg Per Day		Not Reported
	Azithromycin			S	Unknown	On Day 1		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Rifampin			S	Unknown	Upto A Maximum Dosage Of 300 Mg/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019572	NON-EXPEDITED			US-JNJFOC-20140203709		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Levofloxacin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019588	NON-EXPEDITED		OT	US-JNJFOC-20150114028			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Arthralgia; Aspartate Aminotransferase Increased; Hepatitis; Insomnia; Leukopenia; Rash	Levofloxacin			S	Unknown	On Day 1		Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Ethambutol			S	Unknown	15 Mg/Kg/Day To A Maximum Of 1200 Mg Once A Day		Not Reported	
	Azithromycin			S	Unknown	On Day 1		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Rifampin			S	Unknown	10mg/Kg/D To A Maximum Of 600 Mg Once Daily		Not Reported	
	Rifabutin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019654	NON-EXPEDITED			US-JNJFOC-20150219223			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Fluconazole		Y	S	Unknown			Not Reported	
	Levaquin			S	Unknown			Not Reported	
	Atenolol			S	Unknown			Not Reported	

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

Vancomycin	S	Unknown	Not Reported
Amitrip	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Zithromax	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11019777	NON-EXPEDITED			US-JNJFOC-20140615367			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Malaise; Pneumonia; Sinusitis	Levaquin			S	Oral	14 Days		Not Reported
	Levaquin			S	Oral			Not Reported
	Z-Pack			S	Unknown			Not Reported
	Biaxin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11065005	NON-EXPEDITED			US-JNJFOC-20130310434			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Emotional Disorder; Exposure During Pregnancy	Topamax			S	Oral			Not Reported
	Topiramate			S	Unknown			Not Reported
	Metronidazole			S	Vaginal			Not Reported
	Prometrium			S	Vaginal			Not Reported
	Nitrofurantoin			S	Oral			Not Reported
	Nifedipine			S	Oral			Not Reported
	Terbutaline			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ferrous Sulfate			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11065063	NON-EXPEDITED			US-JNJFOC-20111104649			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Exposure During Pregnancy; Stress	Topamax			S	Oral			Not Reported	
	Topamax			S	Oral			Not Reported	
	Topamax			S	Oral			Not Reported	
	Topamax			S	Oral			Not Reported	
	Topamax			S	Oral			Not Reported	
	Zantac			S	Oral			Not Reported	
	Keppra			S	Oral			Not Reported	
	Lexapro			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Sulphacetamide			S	Unknown			Not Reported	
	Phenergan			S	Unknown			Not Reported	
	Acebutolol			S	Unknown			Not Reported	
	Ferrous Sulfate			C	Unknown			Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Prenatal Vitamins			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11065071	NON-EXPEDITED			US-JNJFOC-20130215761			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Emotional Disorder; Exposure During Pregnancy; Product Use In Unapproved Indication	Topamax			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Clindesse			S	Vaginal			Not Reported	
	Vitamin			C	Oral			Not Reported	
	Primacare			C	Oral			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11065903	NON-EXPEDITED			US-JNJFOC-20150209181			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; International Normalised Ratio Increased	Levaquin			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Piperacillin-Tazobactam			S	Unknown			Not Reported	
	Warfarin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11074825	NON-EXPEDITED			US-JNJFOC-20130916779		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Blood Pressure Increased; Diarrhoea; Drug Delivery System Malfunction; Formication; Insomnia; Multiple Allergies; Nausea; Product Dose Omission; Rhinitis; Sinusitis	Simponi			S	Subcutaneous			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Z Pak			S	Unknown			Not Reported	
	Z Pak			S	Unknown			Not Reported	
	Z Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11135191	EXPEDITED (15-DAY)		OT	US-JNJFOC-20150512462			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Arthralgia; Meniscus Injury	Levaquin	S	Oral		Not Reported
	Zithromax	S	Unknown		Not Reported
	Codeine	S	Unknown		Not Reported
	Cipro	S	Unknown		Not Reported
	Tramadol Hydrochloride	C	Oral		Not Reported
	Veramyst	C	Unknown		Not Reported
	Claritin	C	Unknown		Not Reported
	Viagra	C	Unknown		Not Reported
	Albuterol Sulfate	C	Unknown		Not Reported
	Zyrtec	C			Not Reported
	5 Htp [Oxtripitan]	C	Unknown		Not Reported
	Ipratropium Bromide	C	Nasal	0.03% Solution	Not Reported
	Nystatin	C			Not Reported
	Multivitamins	C	Unknown		Not Reported
	Ultravate	C	Unknown		Not Reported
	Imitrex	C	Unknown		Not Reported
	Keflex	C	Unknown		Not Reported
	Tessalon Perles	C	Unknown		Not Reported
	Medrol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2015	11138184	NON-EXPEDITED		OT	GB-JNJFOC-20141004908		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Levaquin			S	Oral			Not Reported	
	Vemurafenib			S	Oral			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	
	Zosyn			S	Intravenous (not			Not Reported	

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

			otherwise specified)	
Lisinopril	C	Oral		Not Reported
Folic Acid	C	Oral		Not Reported
Aspirin	C	Oral		Not Reported
Vitamin D Nos	C	Oral	1 Tablet	Not Reported
Probiotics	C	Oral	1 Tablet	Not Reported
Melatonin	C	Oral	At Bed Time	Not Reported
Ambien	C	Oral	At Bed Time	Not Reported
Ibuprofen	C	Oral	2 Tablets	Not Reported
Colace	C	Oral	1-2 Tablets	Not Reported
Miralax	C	Oral	1-2 Tablets	Not Reported
Loratadine	C	Oral	1 Tablet	Not Reported
Percocet	C	Oral	1 Tablet	Not Reported
Triamcinolone Acetonide	C	Topical	1 Tablet	Not Reported
Clobetasol	C	Topical	1 Tablet	Not Reported
Triamcinolone Acetonide	C	Topical	1 Tablet	Not Reported
Ursodiol	C	Oral	1 Tablet	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2015	10507670	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2014274079		20 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Hypothermia; Tachycardia	Zithromac			S	Oral	1000 Mg, Single		Pfizer
	Zithromac			S				Pfizer
	Ms			C	Transdermal			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2015	11144363	NON-EXPEDITED			US-PFIZER INC-2015171143			Female	USA

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

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

Drug Hypersensitivity; Headache		Azithromycin		S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	11145113	DIRECT					11 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Urticaria	Cefdinir			S	Oral	1 Capsule Twice Daily Taken By Mouth		Lupin	
	Azithromycin			S	Oral	2 Pills Day 1, 1 Pill For 4 Days, Taken By Mouth		Teva	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-May-2015	11145365	EXPEDITED (15-DAY)		OT	IT-TEVA-562232ACC		41 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Lip Oedema; Oral Discomfort; Rash	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11138767	EXPEDITED (15-DAY)		OT	US-TEVA-562932USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pulmonary Congestion; Wheezing	Azithromycin			S		200/5		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11139528	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015174030		12 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Complex Regional Pain Syndrome; Diarrhoea; Dyspepsia; Eating Disorder; Nausea;	Azithromycin			S		250 Mg, 2 Tablets On The First Day		Pfizer	
	Azithromycin			S		250 Mg One Tablet After		Pfizer	

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

Product Complaint;
Vomiting

That

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11139939	NON-EXPEDITED			US-PFIZER INC- 2015175270		66 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Pilocarpine Hcl			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11141820	NON-EXPEDITED			US-PFIZER INC- 2015167769		12 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Complaint; Reaction To Excipient	Azithromycin			S		Unk, As Needed		Pfizer	
	Zithromax			S		Unk, As Needed		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-May-2015	11142730	EXPEDITED (15-DAY)		OT	PHHY2015BR063766		9 YR	Male	BRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Faecal Elastase Concentration Decreased; Glucose Tolerance Impaired; Hyperglycaemia; Pseudomonas Infection; Rhinitis Allergic	Tobramycin			S	Respiratory (inhalation)	300 Mg, Bid (28 Days Every Alternate Month)		Novartis	
	Zoteon Podhaler			S	Respiratory (inhalation)	112 Mg, Bid (On And Off)		Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Colistimethate			S	Respiratory (inhalation)	Unk		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Tiw		Not Reported	
	Dornase Alfa			C	Unknown			Not Reported	
	Salbutamol			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2015	11142830	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2015M1017407			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nervous System Disorder; Pathogen Resistance	Azithromycin			S	Parenteral	500 Mg, Qd		Not Reported	
	Vancomycin			S		Unk		Mylan	
	Vancomycin			S				Mylan	
	Voriconazole			S		Unk		Not Reported	
	Trimethoprim Sulfamethoxazole			S		Unk		Not Reported	
	Cefepime			S		Unk		Not Reported	
	Cefepime			S				Not Reported	
	Valganciclovir			S				Not Reported	
	Tacrolimus			C		Unk		Not Reported	
	Mycophenolate Mofetil			C				Not Reported	
	Prednisone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2015	11146295	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015173944			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Metal Poisoning; Off Label Use; Product Complaint	Azithromycin			S		250 Mg, Unk For A Long Time		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2015	10622998	EXPEDITED (15-DAY)		DE	MY-PFIZER INC-2014326735			Unknown	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia	Zithromax			S	Oral	1000 Mg, Weekly		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2015	10623000	EXPEDITED (15-DAY)		DE	MY-PFIZER INC-2014326653			Unknown	MYS

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Pneumonia	Zithromax			S	Oral	1000 Mg, Weekly		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2015	11057105	EXPEDITED (15-DAY)		DE	JP-PFIZER INC- 2015135412		69 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Respiratory Failure	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
	Mycobutin			C	Oral	300 Mg, Daily		Pfizer	
	Ethambutol			C	Oral	750 Mg, Daily		Not Reported	
	Moxifloxacin			C	Oral	400 Mg, Daily		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11133165	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2015159400		41 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Lip Oedema; Rash	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11145176	NON-EXPEDITED			US-PFIZER INC- 2015174082			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Lead Urine Increased; Lead Urine Increased; Urine Antimony Increased	Azithromycin			S		1 G, Daily		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2015	11151880	NON-EXPEDITED			US-PFIZER INC- 2015180133		59 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Nausea; Rash		Cleocin		S		Unk		Pfizer	
		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2015	11155799	DIRECT		LT			75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Oral	Strength: 250 Mg, Quantity: 6 Tablets 1 Per Day, 1x Day, Mouth		Teva	
	Lopresor			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	10594263	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2014- BI-55		82 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Haematuria	Pradaxa			S	Oral	220 Mg		Boehringer Ingelheim	
	Hydrea			S	Unknown			Not Reported	
	Hydrea			S	Unknown	0.5 Anz		Not Reported	
	Novatrex			S	Oral	15 Mg		Not Reported	
	Ramipril			C	Unknown			Not Reported	
	Spiriva			C	Unknown			Not Reported	
	Seretide Diskus			C	Unknown	Dose Per Application :250/50mcg		Not Reported	
	Cortancyl			C	Unknown			Not Reported	
	Levothyrox			C	Unknown			Not Reported	
	Mecir			C	Unknown			Not Reported	
	Adenuric			C	Unknown			Not Reported	
	Kardegic			C	Unknown			Not Reported	

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

	Inexium		C	Unknown					Not Reported
	Natispray		C	Unknown					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	11155349	NON-EXPEDITED			US-PFIZER INC-2015185276		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Doxycycline Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Benadryl			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	11155633	EXPEDITED (15-DAY)		HO, LT	JP-PFIZER INC-2015135298		81 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acquired Haemophilia	Unasyn-S			S	Intravenous drip	3 G, 2x/Day		Pfizer	
	Zithromac Sr			S	Oral	2 G, Single		Pfizer	
	Physiosol			C	Intravenous drip	500 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	11156172	EXPEDITED (15-DAY)		DS	PHHY2015FI062076		40 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Ineffective; Fatigue; General Physical Health Deterioration; Headache; Insomnia; Nausea; Tinnitus; Tremor	Azithromycin Sandoz			S	Oral	500 Mg, Qd		Novartis	
	Azithromycin Sandoz Duact			S				Novartis	
	Duact			C	Oral	1 Df, Tid		Not Reported	
	Duact			C	Oral	1 Df, Tid		Not Reported	

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

Buventol	C	Respiratory (inhalation)	Not Reported
Flavamed	C	1 Df, Tid, 3 Days And 1 Df Till The End Of Treatment To Remove Mucus	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	11158358	DIRECT		HO, LT			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Cough; Pharyngeal Oedema; Swollen Tongue	Azithromycin			S	Oral			Not Reported	
	Lisinopril			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	11158744	DIRECT	Y	HO, LT			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Lisinopril			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2015	11159595	DIRECT					17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Azithromycin			S	Oral	2 On 1st Day; 1/Day For 4 Days		Teva	
	Ambien			C				Not Reported	
	Ibuprofen			C				Not Reported	
	Excedrin Migraine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2015	10467909	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014256607		43 YR	Female	FRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatic Failure; Hepatitis; Jaundice Cholestatic	Zithromax			S	Oral	Unk		Pfizer	
	Tetralysal [Lymecycline]			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2015	11158623	NON-EXPEDITED			US-PFIZER INC-2015176571		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2015	11159065	NON-EXPEDITED			US-PFIZER INC-2015177505		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Benzonatate			S	Oral	100 Mg, 3 Times Per Day Prn		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2015	11159825	EXPEDITED (15-DAY)		OT	US-SA-2015SA074920		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperthyroidism; Pruritus; Weight Decreased	Lovenox			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Singulair			C				Not Reported	
	Flovent			C	Respiratory (inhalation)			Not Reported	
	Albuterol			C				Not Reported	

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

	Metoclopramide	C	Not Reported
	Norco	C	Not Reported
	Fiorinal	C	Not Reported
	Chlorphenamine	C	Not Reported
	Apap	C	Not Reported
	Coumadin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2015	11164386	NON-EXPEDITED			US-PFIZER INC-2015182527		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2015	11165068	NON-EXPEDITED			US-PFIZER INC-2015185606			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Hydralazine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2015	11170240	EXPEDITED (15-DAY)	Y	HO, OT	A201309457		51 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cytopenia; Diabetes Mellitus; Diarrhoea; Hyperlipidaemia; Hyperuricaemia; Liver Disorder; Lymphadenitis; Mycobacterium Avium Complex Infection; Osteoporosis; Periarthritis; Renal Impairment	Abacavir Sulfate + Lamivudine			S	Oral			Not Reported
	Norvir (Ritonavir) Tablet			S	Oral			Not Reported
	Prezistanaive (Darunavir Ethanolate) Tablet			S	Oral			Not Reported
	Valixa (Valganciclovir) Tablet			S	Oral			Not Reported
					Oral			
					Oral			
					Oral			

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

		Oral	
		Oral	
		Oral	
Zithromac	S		Not Reported
Baktar	S	Oral	Not Reported
		Oral	
Esanbutol	S	Oral	Not Reported
		Oral	
Bezatos Sr	S	Oral	Not Reported
Fosamac	S	Oral	Not Reported
Lipidil	S	Oral	Not Reported
Truvada (Emtricitabine + Tenofovir Disoproxil Fumarate) Tablet	C		Not Reported
Denosine (Ambiguous Medication) Injection	C		Not Reported
Mycobutin (Rifabutin) Capsule	C		Not Reported
Samtarel (Atovaquone) Oral Drug Unspecified Form	C		Not Reported
Sawacillin (Amoxicillin Trihydrate) Capsule	C		Not Reported
Risumic (Amezinium Metilsulfate) Tablet	C		Not Reported
Maglax (Magnesium Oxide) Tablet	C		Not Reported
Cephadol (Difenidol Hydrochloride) Oral Drug Unspecified	C		Not Reported
Vfend (Voriconazole) Tablet	C		Not Reported
Talion (Ambiguous Medication) Tablet	C		Not Reported
Fluconazole (Fluconazole) Capsule	C		Not Reported
Enteronon-R (Streptococcus Faecalis) Powder (Except [Dpo])	C		Not Reported
Omeptorol (Omeprazole) Tablet	C		Not Reported
Lopemin (Loperamide Hydrochloride) Capsule	C		Not Reported
Myonal (Eperisone Hydrochloride) Tablet	C		Not Reported

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

Loxonin (Loxoprofen Sodium) Tablet	C	Not Reported
Tannalbin (Albumin Tannate) Powder (Except [Dpo])	C	Not Reported
Nauzelin (Domperidone) Tablet	C	Not Reported
Gasmotin (Mosapride Citrate) Tablet	C	Not Reported
Ceftriaxone Na (Ceftriaxone) Injection	C	Not Reported
Cravit (Levofloxacin) Tablet	C	Not Reported
Myslee (Zolpidem Tartrate) Tablet	C	Not Reported
Marzulene-S (Azulene + Levoglutamide) Grain	C	Not Reported
Rohypnol (Flunitrazepam) Tablet	C	Not Reported
Farom (Faropenem Sodium) Tablet	C	Not Reported
Cefepime Dihydrochloride Hydrate (Cefepime Hydrochloride) Injection	C	Not Reported
Prodif (Fosfluconazole) Injection	C	Not Reported
Foscavir (Foscarnet Sodium) Injection	C	Not Reported
Foliamin (Folic Acid) Tablet	C	Not Reported
Zosyn (Piperacillin Sodium + Tazobactam Sodium) Injection	C	Not Reported
Kefral (Cefaclor) Capsule	C	Not Reported
Rebamipide (Rebamipide) Tablet	C	Not Reported
Calonal (Paracetamol) Tablet	C	Not Reported
Zyloric (Allopurinol) Tablet	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	10471073	EXPEDITED (15-DAY)		HO, OT	PHEH2014US018158		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Immunoglobulin E Increased; Choking; Condition Aggravated; Cough; Cystic Fibrosis;	Tobi Podhaler			S	Respiratory (inhalation)	112 Mg, Twice A Day		Novartis
	Tobi Podhaler			S	Respiratory	4 Df, Bid		Novartis

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

Dyspnoea; Fatigue; General Physical Health Deterioration; Obstructive Airways Disorder; Pneumonia; Pseudomonas Infection; Pulmonary Congestion; Pulmonary Function Test Decreased; Secretion Discharge; Sputum Discoloured	Pulmozyme	S	(inhalation)	1 Mg/MI, Qd	Not Reported
	Albuterol	S	Respiratory (inhalation)	0.083% (2.5mg/3ml)	Not Reported
	Azithromycin	S	Oral	500 Mg, Qm-F-W	Not Reported
	Cayston	S	Respiratory (inhalation)	28 Days On/ Off	Not Reported
	Trazodone	S	Oral	Unk	Not Reported
	Dulera	C	Respiratory (inhalation)	2 Df, Bid	Not Reported
	Fluoxetine	C	Unknown		Not Reported
	Hypersol B	C	Respiratory (inhalation)	Unk Unk, Bid	Not Reported
	Bactroban /Unk/	C	Unknown		Not Reported
	Zenpep	C	Oral	20000 U, Unk	Not Reported
	Prozac	C	Oral	20 Mg, Qd	Not Reported
	Vitamin D3	C	Oral	50000 U, Qw	Not Reported
	Nystatin	C	Unknown		Not Reported
	Omega 3	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported
	Risperdal	C	Oral	3 Mg, Take Tablet At Bedtime (Hs)	Not Reported
	Aquadeks /07679501/	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	11096757	EXPEDITED (15-DAY)		DE, HO	IT-TEVA-559528ACC		93 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiovascular Disorder; Cerebral Haemorrhage; Dysarthria; Dysphagia;	Azitromicina Teva - 500 Mg Comprese Rivestite Con Film			S	Oral	500 Milligram Daily;		Not Reported
	Allopurinolo Molteni - 300 Mg			C				Not Reported

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

Hemiplegia; International Normalised Ratio Increased	Comprese Lanoxin - 0,125 Mg Comprese Coumadin - 5 Mg Comprese Luvion - 50 Mg Comprese Moduretic - 5 Mg + 50 Mg Comprese Microser - 8 Mg Comprese Pursennid - 12 Mg Comprese Rivestite	C C C C C C	Oral	0.5 Dosage Form (Amiloride 5 Mg, Hydrochlorothizide 50 Mg)	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	11138303	NON-EXPEDITED			PHHY2015FR060927			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Complaint; Wrong Technique In Product Usage Process	Azithromycin Sandoz			S	Oral	1000 Mg, Once/Single		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	11167795	NON-EXPEDITED			US-PFIZER INC- 2015186891			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ceclor			S		Unk		Not Reported	
	Erythromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	11168668	EXPEDITED (15-DAY)		OT	CA-ACTAVIS-2015- 10856		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Actinic Keratosis; Drug Interaction;	Voriconazole (Unknown)	S	Oral	Unk	Not Reported
Photodermatosis;	Voriconazole (Unknown)	S	Oral	Unk	Not Reported
Photosensitivity Reaction;	Tacrolimus (Unknown)	S	Oral	Unk	Watson
Solar Lentigo; Squamous Cell Carcinoma Of Skin	Mycophenolate Mofetil (Unknown)	S	Oral	Unk	Not Reported
	Prednisone (Unknown)	S	Oral	Unk	Watson
	Trimethoprim-Sulfamethoxazole (Unknown)	S	Oral	Unk	Watson
	Azithromycin (Unknown)	S	Oral	Unk	Not Reported
	Pantoprazole Sodium (Unknown)	S	Oral	Unk	Actavis Totowa
	Lansoprazole (Unknown)	S	Oral	Unk	Not Reported
	Atorvastatin (Unknown)	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	11168669	EXPEDITED (15-DAY)		OT	CA-ACTAVIS-2015-10852		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Voriconazole (Unknown)			S	Oral	Unk		Not Reported
	Voriconazole (Unknown)			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus (Unknown)			S	Oral	Unk		Watson
	Mycophenolate Mofetil (Unknown)			S	Oral	Unk		Not Reported
	Prednisone (Unknown)			S	Oral	Unk		Watson
	Ciprofloxacin Hydrochloride (Unknown)			S	Oral	4 Courses Of 10-14 Days		Watson
	Trimethoprim-Sulfamethoxazole (Unknown)			S	Oral	Unk		Watson
	Azithromycin (Unknown)			S	Oral	Unk		Not Reported
	Pantoprazole Sodium (Unknown)			S	Oral	Unk		Actavis Totowa
	Nifedipine (Unknown)			S	Oral	Unk		Watson
	Montelukast (Unknown)			S	Oral	Unk		Not Reported

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

Caspofungin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Amphotericin B, Liposome	C	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2015	11168993	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2015185912		72 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Off Label Use; Peripheral Swelling; Skin Exfoliation; Urticaria	Azithromycin			S	Oral	250 Mg Unit Dose (Patient Only Took One Dose)		Pfizer
	Acetylsalicylic Acid			C		Unk		Not Reported
	Adcal D3			C		Unk		Not Reported
	Betahistine			C		Unk		Not Reported
	Carbocisteine			C		Unk		Not Reported
	Fexofenadine			C		Unk		Not Reported
	Oramorph			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Risedronate			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported
	Simvador			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Symbicort			C		Unk		Not Reported
	Tiotropium			C		Unk		Not Reported
	Zopiclone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2015	10167526	NON-EXPEDITED			US-PFIZER INC-2014126634			Female	USA

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

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

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2015	10915653	NON-EXPEDITED			US-PFIZER INC-2015091303			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		500 Mg Strength		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2015	11173081	NON-EXPEDITED			US-PFIZER INC-2015188005			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Constipation; Eye Irritation; Fatigue; Insomnia; Memory Impairment; Neuropathy Peripheral; Ocular Hyperaemia; Pruritus; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2015	11173087	NON-EXPEDITED			US-PFIZER INC-2015188300			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2015	11135850	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1015807		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Lip Oedema; Rash	Azithromycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2015	11173874	NON-EXPEDITED		OT	US-DRREDDYS- USA/USA/14/0041087		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balamuthia Infection; Diarrhoea; Transaminases Increased	Tacrolimus			S	Unknown			Not Reported	
	Mycophenolate			S	Unknown			Not Reported	
	Basiliximab			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Antithymocyte Globulin			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Albendazole			S	Oral			Not Reported	
	Fluconazole			S	Oral			Not Reported	
	Pentamidine			S	Intravenous (not otherwise specified)			Not Reported	
	Sulfadiazine			S	Oral			Not Reported	
	Miltefosine			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2015	11173876	NON-EXPEDITED		OT	US-DRREDDYS- USA/USA/14/0041085		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balamuthia Infection; Decreased Appetite; Liver Function Test Increased; Malaise; Nausea	Tacrolimus			S	Unknown			Not Reported	
	Mycophenolate			S	Unknown			Not Reported	
	Basiliximab			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Albendazole			S	Unknown			Not Reported	
	Fluconazole			S	Unknown			Not Reported	
	Pentamidine			S	Intravenous (not			Not Reported	

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

Miltefosine		S		otherwise specified) Unknown		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2015	11173878	NON-EXPEDITED		OT	US-DRREDDYS- USA/USA/14/0041091		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Tacrolimus			S	Unknown			Not Reported	
Balamuthia Infection;	Mycophenolate			S	Unknown			Not Reported	
Balance Disorder;	Alemtuzumab			S	Unknown			Not Reported	
Dehydration; Dizziness;	Methylprednisolone			S	Unknown			Not Reported	
Gait Disturbance;	Clarithromycin			S	Unknown			Not Reported	
Hallucination; Nausea;	Fluconazole			S	Unknown			Not Reported	
Toxicity To Various	Albendazole			S	Unknown			Not Reported	
Agents; Vomiting	Miltefosine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2015	11174574	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015184828		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective For Unapproved Indication; Drug Intolerance; Eating Disorder	Zithromax			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2015	11175798	NON-EXPEDITED			US-PFIZER INC- 2015189839			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Intolerance		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2015	10627000	EXPEDITED (15-DAY)		OT	PHHY2014US157833		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Cough; Crepitations; Dyspnoea; Kyphosis; Lumbar Spinal Stenosis; Lung Disorder; Medication Error; Muscle Spasms; Spinal Compression Fracture; Therapy Non-Responder	Lioresal			S	Oral	1 Df, Tid		Not Reported	
	Baclofen Intrathecal			S	Intrathecal	6.545 Ug, Qd		Not Reported	
	Baclofen Intrathecal			S	Intrathecal	12.908 Ug, Qd		Not Reported	
	Baclofen Intrathecal			S	Intrathecal	22.928 Ug, Qd		Not Reported	
	Baclofen Intrathecal			S	Intrathecal	0.453 Ug, Unk		Not Reported	
	Acetylsalicylic Acid			S	Oral	81 Mg, Qd		Not Reported	
	Mirtazapine			S	Unknown	30 Mg, Qhs		Novartis	
	Fluvoxamine			S	Unknown	50 Mg, Bid		Not Reported	
	Chlorzoxazone			S	Unknown			Not Reported	
	Gabapentin			S	Unknown	900 Mg, Tid		Not Reported	
	Bupropion			S	Oral	100 Mg, Qd		Not Reported	
	Loratadine			S	Oral	20 Mg, Qd		Not Reported	
	Bupivacaine			S	Intrathecal	1.032 Mg, Qd		Not Reported	
	Bupivacaine			S	Intrathecal	2.065 Mg, Qd		Not Reported	
	Bupivacaine			S	Intrathecal	3.668 Mg, Qd		Not Reported	
	Bupivacaine			S	Intrathecal	0.072 Mg, Unk		Not Reported	
	Morphine			S	Intrathecal	0.189 Mg, Qd		Not Reported	
	Morphine			S	Intrathecal	0.378 Mg, Qd		Not Reported	
	Morphine			S	Intrathecal	0.672 Mg, Qd		Not Reported	
	Morphine			S	Intrathecal	0.013 Mg, Qd		Not Reported	
	Dantrolene			S	Unknown			Not Reported	
	Robaxin			S	Unknown			Not Reported	
	Celebrex			S	Oral	200 Mg, Qd		Not Reported	

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

Wellbutrin	S	Oral	100 Mg, Qd	Not Reported
Skelaxin	S	Unknown	800 Mg, Tid	Not Reported
Skelaxin	S	Oral	800 Mg, Tid	Not Reported
Fosamax	S	Oral	70 Mg, Qw	Not Reported
Augmentan /00756801/	S	Oral	1 Df, Bid, (875/125 Mg)	Not Reported
Lipitor	S	Oral	10 Mg, Qd	Not Reported
Zithromax	S	Oral	250 Mg, Qod	Not Reported
Symbicort	S	Respiratory (inhalation)	1 Df, Bid Two Puffs Into Lungs	Not Reported
Calcium	S	Oral	830 Mg, Bid	Not Reported
Avodart	S	Unknown	0.5 Mg, Qd	Not Reported
Vitamin D Nos	S	Oral	50000 U, Once Every Other Week	Not Reported
Luvox	S	Oral	50 Mg, Bid	Not Reported
Neurontin	S	Oral	900 Mg, Tid	Not Reported
Guaifenesin Ac	S	Oral	5 MI, Bid (As Needed)	Not Reported
Guaifenesin Ac	S			Not Reported
Guaifenesin Ac	S			Not Reported
Duoneb	S	Respiratory (inhalation)	3 MI, Bid (0.5 Mg/3mg (2.5 Mg Base) /3ml)	Not Reported
Dolophine	S	Oral	5 Mg, Bid	Not Reported
Remeron	S	Oral	30 Mg, Qhs	Not Reported
Nasonex	S	Nasal	1 Df, Qd 50 Ug Actuation Spray, One Spray	Not Reported
Zofran	S	Oral	4 Mg, Qd	Not Reported
Protonix	S	Oral	40 Mg, Bid	Not Reported
Sodium Chloride	S	Respiratory (inhalation)	4 MI, One To Two Times Daily	Not Reported
Carafate	S	Oral	1 G, Tid	Not Reported
Flomax	S	Oral	0.8 Mg, Daily Take Two Capsules	Not Reported
Androgel	S	Unknown	1.62 Percent 20.25	Not Reported

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

Parafon Forte		S		Oral		Mg/1.25 Gram Gelpkt Place Onto Skin		Not Reported	
						500 Mg, Tid (As Needed)			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2015	11098774	EXPEDITED (15-DAY)	OT		JP-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-028303		77 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased	Metgluco			S	Oral	500 Mg, Bid		Bristol Myers Squibb	
	Moxifloxacin Hydrochloride			S	Oral	400 Mg, Qd		Not Reported	
	Cisdylene			S	Oral	1500 Mg, Qd		Not Reported	
	Hustazol /00398402/			C	Oral	60 Mg, Qd		Not Reported	
	Ceftriaxone Sodium			S	Unknown	0.5 G, Qd		Not Reported	
	Zithromac			S	Oral	500 Mg, Qd		Not Reported	
	Amlodin			C	Oral			Not Reported	
	Candesartan Cilexetil			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2015	11176505	EXPEDITED (15-DAY)	OT		GB-TEVA-567439ACC		72 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Peripheral Swelling; Skin Exfoliation; Urticaria	Azithromycin			S	Oral	Patient Only Took One Dose.		Not Reported	
	Aspirin			C				Not Reported	
	Adcal-D3			C				Not Reported	
	Betahistine			C				Not Reported	
	Carbocisteine			C				Not Reported	
	Fexofenadine			C				Not Reported	
	Oramorph			C				Not Reported	
	Paracetamol			C				Not Reported	
	Risedronate			C				Not Reported	
	Salbutamol			C				Not Reported	
	Simvador			C				Not Reported	

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

	Spironolactone	C	Not Reported
	Symbicort	C	Not Reported
	Tiotropium	C	Not Reported
	Zopiclone	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2015	11177699	NON-EXPEDITED			US-PFIZER INC-2015194042		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Inderal			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Witch Hazel		Y	S		Unk		Unknown	
	Pepcid			S		Unk		Not Reported	
	Zomig			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2015	11178635	NON-EXPEDITED			US-PFIZER INC-2015189727			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Gastrointestinal Disorder	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2015	11180587	NON-EXPEDITED			US-PFIZER INC-2015192257			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2015	11181352	NON-EXPEDITED			US-PFIZER INC-2015192721			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Exemestane	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2015	11181373	EXPEDITED (15-DAY)	LT		FR-PFIZER INC-2015193073		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Novatrex			S	Oral	2.5 Mg, Unk		Pfizer	
	Salazopyrine			S		Unk		Pfizer	
	Enbrel			S		Unk		Pfizer	
	Metoject			S		Unk		Not Reported	
	Metoject			S		Unk		Not Reported	
	Metoject			S		Unk		Not Reported	
	Arava			S	Oral	Unk		Not Reported	
	Plaquenil /00072602/			S	Oral	Unk		Not Reported	
	Orencia			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2015	11182024	NON-EXPEDITED			US-PFIZER INC-2015192401			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Reaction To Excipient	Azithromycin			S		250 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2015	11182680	NON-EXPEDITED			US-PFIZER INC-2015194135		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Vistaril			S		Unk		Pfizer	

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

Erythromycin	S	Unk	Pfizer
Codeine	S	Unk	Not Reported
Z-Pack	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2015	11186767	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1018129			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Peripheral Swelling; Skin Exfoliation; Urticaria	Azithromycin			S	Oral	250 Mg, Unk (Patient Only Took One Dose.)		Not Reported
	Aspirin /00002701/			C		Unk		Not Reported
	Adcal D3			C		Unk		Not Reported
	Betahistine			C		Unk		Not Reported
	Carbocisteine			C		Unk		Not Reported
	Fexofenadine			C		Unk		Not Reported
	Oramorph			C		Unk		Not Reported
	Paracetamol			C		Unk		Not Reported
	Risedronate			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported
	Simvador			C		Unk		Not Reported
	Spironolactone			C		Unk		Not Reported
	Symbicort			C		Unk		Not Reported
	Tiotropium			C		Unk		Not Reported
	Zopiclone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11116822	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015160317		87 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
liird Nerve Paralysis	Zithromac Sr			S	Oral	2 G, Unk		Pfizer

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

Bufferin A81	C	Oral	Unk	Not Reported
Coniel	C	Oral	Unk	Not Reported
Epadel-S600	C	Oral	Unk	Not Reported
Lac-B Granular Powder N	C	Oral	Unk	Not Reported
Gascon	C	Oral	Unk	Not Reported
Vectan	C	Oral	Unk	Not Reported
Cinal (Ascorbic Acid\Calcium Pantothenate)	C	Oral	Unk	Not Reported
Maglax	C	Oral	Unk	Not Reported
Lipitor	C	Oral	Unk	Not Reported
Benzalin (Nitrazepam)	C	Oral	Unk	Not Reported
Laxoberon	C	Oral	Unk	Not Reported
Sulpiride	C	Oral	Unk	Not Reported
Xalatan	C	Ophthalmic	Unk	Not Reported
Catalin K	C	Ophthalmic	Unk	Not Reported
Timoptol Xe	C	Ophthalmic	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11167509	EXPEDITED (15-DAY)			JP-PFIZER INC-2015183977			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urine Abnormality	Zithromac			S	Oral			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11188294	NON-EXPEDITED		OT	US-JNJFOC-20150521185		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Remicade			S	Intravenous (not otherwise specified)			Not Reported
Agitation; Chills; Chills;	Arava			S	Unknown			Not Reported
Gait Disturbance;								
Headache; Pyrexia;								
Speech Disorder; Tonic								

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

Clonic Movements; Visual Impairment		Zithromax	S		Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11188610	EXPEDITED (15-DAY)		OT	GB-TEVA-569181ACC		33 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Palpitations; Presyncope; Syncope; Tremor	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11189263	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2015191673		33 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Palpitations; Presyncope; Syncope; Tremor	Azithromycin			S	Oral	Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11189857	NON-EXPEDITED			US-PFIZER INC-2015195920		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2015	11190859	NON-EXPEDITED			US-ELI_LILLY_AND_COMP ANY-US201505007087			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection; Sinusitis	Trulicity			S	Unknown	0.75 Mg, Weekly (1/W)			Eli Lilly And Co
	Zithromax			S	Unknown	Unk, Unknown			Not Reported
	Metformin			C	Unknown	Unk, Qd			Not Reported

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

	Losartan	C	Unknown	Unk, Unknown			Not Reported		
	Glyparamide	C	Unknown	Unk, Qd			Not Reported		
	Pravastatin	C	Unknown	Unk, Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2015	11192526	NON-EXPEDITED			US-PFIZER INC-2015198067		41 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anxiety; Dysgeusia; Expired Product Administered; Intentional Product Misuse; Tongue Disorder	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2015	11193324	NON-EXPEDITED			US-PFIZER INC-2015196957			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2015	11193426	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2015M1019359			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Potassium Increased; Drug Ineffective; Dyspnoea; Endocarditis; Endocarditis Staphylococcal; Fluid Overload; Hypotension; Mental Status Changes; Multiple Organ Dysfunction Syndrome; Muscle Haemorrhage; Pneumonitis; Pulse	Piperacillin/Tazobactam			S	Unknown	Unk		Mylan	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Oral	Unk		Mylan	
	Methylprednisolone			S	Unknown	Unk		Not Reported	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Ipratropium			C				Not Reported	

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

Absent; Respiratory
Distress; Sepsis;
Thrombosis In Device

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2015	11193685	NON-EXPEDITED			US-PFIZER INC- 2015198382			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11119874	NON-EXPEDITED			US-PFIZER INC- 2015162289			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11182095	EXPEDITED (15-DAY)		OT	PHHY2015GB066310		72 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Peripheral Swelling; Skin Exfoliation; Urticaria	Azithromycin			S	Oral	Patient Only Took One Dose.		Novartis	
	Aspirin			C	Unknown			Not Reported	
	Adcal-D3			C	Unknown			Not Reported	
	Betahistine			C	Unknown			Not Reported	
	Carbocisteine			C	Unknown			Not Reported	
	Fexofenadine			C	Unknown			Not Reported	
	Oramorph			C	Unknown			Not Reported	
	Paracetamol			C	Unknown			Not Reported	

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

	Risedronate	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported
	Simvador	C	Unknown	Not Reported
	Spironolactone	C	Unknown	Not Reported
	Symbicort	C	Unknown	Not Reported
	Tiotropium	C	Unknown	Not Reported
	Zopiclone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11195778	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015R1-99020		36 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Azithromycin			S	Oral	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11196188	EXPEDITED (15-DAY)		LT	FR-SA-2015SA080928		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Arava			S	Oral				Not Reported
	Plaquenil			S	Oral				Not Reported
	Novatrex			S	Oral				Not Reported
	Metoject			S	Unknown				Not Reported
	Metoject			S	Unknown				Not Reported
	Metoject			S	Unknown				Not Reported
	Metoject			S	Unknown				Not Reported
	Salazopyrine			S	Unknown				Not Reported
	Enbrel			S	Unknown				Not Reported
	Orencia			S	Unknown				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11198054	EXPEDITED (15-DAY)		OT	PHHY2015GB068421		33 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Palpitations; Presyncope; Syncope; Tremor	Azithromycin			S	Oral			Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11202082	EXPEDITED (15-DAY)		HO	PR 10421		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; General Physical Health Deterioration; Multiple Organ Dysfunction Syndrome; Sepsis; Skin Infection	Azasite Promethazine Hydrochloride Dextromethorphan Hydrobromide			S C C				Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11202564	DIRECT	Y	DS			85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Congestive; Condition Aggravated; Deafness; Tinnitus; Vision Blurred; Visual Impairment	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11202656	DIRECT		HO, LT, RI			75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Electrocardiogram Qt Prolonged; Sudden Cardiac Death; Torsade De Pointes	Azithromycin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2015	11203082	DIRECT		OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea	Azithromycin			S	Oral	250mg 6 Tablets (Pills) 2-Day 1 1- Day 2 1- Day 3 1- Day 4 1 - Day 5		Greenstone
	Symbicort			C				Not Reported
	Pro Air Hfa			C				Not Reported
	Methyclothiazide			C				Not Reported
	Aspirin			C				Not Reported
	Spiriva			C				Not Reported
	Vd			C				Not Reported
	Glucosamin			C				Not Reported
	Bioin			C				Not Reported
	Milk Thistle			C				Not Reported
	Alpha Lipoic Acid			C				Not Reported
	Calcium			C				Not Reported
	Potassium			C				Not Reported
	Omega-3 Fatty Acids			C				Not Reported
	Multi Vitamin			C				Not Reported
	Multi Vitamin			C				Not Reported
	Vc			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2015	9344946	NON-EXPEDITED			US-PFIZER INC-2013173251		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2015	11098031	NON-EXPEDITED		HO	US-BAYER-2015-182515		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Vessel Puncture Site Rash	Avelox I.V.			S	Intravenous (not otherwise specified)	400 Mg, Qd		Bayer	
	Doxycycline			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2015	11197956	EXPEDITED (15-DAY)		DE, HO	PHHY2015CN072366		365 DAY	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Haemophagocytic Lymphohistiocytosis; Multiple Organ Dysfunction Syndrome; Off Label Use	Ciclosporin			S	Oral	6 Mg/Kg, Qd		Novartis	
	Ciclosporin			S				Novartis	
	Dexamethasone			S	Oral	10 Mg/M2, Unk		Not Reported	
	Dexamethasone			S				Not Reported	
	Etoposide			S	Intravenous (not otherwise specified)	150 Mg/M2, Qd (2 Times/Week)		Not Reported	
	Cefepime			S				Not Reported	
	Vancomycin			S				Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Voriconazole			S				Not Reported	
	Azithromycin			S				Not Reported	
	Gamma Globulin			S	Intravenous (not otherwise specified)	1 G/Kg, Unk		Not Reported	
	Gamma Globulin			S				Not Reported	
	Micafungin			S	Unknown			Not Reported	
	Itraconazole			C				Not Reported	
	Sulfamethoxazole			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2015	11200362	NON-EXPEDITED			US-ALLERGAN-1419447US		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Dry Throat; Dyspnoea; Pruritus; Pruritus; Pruritus	Zymaxid			S	Ophthalmic	1 Gtt, Single		Allergan	
	Azithromycin			S				Not Reported	
	Lumigan			C				Not Reported	
	Benzonatate			C				Not Reported	
	Claritin-D			C				Not Reported	
	Prevacid			C				Not Reported	
	Toprol XL			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2015	11200985	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2015M1018984			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Palpitations; Presyncope; Syncope; Tremor	Azithromycin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2015	11202688	DIRECT	Y	HO			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Rash Maculo-Papular; Rash Pruritic; Wheezing	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2015	10594336	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2014315375		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Jaw Disorder; Temporal Arteritis; Urinary	Lyrica			S	Oral	50 Mg, 3x/Day		Pfizer	

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

Tract Infection	Lyrica	S	Oral	50 Mg, 3x/Day	Pfizer
	Lyrica	S	Oral	Weaned To Daily	Pfizer
	Zithromax	S		Unk	Pfizer
	Pregabalin	S		Unk	Not Reported
	Zantac	S		Unk, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2015	11148622	NON-EXPEDITED			US-PFIZER INC-2015176106			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2015	11200557	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015198866		44 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Zithromac			S	Oral	250 Mg, Daily		Pfizer	
	Minomycin			S	Oral	50 Mg, 2x/Day		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2015	11203261	NON-EXPEDITED			US-PFIZER INC-2015203498			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S				Pfizer	
	Neosporin			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2015	6917255	EXPEDITED (15-DAY)		OT	US-ROCHE-615960			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2015	11058569	EXPEDITED (15-DAY)		HO	IT-ROCHE-1566246		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute; Transaminases Increased	Rocefin			S	Intravenous (not otherwise specified)			Not Reported	
	Zitromax			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2015	11205555	NON-EXPEDITED			US-PFIZER INC- 2015203476			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Ultram			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2015	11206175	NON-EXPEDITED			US-PFIZER INC- 2015207090			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	
	Clarithromycin			S		Unk		Pfizer	
	Tylenol With Codeine			S		Unk		Not Reported	

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

	Keflex		S			Unk			Not Reported
	Tegretol		S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2015	11213106	DIRECT		OT			62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Food Aversion; Nausea	Zithromax			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2015	11213281	DIRECT		RI			12 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Facial Paralysis	Zithromax			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2015	10766815	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2015046559		5 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia	Azithromycin			S	Oral	1 Df, Daily			Pfizer
	Tachipirina			C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2015	11211200	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2015201130		83 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Seizure; Toxicity To Various Agents	Azithromycin			S	Oral	250 Mg; Three Times A Week			Pfizer
	Diltiazem			S	Oral	60 Mg, 2x/Day			Not Reported
	Theophylline			S	Oral	200 Mg, 2x/Day			Not Reported

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

Adcal D3	C	Unk	Not Reported
Bumetanide	C	Unk	Not Reported
Carbocisteine	C	Unk	Not Reported
Folic Acid	C	Unk	Not Reported
Paracetamol	C	Unk	Not Reported
Ranitidine	C	Unk	Not Reported
Rivaroxaban	C	Unk	Not Reported
Salbutamol	C	Unk	Not Reported
Symbicort	C	Unk	Not Reported
Tiotropium Bromide	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2015	11292683	NON-EXPEDITED		OT	RB-74127-2015		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyskinesia; Hyperaesthesia; Muscle Spasms; Pain In Extremity	Dextromethorphan/Guaifenesin 1200 Mg (Rb (Reckitt Benckiser))			S		(1200 Mg Total, Took 1 Tablet (Total) At 9p.M On 19-Feb-2015. Unknown)		Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2015	11196436	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC- 2015197449			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tonic Convulsion	Zithromac Sr			S	Oral	Single Dose		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2015	11215002	EXPEDITED (15-DAY)		HO	GB-TEVA-571844ACC		83 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure; Toxicity To	Azithromycin			S	Oral			Not Reported

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

Various Agents	Diltiazem		S	Oral	120 Milligram Daily; Modified Release.			Teva	
	Theophylline		S	Oral	400 Milligram Daily;			Not Reported	
	Adcal-D3		C					Not Reported	
	Bumetanide		C					Not Reported	
	Carbocisteine		C					Not Reported	
	Folic Acid		C					Not Reported	
	Paracetamol		C					Not Reported	
	Ranitidine		C					Not Reported	
	Rivaroxaban		C					Not Reported	
	Salbutamol		C					Not Reported	
	Symbicort		C					Not Reported	
	Tiotropium Bromide		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2015	6917261	EXPEDITED (15-DAY)		DE, OT	US-ROCHE-614835		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Drug-Induced Liver Injury	Ceftriaxone				S	Unknown			Not Reported
	Azithromycin				S	Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2015	11217527	EXPEDITED (15-DAY)		HO	PHHY2015GB072262		83 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure; Toxicity To Various Agents	Azithromycin				S	Oral	250 Mg, Qw3		Novartis
	Diltiazem				S	Oral	60 Mg, Bid (Modified Release)		Not Reported
	Theophylline				S	Oral	200 Mg, Bid		Not Reported
	Adcal-D3				C	Unknown			Not Reported
	Bumetanide				C	Unknown			Not Reported
	Carbocisteine				C	Unknown			Not Reported
	Folic Acid				C	Unknown			Not Reported

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

Paracetamol	C	Unknown	Not Reported
Ranitidine	C	Unknown	Not Reported
Rivaroxaban	C	Unknown	Not Reported
Salbutamol	C	Unknown	Not Reported
Symbicort	C	Unknown	Not Reported
Tiotropium Bromide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2015	11181247	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2015191206		93 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia	Zithromac			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Bfluid			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Vitamedin Intravenous			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Gaster			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Solita-T1			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Morphine Hydrochloride Trihydrate			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2015	11185063	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015191353		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Pancreatitis Acute	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Levofloxacin Actavis			S	Intravenous (not otherwise specified)	500 Mg, 2x/Day		Not Reported
	Levofloxacin Actavis			S	Intravenous (not otherwise specified)	Dose Reduced		Not Reported

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

otherwise specified)									
	Ceftriaxone Panpharma	C				Unk			Not Reported
	Tranxene	C				Unk			Not Reported
	Haloperidol	C				Unk			Not Reported
	Esmolol	C				Unk			Not Reported
	Cisatracurium	C				Unk			Not Reported
	Ketamine	C				Unk			Not Reported
	Suxamethonium	C				Unk			Not Reported
	Norepinephrine	C				Unk			Not Reported
	Midazolam Hydrochloride	C				Unk			Not Reported
	Remifentanil	C				Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2015	11219166	EXPEDITED (15-DAY)		HO	PHHY2015CA060899		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Eye Swelling; Impaired Healing; Knee Operation; Lip Swelling; Urticaria	Metformin Hydrochloride Sandoz			S	Oral	500 Mg, Bid		Novartis
	Supeudol			S	Oral	5 Mg		Not Reported
	Supeudol			S				Not Reported
	Rabeprazole Sandoz			S	Oral	20 Mg, Unk		Not Reported
	Tamsulosin Sandoz			S	Oral	0.4 Mg, Unk		Not Reported
	Azithromycin Sandoz			S	Oral	250 Mg		Not Reported
	Tobramycin Sandoz			S	Unknown	0.3 %,		Not Reported
	Apo-Hydroxyzine			C				Not Reported
	Aerius (Desloratadine)			C				Not Reported
	Benadryl /00647601/			C	Unknown			Not Reported
	Zantac			C				Not Reported
	Cozaar			C				Not Reported
	Amlodipine			C				Not Reported
	Tamsulosin Ratiopharm			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2015	11221506	NON-EXPEDITED			US-PFIZER INC-2015212897			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2015	11222530	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2015209191		75 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tubulointerstitial Nephritis	Azithromycin			S		Unk		Pfizer	
	Acetylcysteine			C		Unk		Not Reported	
	Desloratadine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2015	11223038	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2015M1020256			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure; Toxicity To Various Agents	Azithromycin			S	Oral	250 Mg, 3xw		Not Reported	
	Diltiazem			S	Oral	60 Mg, Bid (Modified Release)		Not Reported	
	Theophylline			S	Oral	200 Mg, Bid		Not Reported	
	Adcal-D3			C		Unk		Not Reported	
	Bumetanide			C		Unk		Not Reported	
	Carbocisteine			C		Unk		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Paracetamol			C		Unk		Not Reported	
	Ranitidine			C		Unk		Not Reported	
	Rivaroxaban			C		Unk		Not Reported	

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

	Salbutamol		C		Unk		Not Reported		
	Symbicort		C		Unk		Not Reported		
	Tiotropium Bromide		C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2015	11159719	NON-EXPEDITED			US-PFIZER INC-2015182321			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2015	11202346	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1020404			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Constipation; Gastrointestinal Sounds Abnormal	Azitromicina			S	Oral	500 Mg, Qd		Mylan	
	Azitromicina			S				Mylan	
	Coumadin /00014802/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2015	11224379	EXPEDITED (15-DAY)		HO	GB-WATSON-2015-12691		83 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure; Toxicity To Various Agents	Theophylline (Unknown)			S	Oral	200 Mg, Bid		Not Reported	
	Azithromycin (Unknown)			S	Oral	250 Mg, 3/Week		Not Reported	
	Diltiazem (Unknown)			S	Oral	60 Mg, Bid		Watson	
	Adcal D3			C	Unknown	Unk		Not Reported	
	Bumetanide			C	Unknown	Unk		Not Reported	
	Carbocisteine			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	

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

	Ranitidine	C	Unknown	Unk		Not Reported
	Rivaroxaban	C	Unknown	Unk		Not Reported
	Salbutamol	C	Unknown	Unk		Not Reported
	Symbicort	C	Unknown	Unk		Not Reported
	Tiotropium Bromide	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2015	11225200	EXPEDITED (15-DAY)		OT	PHHY2015AT075516		70 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Hypertensive Crisis	Augmentin /00852501/			S	Oral			Not Reported
	Azithromycin			S	Oral	500 Mg, Unk		Novartis
	Ospen			S	Oral	1500 Mg		Not Reported
	Nebivolol			C	Unknown	5 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2015	11225907	EXPEDITED (15-DAY)		OT	PHHY2015NL072762		86 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness	Azithromycin Sandoz			S	Oral	3dd1		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2015	11230713	DIRECT		HO, LT			10 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2015	9628431	NON-EXPEDITED			US-PFIZER INC- 2013293169		62 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported
	Doxycycline			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Ampicillin			S		Unk		Pfizer
	Lincomycin Hcl			S		Unk		Pfizer
	Tessalon			S		Unk		Pfizer
	Doxycycline Hyclate			S				Pfizer
	Percodan			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2015	11215949	EXPEDITED (15-DAY)		OT	IT-TEVA-571497ACC		24 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Distension; Constipation; Gastrointestinal Sounds Abnormal; Quality Of Life Decreased	Azithromycin			S	Oral	50 Milligram Daily;		Pliva
	Coumadin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2015	11228498	NON-EXPEDITED		OT	US-BAYER-2015-366784			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus; Rash; Swelling Of Eyelid	Avelox			S	Oral	400 Mg, Qd		Bayer
	Neomycin [Neomycin]			S				Not Reported
	Zithromax			S				Not Reported
	Chloramphenicol [Chloramphenicol]			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2015	11229143	NON-EXPEDITED			US-PFIZER INC-2015215287			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Lidocaine Hcl			S		Unk		Pfizer	
	Proventil Hfa			S		Unk		Not Reported	
	Elavil			S		Unk		Not Reported	
	Thorazine			S		Unk		Not Reported	
	Stelazine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2015	11231421	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error; Product Preparation Issue	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2015	10930420	EXPEDITED (15-DAY)		HO	US-GLAXOSMITHKLINE INC.-US2015GSK035275		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Chronic Obstructive Pulmonary Disease; Drug Ineffective; Dyspnoea	Advair			S	Unknown	250/50 Mcg, U		Glaxosmithkline	
	Advair			S	Unknown	500/50 Mcg,U		Glaxosmithkline	
	Ventolin			S	Respiratory (inhalation)	Unk, U		Glaxosmithkline	
	Ventolin			S	Respiratory (inhalation)	Unk, U		Glaxosmithkline	
	Z Pak			S	Unknown	Unk, U		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2015	11111034	EXPEDITED (15-DAY)		HO, OT	FR- ELI_LILLY_AND_COMP ANY-FR201504010468		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Eye Pain; Thrombocytopenia; Vision Blurred	Adcirca			S	Oral	40 Mg, Qd		Eli Lilly And Co	
	Zithromax			S	Unknown	250 Mg, Qd		Not Reported	
	Zithromax			S				Not Reported	
	Tegeline			C		Unk, Monthly (1/M)		Not Reported	
	Rituximab			C		Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2015	11205295	EXPEDITED (15-DAY)		HO	FR-WATSON-2015-12278		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Pancreatitis Acute	Levofloxacin Actavis			S	Intravenous (not otherwise specified)	500 Mg, Bid		Watson	
	Zitromax			S	Oral	500 Mg, Daily		Not Reported	
	Tranxene			C	Unknown	Unk Unk, Unknown		Not Reported	
	Haloperidol			C	Unknown	Unk Unk, Unknown		Not Reported	
	Esmolol			C	Unknown	Unk Unk, Unknown		Not Reported	
	Cisatracurium			C	Unknown	Unk Unk, Unknown		Not Reported	
	Ketamine			C	Unknown	Unk Unk, Unknown		Not Reported	
	Suxamethonium			C	Unknown	Unk Unk, Unknown		Not Reported	
	Norepinephrine			C	Unknown	Unk Unk, Unknown		Not Reported	
	Midazolam Hydrochloride			C	Unknown	Unk Unk, Unknown		Not Reported	
	Remifentanyl			C	Unknown	Unk Unk, Unknown		Not Reported	
	Rocephin			C	Unknown	Unk Unk, Unknown		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2015	11239635	DIRECT		DS, OT			40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Erythema Multiforme	Zithromax Blended Frozen Cranberries			S C	Oral		4-5 DAY	Pfizer Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2015	11239918	DIRECT					92 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pollakiuria; Product Shape Issue	Azithromycin Made In India- Code No: Gu3/Drugs/G/585distributed By Greenstone Llc Pedpack, Nj			S	Oral	250 Mg Tablets 6 Pills 2 First Day 1 Next 4 Days By Mouth		Greenstone	
	Timolol Maleate			C				Not Reported	
	Aspirin			C				Not Reported	
	Bicalutamide			C				Not Reported	
	Casodex			C				Not Reported	
	Simvastatin			C				Not Reported	
	Thyroxine			C				Not Reported	
	Seniors Vitamins Mixture In Winter			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2015	11094503	EXPEDITED (15-DAY)			US- GLAXOSMITHKLINE- US2015060637		55 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment; Xanthopsia	Mepron Oral Suspension			S	Oral	5 MI, Bid		Glaxosmithkline	
	Azithromycin			S		250 Mg, 1d		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2015	11203206	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2015202604		24 YR	Female	ITA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Astringent Therapy; Constipation	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Coumadin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2015	11234186	NON-EXPEDITED			US-PFIZER INC- 2015216687			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Solu-Medrol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2015	11234688	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC- 2015216230		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Leukaemoid Reaction; Megacolon; Multiple Organ Dysfunction Syndrome; Septic Shock	Azithromycin			S		Unk		Pfizer	
	Pantoprazole			S		Unk		Pfizer	
	Vancomycin			S		Unk		Unknown	
	Ceftriaxone			S		Unk		Not Reported	
	Levothyroxine			C		Unk		Not Reported	
	Diltiazem			C		Unk		Not Reported	
	Losartan			C		Unk		Not Reported	
	Atorvastatin			C		Unk		Not Reported	
	Aspirin			C		Unk		Not Reported	
	Donepezil			C		Unk		Not Reported	
	Sertraline			C		Unk		Not Reported	
	Budesonide W/Formoterol			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2015	11235494	NON-EXPEDITED			US-PFIZER INC-2015218177			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline			S		Unk		Pfizer	
	Meclizine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2015	11220451	EXPEDITED (15-DAY)		OT	PHHY2015IT073070		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Constipation; Gastrointestinal Sounds Abnormal	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Coumadin//Warfarin Sodium			C	Unknown			Not Reported	
	Butyric Acid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2015	11239630	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015185771		45 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Hyperthermia; Renal Pain	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2015	11239964	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015217201			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspiration; Drug Ineffective; Pyrexia	Zithromac Sr			S	Oral	Single Dose		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2015	11241221	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2015220192		3 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Partial Seizures; Somnolence; Trismus	Zitromax			S	Oral	150 Mg, Total		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2015	11246268	DIRECT		DS, HO, LT			44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Brain Injury; Drug Interaction; Haemorrhage; Head Injury; Hypokalaemia; Hyponatraemia; Hypoxia; Seizure; Syncope; Torsade De Pointes; Unresponsive To Stimuli	Zithromax 250mg Pfizer Zestoretic/Hydrocodone			S C	Oral			Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2015	11250059	NON-EXPEDITED			US-PFIZER INC-2015223405			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Detrol			S		Unk		Pfizer	
	Demerol			S		Unk		Not Reported	
	Indocin /00003801/			S		Unk		Not Reported	
	Ergotrate			S		Unk		Not Reported	
	Terfex (Terfenadine)			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2015	11252701	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2784841		2 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown	Not Reported		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2015	10950516	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015033783		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Chest Pain; Costochondritis; Dysphonia; Oral Fungal Infection; Pleurisy	Advair Diskus Inhalation Powder			S	Oral	1 Puff(S), 1d		Glaxosmithkline	
	Tessalon Perles			S				Not Reported	
	Z-Pack			S				Not Reported	
	Dimetapp			C				Not Reported	
	Synthroid Tablet			C				Glaxosmithkline	
	Vitamin D3			C				Glaxosmithkline	
	Prevacid			C				Not Reported	
	Albuterol Sulfate Inhalational Powder			C				Glaxosmithkline	
	Lyrica			C				Not Reported	
	Lisinopril			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2015	11223938	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2015-05422		9 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Condition Aggravated; Cough; Drug Hypersensitivity; Dyspnoea; Eosinophilic Pneumonia; Hypophagia; Myalgia; Nausea; Oxygen	Trimethoprim+Sulfamethoxazole			S	Unknown			Aurobindo	
	Trimethoprim+Sulfamethoxazole			S				Aurobindo	
	Azithromycin			S				Aurobindo	
	Amoxicillin			S				Aurobindo	

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

Saturation Decreased;
Pneumomediastinum;
Pneumopericardium;
Pneumothorax; Pyrexia;
Rash; Tachycardia;
Tachypnoea; Thoracic
Cavity Drainage; Urticaria;
Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2015	11256016	EXPEDITED (15-DAY)		DE, OT	ZM-PFIZER INC- 2015223485		9 YR	Unknown	ZMB

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cervical Vertebral Fracture; Choking	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2015	11256061	NON-EXPEDITED			US-FRESENIUS KABI- FK201503279			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Route Of Product Administration	Azithromycin For Injection			S	Intramuscular			Fresenius Medical Care

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2015	11257282	EXPEDITED (15-DAY)		HO	PT-MYLANLABS- 2015M1022249			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Glycosuria; Metabolic Acidosis; Normochromic Normocytic Anaemia; Proteinuria; Tubulointerstitial Nephritis	Azithromycin			S	Unknown	Unk		Not Reported
	Acetylcysteine			S	Unknown	Unk		Not Reported
	Desloratadine			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2015	11257295	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2015M1022765			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Leukaemoid Reaction; Megacolon; Multiple Organ Dysfunction Syndrome; Septic Shock	Azithromycin			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Mylan
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Levothyroxine			C	Unknown	Unk		Not Reported
	Diltiazem			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Aspirin /00002701/			C	Unknown	Unk		Not Reported
	Donepezil			C	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	Unk		Not Reported
	Budesonide W/Formoterol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11130036	EXPEDITED (15-DAY)		HO, LT	IT-MYLANLABS-2015M1016005			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Hepatitis Acute	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Amoxicillin			S		Unk		Not Reported
	Deflazacort			S	Oral	30 Mg, Qd		Not Reported
	Ampicillin			S		3 G, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11185603	NON-EXPEDITED			US-PFIZER INC-2015195925		59 YR	Male	USA

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

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

Feeling Abnormal	Zithromax	S	500 Mg, 1x/Day	Pfizer
	Zithromax	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11257621	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2015US05633			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Fatigue; Malignant Neoplasm Progression; Neuropathy Peripheral; Pancytopenia; Physical Deconditioning	Ritonavir			S	Unknown	Unk		Cipla
	Darunavir			S	Unknown			Not Reported
	Etosid			S	Unknown			Not Reported
	Vincristine			S	Unknown			Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Doxorubicin			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Truvada			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown			Not Reported
	Azee 250 Cipla			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11258379	EXPEDITED (15-DAY)		HO, OT	US-MALLINCKRODT- T201503306		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Drug Interaction; Electrocardiogram Qt Prolonged; Hyperhidrosis; Tachycardia	Methadose			S	Unknown	60 Mg, Qd		Mallinckrodt
	Azithromycin			S	Unknown	500 Mg, Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11260474	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2728807		52 YR	Female	CAN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Dizziness; Drug Ineffective; Infusion Related Reaction; Lip Swelling; Off Label Use; Psoriasis; Rash Pruritic; Weight Decreased	Rituxan			S	Intravenous (not otherwise specified)	Not Reported		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported		Not Reported
	Rituxan			S	Intravenous (not otherwise specified)	Not Reported		Not Reported
	Diphenhydramine Hydrochloride			C	Oral			Not Reported
	Methylprednisolone			C	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Unknown	Not Reported		Not Reported
	Naprosyne			S	Unknown	Not Reported		Not Reported
	Metoclopramide			C		Not Reported		Not Reported
	Omega 3-6-9 /01333901/			C		Not Reported		Not Reported
	Leflunomide			S	Unknown	Not Reported		Not Reported
	Orencia			C	Unknown	Not Reported		Not Reported
	Prednisone			C		Not Reported		Not Reported
	Synthroid			C		Not Reported		Not Reported
	Tylenol /00020001/			C	Oral	Not Reported		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11261671	NON-EXPEDITED			US-PFIZER INC-2015225789			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2015	11263031	EXPEDITED (15-DAY)		HO	PHHY2015GB079232		66 YR	Unknown	GBR

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jul-2015	11265076	DIRECT					62 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Heart Rate Increased; Palpitations; Product Substitution Issue	Zpack			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11266105	EXPEDITED (15-DAY)		DE	ZM-PFIZER INC- 2015221995		2 YR	Unknown	ZMB
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Death; Foaming At Mouth	Zithromax			S	Oral	1200 Mg, Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11266410	NON-EXPEDITED		HO	US-PFIZER INC- 2015227648		60 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bronchitis; Chronic Obstructive Pulmonary Disease; Drug Ineffective; Dyspnoea	Zithromax			S		Unk		Pfizer	
	Advair			S		(250/50 Mcg); Unk		Not Reported	
	Advair			S				Not Reported	
	Ventolin Inhaler			S		Unk		Not Reported	
	Ventolin Nebulizer			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11266572	NON-EXPEDITED			US-PFIZER INC- 2015229042			Female	USA

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2015	11267313	NON-EXPEDITED			US-PFIZER INC-2015228373		30 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Screen Positive	Azithromycin			S	Oral	1000 Mg, Unk (500mg Tablet, Two Tablets By Mouth As A One Time Dose)		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	10219574	EXPEDITED (15-DAY)		OT	FR-ABBVIE-14P-056-1241918-00		74 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Off Label Use; Optic Neuropathy; Peripheral Sensory Neuropathy; Polyarthrititis	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Novatrex			S	Oral	3 Tablet Of 2.5mg (7.5mg A Week)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jul-2015	11116539	EXPEDITED (15-DAY)		LT	IT-TEVA-562444ACC		48 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Autoimmune Hepatitis; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram Daily; 500 Mg Daily		Not Reported	
	Amoxicillin Deflazacort			S S	Oral	30 Milligram Daily; 30 Mg Daily		Teva Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2015	11116645	EXPEDITED (15-DAY)		LT	PHHY2015IT057234		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Hepatitis	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Deflazacort			S	Oral	30 Mg, Qd		Not Reported	
	Piperacilin/Tazobactam			C	Unknown			Not Reported	
	Vancomycine			C	Unknown			Not Reported	
	Prednisone			C	Unknown	25 Mg, Qd		Not Reported	
	Mycophenolate			C	Unknown	2 G, Qd		Not Reported	
	Ursodeoxycholic Acid			C	Unknown	Unk		Not Reported	
	Cholestyramin			C	Unknown	Unk		Not Reported	
	Proton Pump Inhibitors			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2015	11270409	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2015228917		37 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Eructation; Flatulence	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2015	11270945	EXPEDITED (15-DAY)		HO	GB-MYLANLABS- 2015M1022274			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Electrocardiogram Qt Prolonged	Azithromycin			S		250 Mg, 3xw		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2015	10817856	EXPEDITED (15-DAY)		OT	US-BAYER-2014-190612		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Infection; Infection; Influenza; Neuropathy Peripheral; Pruritus; Skin Irritation; Viral Infection; Weight Decreased	Stivarga Azithromycin			S S	Oral	120 Mg, (3 X 40 Mg) Qd		Bayer Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2015	11229144	NON-EXPEDITED			US-PFIZER INC-2015216666			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2015	11264639	NON-EXPEDITED			US-PFIZER INC-2015227426		34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Screen Positive	Azithromycin			S	Oral	1000 Mg, (Two Tablets As A One Time Dose)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2015	11273925	NON-EXPEDITED			US-PFIZER INC-2015231487			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin Cipro			S S		Unk Unk		Pfizer Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2015	11218766	NON-EXPEDITED			US-PFIZER INC-2015211725			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	
	Metformin Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Asa			S		Unk		Not Reported	
	Oxycontin			S		Unk		Not Reported	
	Phenergan			S		Unk		Not Reported	
	Aztec			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2015	11275990	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-2015-02123		15 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	11 Mg/Kg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2015	11276446	NON-EXPEDITED			US-PFIZER INC-2015233088			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2015	11276615	NON-EXPEDITED			US-PFIZER INC-2015232986			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Tikosyn			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Influenza Virus Vaccine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2015	11276620	EXPEDITED (15-DAY)		HO	GXKR2015DE003347			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysaesthesia; Language Disorder; Lip Swelling	Azithromycin 500 Mg			S	Oral	500 Mg, Once/Single		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2015	11277370	NON-EXPEDITED			US-PFIZER INC-2015233599			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Methotrexate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2015	11131058	EXPEDITED (15-DAY)		LT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-97411			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Hepatitis Acute	Azithromycin			S	Oral	500 Mg, Daily		Not Reported	
	Amoxicillin			S	Unknown	Unk		Ranbaxy	
	Deflazacort			S	Oral	30 Mg, Daily		Not Reported	

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

Goji Berries			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2015	11279956	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1023585			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Haemorrhagic Oedema Of Infancy	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2015	11282006	EXPEDITED (15-DAY)		OT	CN-JNJFOC-20150705281		28 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pigmentation Disorder; Pruritus; Rash; Skin Exfoliation	Tylenol		Y	S	Oral				Not Reported
	Azithromycin			S	Oral				Not Reported
	Qingrejedupian			C	Oral				Not Reported
	Qingrejedupian			C	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11283232	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015223234		40 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sepsis	Zithromac			S	Intravenous drip	500 Mg, Daily			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11283374	NON-EXPEDITED			US-BAYER-2015-372431		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Nausea; Product Use In Unapproved Indication;	Moxifloxacin Oral			S		400 Mg, Qd			Bayer
	Ethambutol			S		800 Mg, Qd			Not Reported
	Azithromycin			S		500 Mg, Unk			Not Reported

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

Vomiting; Weight Decreased	Levothyroxine	C	Unk	Not Reported
	Lisinopril	C	Unk	Not Reported
	Propranolol	C	Unk	Not Reported
	Venlafaxine	C	Unk	Not Reported
	Alprazolam	C	Unk	Not Reported
	Warfarin	C	Unk	Not Reported
	Amiodarone	C	Unk	Not Reported
	Insulin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11283816	NON-EXPEDITED			US-PFIZER INC-2015000061			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Cephalexin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11284255	EXPEDITED (15-DAY)		HO	DE-TEVA-578511GER		61 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysaesthesia; Language Disorder; Lip Swelling	Azithromycin 500 Mg			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11284264	NON-EXPEDITED			US-PFIZER INC-2015236660			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Tetracycline Hcl	S	Unk	Pfizer
	Amoxicillin	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Iodine	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported
	Dicyclomine	S	Unk	Not Reported
	Ceclor	S	Unk	Not Reported
	E-Mycin	S	Unk	Not Reported
	Toradol	S	Unk	Not Reported
	Benadryl	S	Unk	Not Reported
	Vicodin	S	Unk	Not Reported
	Dilaudid	S	Unk	Not Reported
	Cephalexin	S	Unk	Not Reported
	Cipro	S	Unk	Not Reported
	Augmentin	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2015	11285576	NON-EXPEDITED			US-AMGEN- USASP2015070718		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Enbrel			S	Unknown	Unk		Amgen	
Immune System Disorder;	Z-Pack			S	Unknown	Unk		Not Reported	
Rash									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2015	11129553	EXPEDITED (15-DAY)		HO, LT, OT	IT-APOTEX- 2015AP009197			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Autoimmune Hepatitis;	Azithromycin	S	Oral	500 Mg, Qd	Apotex
Drug-Induced Liver Injury;	Ampicillin	S	Unknown	3 G, Daily	Not Reported
Hepatitis Acute	Deflazacort	S	Oral	30 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2015	11158717	NON-EXPEDITED			US-PFIZER INC-2015175836		60 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Zithromax			S		200 Mg For 5 MI, Day 1		Pfizer	
	Zithromax			S		2 MI For Day 2 To 5, Daily		Pfizer	
	Azithromycin			S		Unk		Not Reported	
	Phenergan Promethazine-Dm			C		(6.25-15mg/5ml)		Not Reported	
	Phenergan Promethazine-Dm			C	Oral	2 MI (2 MI By Mouth, 3 To 4 Times A Day), Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2015	9914449	NON-EXPEDITED			US-GILEAD-2011-0047782			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyschezia; Rectal Haemorrhage	Atripla			S		Unk		Gilead	
	Azithromycin			S	Unknown			Not Reported	
	Mepron /01181501/			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2015	11293566	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2015236967		61 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysaesthesia; Language Disorder; Lip Swelling	Azithromycin			S		500 Mg, Single		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2015	11294769	DIRECT					36 YR	Female	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fluid Retention; Weight Increased	Azithromycin 250mg			S	Oral			Cvs Caremark	
	Levothyroxine			C				Not Reported	
	Triamterene/Hydrochlorothiazide			C				Not Reported	
	Generic Zyrtec			C				Not Reported	
	Sublingual Allergy Drops			C				Not Reported	
	Calcium Supplements			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2015	11307175	EXPEDITED (15-DAY)		OT	CH-PFIZER INC-2015238825		334 DAY	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Growth Restriction; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2015	11310226	NON-EXPEDITED			US-PFIZER INC-2015245630			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2015	11310975	EXPEDITED (15-DAY)		HO, LT, OT	FR-ROCHE-603290		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Febrile Bone Marrow Aplasia	Mabthera			S				Not Reported	
	Novatrex			S				Not Reported	
	Insulatard			C		Dosage Unchanged		Not Reported	

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

Solupred (France)			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2015	11314485	EXPEDITED (15-DAY)		DE	US-BAXTER-2015BAX040970		175 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stillbirth	Cefazolin Injection			S	Transplacental			Baxter	
	Ceftriaxone Injection, Usp (In Dextrose)			S	Transplacental			Baxter	
	Cefepime Injection			S	Transplacental			Baxter	
	Vancomycin Injection, Usp			S	Transplacental			Baxter	
	Metronidazole Injection, Usp			S	Transplacental			Baxter	
	Betamethasone			S	Transplacental	Two Doses 24 Hours Apart		Not Reported	
	Magnesium Sulfate			S	Transplacental			Not Reported	
	Acetaminophen			S	Transplacental			Not Reported	
	Morphine			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental			Not Reported	
	Ivermectin			S	Transplacental			Not Reported	
	Albendazole			S	Transplacental			Not Reported	
	Oseltamivir			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2015	11314756	NON-EXPEDITED			US-PFIZER INC-2015245250			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2015	11314994	EXPEDITED (15-DAY)		DE, OT	US-BAXTER-2015BAX039775		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Cardio-Respiratory Arrest; Escherichia Sepsis; Pneumonia; Pneumonia; Premature Delivery; Septic Shock; Strongyloidiasis; Superinfection; Systemic Inflammatory Response Syndrome	Cefazolin Injection	S	Intravenous (not otherwise specified)		Baxter
	Ceftriaxone Injection, Usp (In Dextrose)	S	Intravenous (not otherwise specified)		Baxter
	Cefepime Injection	S	Intravenous (not otherwise specified)		Baxter
	Vancomycin Injection, Usp	S	Intravenous (not otherwise specified)		Baxter
	Metronidazole Injection, Usp	S	Intravenous (not otherwise specified)		Baxter
	Betamethasone	S	Unknown	Two Doses 24 Hours Apart	Not Reported
	Magnesium Sulfate	S	Unknown		Not Reported
	Acetaminophen	S	Unknown		Not Reported
	Morphine	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Ivermectin	S	Unknown		Not Reported
	Albendazole	S	Unknown		Not Reported
	Oseltamivir	S	Unknown		Not Reported
	Indometacin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2015	11317525	DIRECT		OT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia; Decreased Appetite	Zithromax 500 Mg App			S	Oral			Cvs Caremark	
	Vitamin C			C				Not Reported	
	Elderberry			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2015	11317516	NON-EXPEDITED			US-PFIZER INC- 2015246791			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Nexium	S	Unk	Not Reported
	Lortab	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2015	11317538	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015245924		46 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erectile Dysfunction;	Zithromac Sr			S		2 G, 1x/Day		Pfizer
Pollakiuria; Suicidal	Zithromac Sr			S				Pfizer
Ideation; Thirst								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2015	11317910	NON-EXPEDITED			US-PFIZER INC-2015248948			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Demerol			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11143598	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015051475		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction;	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
Cataract; Diarrhoea; Drug	Enbrel			S				Amgen
Hypersensitivity; Nausea;	Augmentin /00756801/			S	Unknown	Unk		Not Reported
Parkinson'S Disease;	Guaifenesin/Codeine			S	Unknown	Unk		Not Reported
Rash; Urticaria; Vomiting	Levemir			S	Unknown	Unk		Not Reported
	Ceftizoxime			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported

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

Eryzole	S	Unknown		Not Reported
Levaquin	S	Unknown	Unk	Not Reported
Tetanus Toxoid	S	Unknown	Unk	Not Reported
Diphtheria Toxoid	S	Unknown	Unk	Not Reported
Zithromax	S	Unknown	Unk	Not Reported
Folvite /00024201/	C	Oral	1 Tablet Daily	Not Reported
Sinemet	C	Oral	01 Tablet, Tid	Not Reported
Domperidone	C	Oral	10 Mg, Daily	Not Reported
Methotrexate	C	Oral	2.5 Mg, 3 Tablets Once A Week	Not Reported
Topamax	C	Oral	100 Mg, Take 100 Mg By Mouth Daily	Not Reported
Neurontin	C	Oral	100 Mg, Tid	Not Reported
Ranexa	C	Oral	500 Mg, Bid	Not Reported
Crestor	C	Oral	10 Mg, Daily	Not Reported
Xanax	C	Oral	1 Mg, One To Two Tablets One Hour Before Mri	Not Reported
Zofran /00955301/	C	Sublingual	24 Mg, Under The Tongue Every 6 Hours As Needed.	Not Reported
Vitamin D3	C	Oral	5000 Unk, Daily.	Not Reported
Nexium /01479302/	C	Oral	40 Mg, Qd, Every Morning Before Breakfast	Not Reported
Humulin Regular	C		100 Unit, Tid, Before Meals	Not Reported
Novolin R	C		100 Unit, Tid, Before Meals	Not Reported
Metoprolol	C	Oral	100 Mg, Daily	Not Reported
Nitrostat	C	Sublingual	0.4 Mg, As Necessary, Every 5 Minutes As Needed	Not Reported
K-Dur	C	Oral	10 Meq, Daily	Not Reported
Phenergan /00033001/	C	Oral	25 Mg, Unk	Not Reported

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

Lantus	C		70 Unit, Nightly	Not Reported
Oxycontin	C	Oral	15 Mg, Unk	Not Reported
Aspirin /00002701/	C	Oral	325 Mg, Daily.	Not Reported
Plavix	C	Oral	75 Mg, Daily	Not Reported
Imdur	C	Oral	60 Mg, Daily.	Not Reported
Prinivil	C	Oral	20 Mg, Daily.	Not Reported
Zestril	C		20 Mg, Daily	Not Reported
Depo-Medrol	C	Intraocular	40 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11200673	NON-EXPEDITED			US-MYLANLABS-2014M1003050			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection	Levofloxacin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Warfarin			C		Unk		Not Reported	
	Calcium			C		Unk		Not Reported	
	Vitamins /00067501/			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11318724	EXPEDITED (15-DAY)		DE, OT	US-HOSPIRA-2953847		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Bronchiolitis; Drug-Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11320917	NON-EXPEDITED			US-PFIZER INC-2015247907		57 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11320975	NON-EXPEDITED		OT	US-PFIZER INC-2015248471		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Ear Disorder; Ear Pain	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromax			S			Pfizer		
	Zithromax			S			Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2015	11321585	NON-EXPEDITED			US-PFIZER INC-2015248669			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11200672	NON-EXPEDITED			US-MYLANLABS-2014M1002579			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Nail Disorder; Onychomycosis	Levothyroxine Sodium Tablets, Usp			S	Oral	25 Mg, Qd, 4x/Week		Mylan	
	Levothyroxine Sodium Tablets, Usp			S	Oral	37.5 Mg, Qd, 3x/Week		Mylan	
	Levothyroxine Sodium Tablets, Usp			S				Mylan	
	Levofloxacin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Warfarin			C		5 Mg, Unk		Not Reported	
	Warfarin			C		7.5 Mg, Unk		Not Reported	

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

	Calcium		C			Unk			Not Reported	
	Vitamins /00067501/		C			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11322449	NON-EXPEDITED				US-PFIZER INC-2015251599		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin				S	Oral	500 Mg, Daily (2 Tablets)			Pfizer
	Cefuroxime Axetil				S	Oral	500 Mg, 2x/Day			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11322451	NON-EXPEDITED				US-PFIZER INC-2015249014			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk			Pfizer
	Codeine				S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11322590	NON-EXPEDITED				US-PFIZER INC-2015250462		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pyrexia; Therapeutic Product Effect Incomplete	Zithromax				S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11324987	NON-EXPEDITED				US-PFIZER INC-2015249895			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin				S					Pfizer
	Xanax				S					Pfizer
	Metronidazole				S					Pfizer
	Cleocin				S					Pfizer

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

Ciprofloxacin	S			Not Reported
Codeine	S			Not Reported
Ketorolac	S			Not Reported
Neosporin /00130801/	S	Unk		Not Reported
Oxycontin	S	Unk		Not Reported
Plaquenil	S			Not Reported
Ultram	S			Not Reported
Cefdinir	S			Not Reported
Azasite	S	Ophthalmic	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11330334	DIRECT		DS			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Dizziness; Dyspepsia; Gastrointestinal Disorder; Vomiting	Azithromycin 250 Mg Greenstone Llc			S	Oral	2 Pills 1st Day 1 Pill Next 4 Once Daily Taken By Mouth		Greenstone
	Cod Liver Oil			C				Not Reported
	Evening Primrose Oil			C				Not Reported
	Coq-10 Ubiquinone			C				Not Reported
	Vitamin & Mineral Supplement			C				Not Reported
	Vitamin C With Bioflavonoids			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2015	11330468	DIRECT		DS			46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia; Product Label Issue	Flonase 50 Mcg Per Spray Gsk Consumer Hedalthcare, Lp			S	Nasal	2 Sprays Per Nostril, Sniffed Into Nasal Passages, Once Daily		Glaxosmithkline
	Azithromycin Z-Pack 250 Mg			S	Oral	2 Pills First Day, Then 1 Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2015	10794788	EXPEDITED (15-DAY)			US- GLAXOSMITHKLINE-		52 YR	Male	USA

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

US2014GSK051071

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia; Nausea; Vision Blurred; Visual Impairment	Wellbutrin Sr Prolonged-Release Tablet			S	Oral	200 Mg, Bid		Glaxosmithkline
	Wellbutrin Sr Prolonged-Release Tablet			S		100 Mg, Bid		Glaxosmithkline
	Align			S				Not Reported
	Ativan			S				Not Reported
	Azithromycin			S				Not Reported
	Fiorinal			S				Not Reported
	Fluticasone Propionate			S				Glaxosmithkline
	Imodium			S				Not Reported
	Inderal			S				Not Reported
	Lisinopril			S				Not Reported
	Miralax			S				Not Reported
	Motrin			S				Not Reported
	Mucinex D			S				Not Reported
	Nexium			S				Not Reported
	Robaxin			S				Not Reported
	Tylenol			S				Not Reported
	Ultram			S				Not Reported
	Zofran			S		Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2015	11273990	NON-EXPEDITED			US-PFIZER INC-2015231217			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2015	11327397	EXPEDITED (15-DAY)		OT	PL-APOTEX-2015AP010980		8 YR	Male	POL

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

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

Bronchopulmonary Aspergillosis; Haemoptysis; Staphylococcal Infection	CanbioX, Tabletki Powlekane	S	Oral	Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	10312565	EXPEDITED (15-DAY)		LT, OT	JP-009507513-1008USA00405		64 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Mycobacterium Avium Complex Infection; Pancytopenia; Tuberculosis; Tuberculosis	Efavirenz			S	Oral	600 Mg Daily, Divided Dose Frequency Unknown		Merck
	Isentress Tablets 400mg			S	Oral	800 Mg Daily, Divided Dose Frequency Unknown		Merck
	Isentress Tablets 400mg			S	Oral	800 Mg Daily, Divided Dose Frequency Unknown		Merck
	Retrovir			S	Oral	400 Mg Daily, Divided Dose Frequency Unknown		Not Reported
	Mycobutin			S	Oral	150 Mg, Qd		Not Reported
	Zithromac			S	Unknown	600 Mg, Qd		Not Reported
	Zithromac			S	Unknown	1200 Mg, Qw		Not Reported
	Pyramide			S	Oral	1 G, Qd		Not Reported
	Iscotin			S	Unknown	300 Mg, Qd		Not Reported
	Esanbutol			S	Oral	750 Mg, Qd		Not Reported
	Endoxan			C	Unknown	1300 Mg, Qd		Not Reported
	Adriacin			C	Intravenous (not otherwise specified)	87 Mg, Qd		Not Reported
	Oncovin			C	Intravenous (not otherwise specified)	2 Mg, Qd		Not Reported
	Baktar			C	Oral	480 Mg, Qd		Not Reported
	Predonine			C	Unknown	50 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	10704676	EXPEDITED (15-DAY)			US-			Male	USA

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

GLAXOSMITHKLINE-
US2014GSK046379

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhinorrhoea; Sneezing	Flonase Nasal Spray			S	Respiratory (inhalation)			Glaxosmithkline
	Allegra D 12 Hour Allergy And Congestion Z-Pack			S				Not Reported
				S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	11073441	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015140340		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematuria; Rash	Zithromax			S	Oral	500 Mg, Single		Pfizer
	Zithromax			S	Oral	250 Mg, Unk ((2d# 1, 1d# 2-5))		Pfizer
	Cheratussin Ac			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	11330078	EXPEDITED (15-DAY)		DE, LT	FR-PFIZER INC- 2015250846		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haematoma; Drug Interaction; International Normalised Ratio Increased	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Previscan (Fluindione)			S	Oral	20 Mg, Scored Tablet: ¾ Tablet Alternating With ½ Tablet Every Two Days		Not Reported
	Ceftriaxone Mylan			S	Intravenous drip	1 Df, 2x/Day		Not Reported
	Coversyl /00790702/			C				Not Reported
	Loxen /00639802/			C				Not Reported
	Diffu K			C				Not Reported
	Diamicron			C				Not Reported
	Kardegic			C				Not Reported

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

Augmentin /00756801/

C

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	11330448	EXPEDITED (15-DAY)		HO	BG-ACTAVIS-2015-15627		67 YR	Female	BGR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Azatriel			S	Oral	1 Df, Daily			Not Reported
	Ibuprofen			S	Oral	1 Df, Bid			Actavis Mid Atlantic
	Diaprel			C	Oral	Unk			Not Reported
	Mixtard /00806401/			C	Unknown	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	11330482	EXPEDITED (15-DAY)		OT	JP-BAYER-2015-391360		52 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Bayaspirin			S	Oral				Bayer
	Zithromac			S		250 Mg, Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	11331498	NON-EXPEDITED			US-PFIZER INC-2015253311			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Zithromax			S		Unk			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2015	11333895	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015252125			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Zithromac			S	Intravenous (not otherwise specified)	Unk			Pfizer

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

Increased; Blood Creatine
Phosphokinase Increased;
Rhabdomyolysis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2015	11249492	EXPEDITED (15-DAY)		OT	US-TEVA-575457USA		88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Diarrhoea; Drug Ineffective; Eye Swelling; Headache; Hepatic Function Abnormal; Jaw Disorder; Liver Disorder; Musculoskeletal Pain; Nausea; Neck Pain; Oral Pustule; Oxygen Saturation Decreased; Platelet Count Decreased; Rash; Somnolence; Vomiting	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2015	11328244	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2015US089766		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Betamethasone			S	Unknown	2 Doses 24 Hours Apart		Not Reported
Abdominal Pain Upper;	Magnesium Sulfate Inj			S	Unknown			Not Reported
Cardio-Respiratory Arrest;	Cefazolin Sodium			S	Unknown			Not Reported
Chest Pain; Dyspnoea;	Acetaminophen (Paracetamol)		Y	S	Unknown			Novartis
Foetal Death; Maternal Exposure During Pregnancy; Pneumonia;	Morphine			S	Unknown			Not Reported
Septic Shock;	Ceftriaxone			S	Unknown			Not Reported
Strongyloidiasis; Systemic Inflammatory Response Syndrome; Vomiting	Azithromycin			S	Unknown			Not Reported
	Cefepime			S	Unknown			Not Reported
	Ivermectin			S	Unknown			Not Reported

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

Vancomycin	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2015	11335027	NON-EXPEDITED			US-PFIZER INC-2015247258			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Feldene			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Flonase /00908302/			S		Unk		Not Reported
	Vesicare			S		Unk		Not Reported
	Zocor			S		Unk		Not Reported
	Evista			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2015	11335827	NON-EXPEDITED			US-PFIZER INC-2015255936			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Bacitracin			S		Unk		Pfizer
	Cipro /00697201/			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2015	11229108	NON-EXPEDITED			US-PFIZER INC-2015215366		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased;	Zithromax			S		Unk		Pfizer

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

Bronchitis; Drug	Zithromax	S						Pfizer
Ineffective; Insomnia;	Zithromax	S						Pfizer
Malaise; Product Use In	Zithromax	S						Pfizer
Unapproved Indication								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2015	11330895	EXPEDITED (15-DAY)		OT	PHHY2015IT091587		64 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azithromycin			S		1 Df, Qd		Not Reported	
	Paracetamol		Y	S	Oral	1 Df, Qd		Novartis	
	Tantum Verde			S	Respiratory (inhalation)	1 Df, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2015	11344183	DIRECT					19 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Drug-Induced Liver Injury; Dysuria; Fatigue; Jaundice; Pruritus	Azithromycin			S			4 DAY	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2015	11282663	EXPEDITED (15-DAY)		OT	IT-TEVA-579211ISR		2 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Haemorrhagic Oedema Of Infancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2015	11327119	EXPEDITED (15-DAY)		CA	US-JNJFOC-20150720635		< 1 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Calcification; Foetal Exposure During Pregnancy; Foetal Growth Restriction	Prezista			S	Transplacental			Not Reported	
	Miconazole		Y	S	Vaginal			Not Reported	
	Miconazole			S	Vaginal	At Bedtime For 7 Days		Not Reported	
	Diflucan		Y	S	Unknown			Not Reported	
	Truvada			S	Transplacental	1 Tablet/Capsule		Not Reported	
	Norvir			S	Transplacental			Not Reported	
	Cephalexin			S	Unknown	For 7 Days		Not Reported	
	Amoxicillin			S	Unknown	For 5 Days		Not Reported	
	Macrobid (Nitrofurantoin)			S	Unknown	For 7 Days		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Metronidazole			S	Unknown			Not Reported	
	Dapsone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2015	11345477	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015182565		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Diarrhoea; Drug Hypersensitivity; Nausea; Parkinson'S Disease; Rash; Urticaria; Vomiting	Enbrel			S		50 Mg, Qwk		Unknown	
	Enbrel			S				Unknown	
	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
	Guaifenesin/Codeine			S	Unknown	Unk		Not Reported	
	Levemir			S		Unk		Not Reported	
	Ceftizoxime			S		Unk		Not Reported	

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

Ciprofloxacin	S		Unk	Not Reported
Eryzole	S		Unk	Not Reported
Tetanus Toxoid	S		Unk	Not Reported
Diphtheria Toxoid	S		Unk	Not Reported
Folvite	C	Oral	1 Tablet Daily	Not Reported
Sinemet	C	Oral	01 Tablet, Tid	Not Reported
Domperidone	C	Oral	10 Mg, Daily	Not Reported
Methotrexate	C	Oral	2.5 Mg, 3 Tablets Once A Week	Not Reported
Topamax	C	Oral	100 Mg, Take 100 Mg By Mouth Daily	Not Reported
Neurontin	C	Oral	100 Mg, Tid	Not Reported
Ranexa	C	Oral	500 Mg, Bid	Not Reported
Crestor	C	Oral	10 Mg, Daily	Not Reported
Xanax	C	Oral	1 Mg, One To Two Tablets One Hour Before Mri	Not Reported
Zofran	C	Sublingual	24 Mg, Under The Tongue Every 6 Hours As Needed.	Not Reported
Vitamin D3	C	Oral	5000 Unk, Daily.	Not Reported
Nexium	C	Oral	40 Mg, Qd, Every Morning Before Breakfast	Not Reported
Humulin Regular	C		100 Unit, Tid, Before Meals	Not Reported
Novolin R	C		100 Unit, Tid, Before Meals	Not Reported
Metoprolol	C	Oral	100 Mg, Daily	Not Reported
Nitrostat	C	Sublingual	0.4 Mg, As Necessary, Every 5 Minutes As Needed	Not Reported
K-Dur	C	Oral	10 Meq, Daily	Not Reported
Phenergan	C	Oral	25 Mg, Unk	Not Reported
Lantus	C		70 Unit, Nightly	Not Reported

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

	Oxycontin	C	Oral	15 Mg, Unk	Not Reported
	Aspirin	C	Oral	325 Mg, Daily.	Not Reported
	Plavix	C	Oral	75 Mg, Daily	Not Reported
	Imdur	C	Oral	60 Mg, Daily.	Not Reported
	Prinivil	C	Oral	20 Mg, Daily.	Not Reported
	Zestril	C		20 Mg, Daily	Not Reported
	Depo-Medrol	C	Intraocular	40 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2015	11346088	NON-EXPEDITED			US-PFIZER INC-2015260546			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Acyclovir			S		Unk, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2015	11348236	NON-EXPEDITED			US-PFIZER INC-2015259614		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2015	11348598	EXPEDITED (15-DAY)		HO	GB-BAUSCH-BL-2015-018760		83 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure; Toxicity To Various Agents	Diltiazem			S	Oral			Not Reported
	Theophylline			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Adcal-D3			C				Not Reported
	Bumetanide			C				Not Reported

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

Carbocisteine	C	Not Reported
Folic Acid	C	Not Reported
Paracetamol	C	Not Reported
Ranitidine	C	Not Reported
Rivaroxaban	C	Not Reported
Salbutamol	C	Not Reported
Symbicort	C	Not Reported
Tiotropium Bromide	C	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11349040	EXPEDITED (15-DAY)		DE, OT	ZM-PFIZER INC-2015259065		2 YR	Female	ZMB

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cardiac Arrest; Choking; Vomiting	Zithromax			S	Oral	250 Mg (1 Tablet), Single		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11349144	EXPEDITED (15-DAY)		OT	PL-TEVA-583398ISR		8 YR	Male	POL

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Bronchopulmonary Aspergillosis	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11356294	NON-EXPEDITED			US-PFIZER INC-2015262273			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Aug-2015	11359245	NON-EXPEDITED			US-PFIZER INC-2015261151			Female	USA

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

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

Drug Hypersensitivity	Azithromycin	S	Unknown	Unk	Pfizer
	Daypro	S	Unknown	Unk	Pfizer
	Methotrexate	S	Unknown	Unk	Not Reported
	Vioxx	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2015	11359419	DIRECT		DS, HO			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Gait Inability; Guillain-Barre Syndrome	Azithromycin			S		By Mouth	10 DAY	Not Reported	
	Nebulizer			C				Not Reported	
	Albuterol			C				Not Reported	
	Cyanocobalamin			C				Not Reported	
	Guaifenesin			C				Not Reported	
	Isosorbide Mononitrate			C				Not Reported	
	Lisinopril			C				Not Reported	
	Metformin			C				Not Reported	
	Metoprolol Tartrate			C				Not Reported	
	Pravastatin			C				Not Reported	
	Aspirin			C				Not Reported	
	B-12			C				Not Reported	
	Fish Oil			C				Not Reported	
	Symbicort			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2015	10031612	NON-EXPEDITED			US-PFIZER INC-2014081047		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Protonix			S		Unk		Pfizer	
	Cephalexin			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Toprol XL			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2015	11276414	NON-EXPEDITED			US-PFIZER INC-2015234457		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		500 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2015	11333548	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2015252762		64 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azithromycin			S	Oral	1 Df, Daily		Pfizer	
	Paracetamol			S	Oral	1 Df, Daily		Not Reported	
	Tantum Verde			S	Respiratory (inhalation)	1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2015	11361966	EXPEDITED (15-DAY)		OT	PL-FRESENIUS KABI-FK201503706		8 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchopulmonary Aspergillosis; Bronchopulmonary Aspergillosis Allergic; Haemoptysis	Azithromycin (Manufacturer Unknown) (Azithromycin)			S	Oral			Fresenius Medical Care	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2015	11362475	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2015GSK113983		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Hypoxia; Maternal Exposure During	Serevent			S	Respiratory (inhalation)	Unk		Glaxosmithkline	

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

Pregnancy; Pregnancy; Ventilation Perfusion Mismatch	Salbutamol Sulphate	S	Respiratory (inhalation)	Unk	Glaxosmithkline
	Fluticasone Propionate	S		Unk	Glaxosmithkline
	Ondansetron Hydrochloride	S	Intravenous (not otherwise specified)	4 Mg, Unk	Glaxosmithkline
	Azithromycin	S		Unk	Glaxosmithkline
	Bupivacaine	S	Intravenous (not otherwise specified)	1.8 Ml, Unk	Not Reported
	Fentanyl Citrate Injection	S	Epidural	10 Unk, Unk	Not Reported
	L-Thyroxine	S		125 Unk, Qd	Not Reported
	Morphine	S		100 Unk, Unk	Glaxosmithkline
	Omeprazole	S		40 Mg, Qd	Glaxosmithkline
	Oxytocin Injection	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Phenylephrine Hcl	S	Intravenous (not otherwise specified)	650 Unk, Unk	Glaxosmithkline
	Tobramycin	S	Respiratory (inhalation)	Unk	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	9909288	NON-EXPEDITED			US-GILEAD-2012-0049129		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Hypoaesthesia; Tremor	Letairis			S	Oral	5 Mg, Unk		Gilead	
	Letairis			S				Gilead	
	Zithromax Z-Pak			S				Not Reported	
	Prednisone			S				Not Reported	
	Hydrocodone			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	11219774	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015206854		365 DAY	Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Level Decreased; Hypoglycaemia		Zithromac		S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	11364412	NON-EXPEDITED			US-PFIZER INC- 2015263342			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Asthenia; Nausea	Azithromycin			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	11364456	NON-EXPEDITED			US-PFIZER INC- 2015265221			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Gastritis; Headache; Hypersensitivity; Insomnia; Muscle Spasms; Pain	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	11364567	EXPEDITED (15-DAY)		HO	BR- GLAXOSMITHKLINE- BR2015GSK113331			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eating Disorder; Off Label Use; Pain; Pharyngitis; Pyrexia; Tonsillitis; Weight Decreased	Fluticasone Propionate+Salmeterol Xinafoate Fluticasone Propionate+Salmeterol Xinafoate Azithromycin Prednisolone Curcuma Longa			S S S S C	Respiratory (inhalation) Oral Oral	50/250 ,1 Puff(S), Bid Unk 1 Capsule, Qd		Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Not Reported	

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

	Curcuma Longa	C					Not Reported
	Calcium	C			1 Capsule, Bid		Not Reported
	Vitamin D3	C	Oral		10 Drop(S), Qd		Not Reported
	Omeprazole	C			2 Capsule, Qd		Not Reported
	Risedronate	C	Oral		1 Capsule, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	11365417	NON-EXPEDITED			US-PFIZER INC-2015261523		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer	
Hypotonia; Muscle	Zithromax			S		Unk		Pfizer	
Atrophy; Muscular									
Weakness									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2015	11372253	NON-EXPEDITED			US-ELI_LILLY_AND_COMP ANY-US201310002911			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Disturbance In	Axiron			S	Topical	60 Mg, Qd		Eli Lilly And Co	
Sexual Arousal; Drug	Z-Pack			S	Unknown	Unk, Unknown		Not Reported	
Interaction; Gastroenteritis	Potassium Citrate			S	Unknown	Unk, Unknown		Not Reported	
Viral; Lymphadenopathy;									
Nausea									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	10984082	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015113660		42 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	500 Mg, Total		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	11272215	EXPEDITED (15-DAY)	Y	DE, OT	ADR-2015-01289		47 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Complication; Multiple Sclerosis; Pneumonia; Pneumonia Aspiration	Lioresal			S				Not Reported	
	Oral Baclofen			S				Not Reported	
	Sertraline			S	Oral			Not Reported	
	Azithromycin			S	Oral	200 Mg/5 MI		Not Reported	
	Solu-Medrol			S	Intravenous (not otherwise specified)		3 DAY	Not Reported	
	Tylenol With Codeine #3			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	11336689	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2015M1025797			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azithromycin			S		1 Df, Qd		Not Reported	
	Paracetamol			S	Oral	1 Df, Qd		Not Reported	
	Tantum Verde			S	Respiratory (inhalation)	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	11368838	NON-EXPEDITED		HO	PHHY2015US066158		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Pulmonary Function Test Decreased; Pyrexia; Respiratory Distress	Clofazimine			S	Oral	2 Df, (50 Mg) Qd		Novartis	
	Clofazimine			S	Oral	100 Mg, Qd		Novartis	
	Azithromycin			S	Oral	2500 Mg, Unk		Not Reported	
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
	Ciprofloxacin			C	Intravenous (not otherwise specified)	400 Mg, Tid		Not Reported	
	Ciprofloxacin			C	Unknown	750 Mg, Bid		Not Reported	
	Dornase Alfa			C	Unknown	2.5 Mg, Bid		Not Reported	
	Fluconazole			C	Intravenous (not	400 Mg, Qd		Not Reported	

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

		otherwise specified)		
Fluticasone	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
Imipenem And Cilastatin	C	Intravenous (not otherwise specified)	1000 Mg, Bid	Not Reported
Loratadine	C	Oral	10 Mg, Qd (1 Tablet)	Not Reported
Methylprednisolone	C	Intravenous (not otherwise specified)	30 Mg, Bid	Not Reported
Multi Vitamin & Mineral	C	Oral	2 Df, Bid (2 Capsule)	Not Reported
Pancrelipase	C	Oral	8 Df, Tid	Not Reported
Pantoprazol	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
Hypertonic Saline Solution	C	Unknown	4 MI, Bid	Not Reported
Hypertonic Saline Solution	C	Respiratory (inhalation)	0.28 G, Unk	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	1000 MI, Qd	Not Reported
Acetaminophen	C	Oral	2 Df, (Q 6 Hr) Prn	Not Reported
Ipratropium	C	Unknown	500 Ug, Prn	Not Reported
Ondansetran	C	Unknown	1 Df, Prn	Not Reported
Zenpep	C	Oral	24 Df, Qd	Not Reported
Albuterol	C	Respiratory (inhalation)	3 MI, Qid	Not Reported
Cayston	C	Unknown	75 Mg, Tid	Not Reported
Omeprazole	C	Oral	40 Mg, Qd	Not Reported
Humalog	C	Unknown	100 U/MI, Qd	Not Reported
Humalog	C	Unknown	Varied Dose With Meals, Tid	Not Reported
Insulin Glargine	C	Unknown	12 U, Qd	Not Reported
Cholecalciferol	C	Oral	2000 Iu, Qd	Not Reported
Amikacin	C	Respiratory (inhalation)	500 Mg, Bid	Not Reported

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

Amikacin	C	Intravenous (not otherwise specified)	700 Mg, Qd	Not Reported
Cefoxitin	C	Intravenous (not otherwise specified)	1000 Mg, Q12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	11370479	EXPEDITED (15-DAY)		OT	IT-APOTEX-2015AP011217			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azithromycin			S	Unknown	1 Df, Daily		Apotex	
	Paracetamol			S	Oral	1 Df, Daily		Not Reported	
	Tantum Verde			S	Respiratory (inhalation)	1 Df, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	11371214	NON-EXPEDITED			US-PFIZER INC-2015266461		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Cyclobenzaprine Hcl			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2015	11379146	EXPEDITED (15-DAY)	Y	OT	2015RR-101068		64 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azitromicina		Y	S				Not Reported	
	Paracetamol (Paracetamol)			S				Not Reported	
	Unknown, Unknown								
	Tantum Verde			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2015	9193177	NON-EXPEDITED			US-PFIZER INC-2013010584		51 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
No Adverse Event; Product Packaging Quantity Issue	Azithromycin			S		250 Mg, 2x/Day		Pfizer	
	Azithromycin			S		250 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2015	11262838	EXPEDITED (15-DAY)			JP-PFIZER INC- 2015224730		6 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia	Zithromac			S	Oral	Unk, 2x/Day		Pfizer	
	Zithromac			S				Pfizer	
	Calonal			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2015	11375471	EXPEDITED (15-DAY)		OT	JP- GLAXOSMITHKLINE- JP2007JPN000001		42 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Function Abnormal	Abacavir Sulfate + Lamivudine			S	Oral	1 Df, Qd (Concentration: 300/600 Mg)		Viiv	
	Lamivudine.			S	Oral	300 Mg, Qd		Viiv	
	Zidovudine			S	Oral	400 Mg, Unk		Viiv	
	Zithromac			S	Oral	1200 Mg, We		Not Reported	
	Norvir Soft			C	Oral	100 Mg, Unk		Not Reported	
	Reyataz			C	Oral	400 Mg, Unk		Not Reported	
	Reyataz			C	Oral	300 Mg, Unk		Not Reported	
	Viread			C	Oral	300 Mg, Unk		Not Reported	
	Baktar			C	Oral	1 Df, Qd		Not Reported	
	Hokunalin Tape			C	Transdermal	2 Mg, Qd		Not Reported	
Uniphyl La			C	Oral	400 Mg, Qd		Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2015	11375888	EXPEDITED (15-DAY)		OT	JP-VIIV HEALTHCARE LIMITED-JP2007JPN000001		42 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Function Abnormal	Abacavir Sulfate + Lamivudine			S	Oral	1 Df, Qd (Concentration: 300/600 Mg)		Viiv	
	Lamivudine.			S	Oral	300 Mg, Qd		Viiv	
	Zidovudine			S	Oral	400 Mg, Unk		Viiv	
	Zithromac			S	Oral	1200 Mg, We		Not Reported	
	Norvir Soft			C	Oral	100 Mg, Unk		Not Reported	
	Reyataz			C	Oral	400 Mg, Unk		Not Reported	
	Reyataz			C	Oral	300 Mg, Unk		Not Reported	
	Viread			C	Oral	300 Mg, Unk		Not Reported	
	Baktar			C	Oral	1 Df, Qd		Not Reported	
	Hokunalin Tape			C	Transdermal	2 Mg, Qd		Not Reported	
	Uniphyl La			C	Oral	400 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	10095400	NON-EXPEDITED			US-GILEAD-2013-0077138		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Letairis			S		10 Mg, Qd		Gilead	
	Azithromycin			S				Not Reported	
	Adcirca			C				Not Reported	
	Warfarin			C				Not Reported	
	Remodulin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	10991617	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015114950		40 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Laryngeal Oedema		Azithromycin		S	Oral	500 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	11022312	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015114824		71 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia	Trozocina			S	Oral	500 Mg, Daily		Pfizer	
	Seretide "Glaxo Wellcome"			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	11310262	NON-EXPEDITED			US-PFIZER INC-2015245041			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
	Clarithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	11360614	EXPEDITED (15-DAY)		OT	SG-SUN PHARMACEUTICAL INDUSTRIES LTD-2015RR-101068			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azitromicina			S	Unknown	1 Df, Daily		Not Reported	
	Paracetamol		Y	S	Unknown	1 Df, Daily		Ohm Lab	
	Tantum Verde			S	Respiratory (inhalation)	1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	11382998	NON-EXPEDITED			US-PFIZER INC-2015268002		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Dizziness; Gallbladder Disorder; Gastritis; Nausea; Pain; Weight Decreased	Zithromax	S	Unk	Pfizer
	Acetaminophen W/Hydrocodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2015	11383745	EXPEDITED (15-DAY)		DE, OT	PHHY2015US083611		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Complication; Pneumonia	Lioresal Intratecal			S	Intratracheal	1650 Ug, Qd		Not Reported
	Baclofen			S	Oral	2 Df, Qid		Not Reported
	Sertraline			S	Oral	1 Df, Qd		Novartis
	Azithromycin			S	Oral	200 Mg/5 MI		Not Reported
	Solu-Medrol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tylenol With Codeine No.3			S	Oral	1 Df, Qid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2015	11233663	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2015063901		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Choking; Cough; Feeling Abnormal; Gastric Disorder; Hypertension; Immunosuppression; Insomnia; Laryngitis; Malaise; Migraine; Nasopharyngitis; Retching; Sinusitis; Upper Respiratory Tract Infection	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen
	Xeljanz			S	Unknown	5 Mg, Bid		Not Reported
	Z-Pack			S	Unknown	Unk		Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Z-Pack			S				Not Reported
	Methotrexate			C	Oral	10 Mg, Qwk		Not Reported

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

Prednisone	C	Oral	10 Mg, Qd	Not Reported
Synthroid	C		25 Mcg 1 Tab A Day	Not Reported
Toprol XL	C	Oral	25 Mg, Qd	Not Reported
Omeprazole	C	Oral	20 Mg, Qd	Not Reported
Citracal /00751520/	C		Twice A Day	Not Reported
Vitamin D /00107901/	C		1000 Mg, Qd	Not Reported
Thera Tears	C		2-3 Times A Day	Not Reported
Imitrex /01044801/	C	Oral	50 Mg, Prn	Not Reported
Acetaminophen	C		500 Mg, Prn	Not Reported
Arava	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported
Levothyroxine	C	Oral	25 Mg, Qd	Not Reported
Humira	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2015	11387778	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2015268999			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure	Azithromycin			S	Oral	Unk, As Directed		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2015	11388658	EXPEDITED (15-DAY)		DE	RU-TEVA-585907ISR			Unknown	RUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Death; Foetal Exposure During Pregnancy	Sumamed			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2015	11392640	NON-EXPEDITED			US-PFIZER INC-2015274549			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Malaise	Azithromycin			S		Unk		Pfizer	
	Motrin			C		124 Mg, Unk		Not Reported	
	Tylenol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2015	10717600	NON-EXPEDITED			US-GILEAD-2015-0131979		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Nasopharyngitis; Sinusitis	Letairis			S	Unknown	10 Mg, Qd		Gilead	
	Tyvaso			C				Not Reported	
	Adempas			C				Not Reported	
	Z-Pack			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2015	11397009	NON-EXPEDITED			US-PFIZER INC-2015272454			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Reaction To Excipient; Vomiting	Zithromax			S		Two Tablets Once A Day		Pfizer	
	Zithromax			S		One Tablet Once A Day		Pfizer	
	Sodium Lauryl Sulfate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2015	11397119	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015270095		9 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2015	11397121	EXPEDITED (15-DAY)		LT	PH-PFIZER INC-2015166237		28 YR	Male	PHL

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus; Rash; Urticaria	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Clindamycin			C	Oral	300 Mg, 1x/Day		Not Reported	
	Paracetamol			C	Oral	500 Mg, Q4 Hours		Not Reported	
	Co-Amoxiclav /00756801/			C	Oral	625 Mg, 2x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2015	11397126	EXPEDITED (15-DAY)		LT	PH-PFIZER INC-2015166268		24 YR	Female	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Rash; Urticaria	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Ceftriaxone			C		Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported
	Cefuroxime			C	Intravenous (not otherwise specified)	750 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2015	11397497	NON-EXPEDITED			US-PFIZER INC-2015276082		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2015	11400405	NON-EXPEDITED			US-PFIZER INC-2015269578		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Macrobid		S			Unk		Not Reported	
	Xv Contrast		S			Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2015	11405297	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2015275333		54 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Pain; Parosmia	Azithromycin			S	Oral	250 Mg, 3x/Day		Pfizer	
	Cetirizine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2015	11026608	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2015M1011067			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	500 Mg Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2015	11245460	EXPEDITED (15-DAY)		DE, OT	PHHY2015US080028			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atelectasis; Bronchitis Chronic; Disease Complication; Respiratory Arrest; Respiratory Failure	Lioresal Intratecal			S	Intrathecal	1472 Ug, Qd		Not Reported	
	Lioresal Intratecal			S	Intrathecal	1472.3 Ug, Qd		Not Reported	
	Baclofen			S	Respiratory (inhalation)	Unk, Prn (As Needed)		Not Reported	
	Ibuprofen			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Diazepam			S	Unknown	Unk		Not Reported	
	Triamcinolone			S	Unknown	Unk		Not Reported	
	Tylenol			S	Unknown	Unk		Not Reported	
	Albuterol			S	Unknown	Unk		Not Reported	

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

Zyrtec	S	Endocervical	Unk	Not Reported
Vitamin D Nos	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Patanase	S	Unknown	Unk	Not Reported
Milk Of Magnesia	S	Unknown	Unk	Not Reported
Phenobarbital	S	Unknown	Unk	Not Reported
Miralax	S	Unknown	Unk	Not Reported
Sudafed	S	Unknown	Unk	Not Reported
Benadryl	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2015	11410660	NON-EXPEDITED			US-PFIZER INC-2015277963		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Oxycodone			S		Unk		Pfizer
	Vicodin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2015	11410661	NON-EXPEDITED			US-PFIZER INC-2015279345		35 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		250 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2015	11415830	DIRECT					27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Diarrhoea; Dysphagia; Headache; Oropharyngeal	Azithromycin 500mg Paktab Sandoz Fluconazole Generic For			S	Oral	2 Pills		Not Reported
				C				Not Reported

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

Pain; Pain; Throat Tightness	Diflucan			C					Not Reported
	Metronidazole Generic For Flagyl								
	Green Tea			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2015	10462682	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2014256841		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ectopic Pregnancy; Foetal Death; Pregnancy; Therapeutic Response Unexpected	Zithromax			S	Oral	Unk		Pfizer	
	Metformin			C		Unk		Not Reported	
	Synthroid			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2015	10465371	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2014255991		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Pregnancy; Therapeutic Response Unexpected	Zithromax			S		Unk		Pfizer	
	Metformin			C		Unk		Not Reported	
	Synthroid			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2015	11283621	NON-EXPEDITED			US-PFIZER INC-2015235311		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Disturbance In Attention; Feeling Abnormal; Laryngitis; Loss Of Personal Independence In Daily Activities; Malaise; Weight Decreased	Zithromax			S	Oral	Two To First Day And Then One For Four Days And Then Over		Pfizer	
	Ventolin /00139501/			C		Unk		Not Reported	
	Allegra			C		180 Mg, Daily		Not Reported	
	Prozac			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2015	11321829	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015248572		22 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterocolitis	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2015	11416364	NON-EXPEDITED			US-PFIZER INC-2015280152			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2015	11417440	NON-EXPEDITED			US-PFIZER INC-2015279352			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2015	11419255	EXPEDITED (15-DAY)		OT	PHHY2015FR100293			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Condition Aggravated; Cough; Pyrexia; Respiratory Disorder; Sputum Increased	Tobramycin			S	Unknown			Not Reported	
	Ciprofloxacin			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
	Minocycline\Minocycline Hydrochloride			S	Unknown			Not Reported	
	Ceftazidime			S	Unknown			Not Reported	
	Co Trimoxazole			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2015	11420235	EXPEDITED (15-DAY)		OT	PHHY2015GB099413		54 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Bone Pain; Parosmia	Azithromycin			S	Oral	250 Mg, Qw3		Novartis	
	Cetirizine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2015	11420661	NON-EXPEDITED			US-PFIZER INC- 2015271837			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Urinary Tract Infection	Advil Pm			S		Unk, 1x/Day (Every Day At Night)		Pfizer	
	Zithromax			S		1 Df, Daily(At Night)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2015	11420938	NON-EXPEDITED			US-PFIZER INC- 2015281220		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2015	11420955	NON-EXPEDITED			US-PFIZER INC- 2015281684		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2015	11421049	NON-EXPEDITED			US-PFIZER INC- 2015283808		51 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2015	11422745	EXPEDITED (15-DAY)		OT	MY-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015R3-102241			Unknown	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2015	11423325	NON-EXPEDITED			US-APOTEX- 2014AP004032		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S	Oral			Apotex	
	Ciprofloxacin Hydrochloride			S	Oral	Unk		Apotex	
	Linezolid			S	Oral			Not Reported	
	Ceftriaxone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2015	11431791	EXPEDITED (15-DAY)		DS, OT	GB-PFIZER INC- 2015283007		64 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Feeling Abnormal; Hypoacusis; Insomnia; Malaise; Oropharyngeal Pain; Tremor	Azithromycin			S		500 Mg, Weekly		Pfizer	
	Azithromycin			S		1500 Mg, Taken On Monday, Wednesday And Friday		Pfizer	
	Calcichew			C	Oral	2 Df, 1x/Day		Not Reported	
	Lansoprazole			C	Oral	15 Mg, 1x/Day		Not Reported	

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

		Prednisolone	C	Oral	5 Mg, 1x/Day		Not Reported
		Etanercept	C	Subcutaneous	50 Mg, Weekly		Not Reported
		Simvastatin	C	Oral	20 Mg, 1x/Day		Not Reported
		Methotrexate	C	Oral	10 Mg, Weekly		Not Reported
		Metformin	C	Oral	1 G, 1x/Day Ongoing For Years		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2015	11432038	NON-EXPEDITED		HO, OT	PR-PFIZER INC-2015282254			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Zithromax			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2015	11432100	NON-EXPEDITED			US-PFIZER INC-2015284016		83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2015	11432118	NON-EXPEDITED			US-PFIZER INC-2015283884		40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperhidrosis; Hypersensitivity; Malaise; Vomiting	Zithromax			S		Unk		Pfizer
	Northera			S	Oral	600 Mg, 3x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2015	11432818	NON-EXPEDITED			US-PFIZER INC-2015283357		27 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Delusion	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2015	11437167	NON-EXPEDITED			US-PFIZER INC-2015288619		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cefdinir			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2015	11444990	DIRECT		DS			56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthropathy	Zithromax			S	Oral	6 Pills(2 Day One, Then 1 Pill)	10 DAY	Apotex	
	Levothyroxin			C				Not Reported	
	Reliv (Multi-Vitamin)			C				Not Reported	
	Vit. D3			C				Not Reported	
	Cal/Mag			C				Not Reported	
	Vit B Complex			C				Not Reported	
	Fish Oil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	10576222	NON-EXPEDITED			US-PFIZER INC-2014306763		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11431531	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015279282		59 YR	Female	JPN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cellulitis; Drug Ineffective	Minomycin			S	Oral	100 Mg, 2x/Day		Pfizer	
	Unasyn-S			S	Intravenous drip	1.5 G, Unk		Pfizer	
	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11441711	EXPEDITED (15-DAY)		DE, OT	BR-PFIZER INC-2015286470		1 YR	Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Product Administered To Patient Of Inappropriate Age	Zitromax			S		10 Mg/Kg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11441846	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2015284715		17 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Febrile Neutropenia; Tonsillitis Bacterial	Ponstan			S	Oral	500 Mg, 3x/Day		Pfizer	
	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Dafalgan			C	Oral	500 Mg, Unk		Not Reported	
	Solmucol			C	Oral			Not Reported	
	Avamys			C	Nasal			Not Reported	
	Deaftol Avec Lidocaine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11442728	NON-EXPEDITED			US-APOTEX-2014AP006468			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11442756	NON-EXPEDITED			US-APOTEX-2014AP005302			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Reaction To Excipient	Azithromycin			S	Unknown	2 Pills		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11442787	NON-EXPEDITED			US-APOTEX-2015AP007664		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder; Skin Discolouration	Azithromycin			S	Unknown			Apotex	
	Ciprofloxacin Hydrochloride			S	Unknown			Apotex	
	Rifabutin			S	Unknown			Not Reported	
	Clofazimine			S	Unknown	100 Mg, Daily		Not Reported	
	Ethambutol			C	Unknown	Unk		Not Reported	
	Tacrolimus			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11442815	NON-EXPEDITED			US-APOTEX-2015AP009002			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Eye Pain; Fatigue; Feeling Abnormal; Headache; Muscle Twitching; Off Label Use; Swelling; Xeroderma	Azithromycin			S	Unknown	500 Mg, Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11443063	NON-EXPEDITED		OT	DE-PFIZER INC-2015286252			Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11443083	NON-EXPEDITED			US-PFIZER INC-2015288044		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11443165	EXPEDITED (15-DAY)		DS, OT	PHHY2015GB102085		64 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Feeling Abnormal; Hypoacusis; Insomnia; Malaise; Oropharyngeal Pain; Tremor	Azithromycin			S	Unknown	500 Mg, Qw3		Novartis	
	Azithromycin			S	Unknown	Taken On Monday, Wednesday And Friday		Novartis	
	Calcichew			C	Oral	2 Df, Qd		Not Reported	
	Lansoprazole			C	Oral	15 Mg, Qd Ongoing For Years		Not Reported	
	Prednisolone			C	Oral	5 Mg, Qd Ongoing For Years		Not Reported	
	Etanercept			C	Subcutaneous	50 Mg, Qw Had 3 Doses		Not Reported	
	Simvastatin			C	Oral	20 Mg, Qd Taking For Several Years. Ongoing		Not Reported	
	Methotrexate			C	Oral	10 Mg, Qw		Not Reported	
	Metformin			C	Oral	1 G, Qd Ongoing For Years		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11443222	NON-EXPEDITED			US-APOTEX-2015AP009839			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event	Azithromycin			S	Unknown	Unk, Unknown		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11443226	NON-EXPEDITED			US-LUNDBECK-DKLU2001689			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Hypersensitivity; Malaise; Vomiting	Northera			S	Oral			Lundbeck	
	Z-Pack			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2015	11443362	EXPEDITED (15-DAY)		HO	US-SA-2015SA129904			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Allegra D			S	Oral			Not Reported	
	Z-Pack			S	Unknown			Not Reported	
	Magnesium			C	Unknown			Not Reported	
	Panthenol/Retinol/Thiamine Hydrochloride/Ascorbic Acid/Ergocalciferol/Folic Acid/Riboflavin/Nicotina Vitamin C			C	Unknown			Not Reported	
	Ecotrin			C	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Tylenol			C	Unknown			Not Reported	
	<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>
02-Sep-2015	11387706	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2015262324		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Dry	Advil			S	Oral	400 Mg, 3x/Day		Pfizer	

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

Mouth; Dysgeusia; Paraesthesia	Azithromycine Biogaran	S	Oral	2 Df Of 250 Mg, 1x/Day	Not Reported
	Helicidine	S	Oral	1 Df, As Needed	Not Reported
	Rhinomaxil	S	Nasal	1 Df, As Needed	Not Reported
	Preterax /06377001/	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2015	11444680	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-01614		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Akathisia	Azithromycin			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2015	11444692	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-02324			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Doxycycline			S	Unknown				Not Reported
	Rifampin			S	Unknown				Not Reported
	Azithromycin			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2015	11448456	EXPEDITED (15-DAY)		HO, OT	US-BAYER-2015- 412286		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pericardial Haemorrhage	Rivaroxaban			S					Unknown
	Rivaroxaban			S		Unk			Unknown
	Acetylsalicylic Acid(<=100 Mg)		Y	S					Bayer
	Azithromycin			S					Not Reported
	Metoprolol			C					Not Reported
	Levothyroxine			C					Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Sep-2015	11448917	NON-EXPEDITED			US-PFIZER INC-2015289830		80 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S	Unknown	Unk		Pfizer	
	Erythromycin			S	Unknown	Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11455275	NON-EXPEDITED			US-APOTEX-2015AP009668			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Akathisia	Azithromycin			S	Oral	500 Mg, Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11455288	NON-EXPEDITED			US-APOTEX-2015AP005004			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S	Unknown			Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Sep-2015	11456203	NON-EXPEDITED			US-PFIZER INC-2015291962			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Sep-2015	10884011	EXPEDITED (15-DAY)		HO	IT-ROCHE-1547640		74 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Chronic Obstructive Pulmonary Disease; Drug Ineffective	Rocefin	S	Intramuscular	1g/3.5ml-1 Vial Of Powder+1 Vial Of Solvent 3.5 MI	Not Reported
	Zitromax	S	Oral		Not Reported
	Deponit	C	Transdermal	10 Mg/24 H Transdermal Patches 15 Patches	Not Reported
	Lasix	C	Oral	25 Mg Tablets 30 Tablets	Not Reported
	Norvasc	C	Oral	5 Mg Tablets 28 Tablets	Not Reported
	Cardioaspirin	C	Oral	100 Mg Gastro-Resistant Tablets 60 Tablets	Not Reported
	Clexane	C	Unknown	2000 Iu Axa 0.2 MI 6 Pre-Filled Syringes	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2015	11221493	NON-EXPEDITED		HO	US-PFIZER INC-2015213140		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bacterial Infection; Constipation; Drug Ineffective; Pain; Product Colour Issue	Azithromycin			S		250mg X 4 Large Pills		Pfizer
	Zithromax			S		250 Mg, Unk (250 Mg 4 Pills)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2015	11457176	EXPEDITED (15-DAY)		DS, OT	GB-TEVA-588691ACC		64 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Feeling Abnormal; Hypoacusis; Insomnia; Malaise; Oropharyngeal Pain; Tremor	Azithromycin			S		214.2857 Milligram Daily;		Not Reported
	Azithromycin			S		Taken On Monday, Wednesday And Friday		Not Reported
	Calcichew			C	Oral	2 Dosage Forms Daily; For Several Years; On Going.		Not Reported
	Lansoprazole			C	Oral	15 Milligram Daily; Ongoing For Years		Not Reported

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

Prednisolone	C	Oral	5 Milligram Daily; Ongoing For Years	Not Reported
Etanercept	C	Subcutaneous	Had 3 Doses	Not Reported
Simvastatin	C	Oral	20 Milligram Daily; Taking For Several Years. Ongoing	Not Reported
Methotrexate	C	Oral		Not Reported
Metformin	C	Oral	1 Gram Daily; Ongoing For Years	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2015	11457259	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-2988740		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower;	Azithromycin			S	Unknown			Not Reported
Abdominal Pain Upper;	Estradiol			C				Not Reported
Decreased Appetite;	Azithromycin			S	Unknown			Not Reported
Diarrhoea; Gastrointestinal Inflammation; Hypophagia; Loss Of Personal Independence In Daily Activities; Motion Sickness; Nausea; Nightmare; Sleep Disorder	Tylenol /00020001/			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2015	11458669	EXPEDITED (15-DAY)		DS, OT	GB-MYLANLABS-2015M1028998			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Feeling Abnormal; Hypoacusis; Insomnia; Malaise; Oropharyngeal Pain; Tremor	Azithromycin			S		500 Mg, 3xw		Not Reported
	Azithromycin			S		Taken On Monday, Wednesday And Friday		Not Reported
	Calcichew			C	Oral	2 Df, Qd (For Several Years; On Going.)		Not Reported

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

Lansoprazole	C	Oral	15 Mg, Qd (Ongoing For Years)	Not Reported
Prednisolone	C	Oral	5 Mg, Qd (Ongoing For Years)	Not Reported
Etanercept	C	Subcutaneous	50 Mg, Qw (Had 3 Doses)	Not Reported
Simvastatin	C	Oral	20 Mg, Qd (Taking For Several Years. Ongoing)	Not Reported
Methotrexate	C	Oral	10 Mg, Qw	Not Reported
Metformin	C	Oral	1 G, Qd (Ongoing For Years)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2015	11459929	EXPEDITED (15-DAY)		OT	US-JNJFOC-20150823534		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Disturbance In Attention; Haemoptysis; Memory Impairment; Pneumonia; Product Dose Omission; Skin Discolouration; Skin Disorder; Vein Discolouration	Xarelto			S	Oral			Not Reported	
	Xarelto			S	Oral			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Ethambutol			S	Unknown			Not Reported	
	Lipitor			C	Oral			Not Reported	
	Lipitor			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2015	11468005	NON-EXPEDITED			US-PFIZER INC-2015292075		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lipid Metabolism Disorder; Sexually Transmitted Disease; Visual Impairment	Celebrex			S	Oral	200 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Lipitor			S	Oral	10 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2015	11468102	NON-EXPEDITED			US-PFIZER INC-2015296956		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11033008	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2015M1011083			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Laryngeal Oedema	Azitromicina			S	Oral	500 Mg Daily		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11479268	NON-EXPEDITED			US-JAZZ-2015-US-009668		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Ineffective; Unevaluable Event	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustments		Jazz	
	Xyrem			S	Oral	4 G, Bid		Jazz	
	Prednisone			S		Unk		Not Reported	
	Z-Pack			S		Unk		Not Reported	
	Adderall			C	Oral	Unk, Qid		Not Reported	
	Adderall			C		Unk		Not Reported	
	Aczone			C		Unk		Not Reported	
	Spironolactone			C		Unk, Qd		Not Reported	
	Multivitamins			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11483750	NON-EXPEDITED			US-JAZZ-2015-US-000087		24 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Confusional State; Feeling Abnormal; Musculoskeletal Stiffness; Myalgia; Nausea; Pain; Paraesthesia; Respiratory Tract Infection Viral; Tremor	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	3 G, Bid		Jazz	
	Azithromycin			S		Unk		Not Reported	
	Adderall			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11487118	NON-EXPEDITED			US-JAZZ-2015-US-003979		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Blood Pressure Increased; Bronchitis; Drug Hypersensitivity; Dyspnoea; Panic Attack	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	3 G, Bid		Jazz	
	Zithromax Tri-Pak			S		Unk		Not Reported	
	Fluoxetine Hcl			C		Unk		Not Reported	
	Mucinex Dm			C		Unk		Not Reported	
	Tessalon Perle			C		Unk		Not Reported	
	Buspirone Hcl			C		Unk		Not Reported	
	Junel Fe 1/20			C		Unk		Not Reported	
	Provigil			C		Unk		Not Reported	
	Wellbutrin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11487704	NON-EXPEDITED			US-TAKEDA-2015TUS003236			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Actos			S	Unknown	Unk		Takeda	
	Percocet /00446701/			S	Unknown	Unk		Not Reported	
	Zithromax			S	Unknown	Unk		Not Reported	

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

Synthroid	C	Oral	1 Tablet Every Morning On Empty Stomach	Not Reported
Lantus Solostar	C	Subcutaneous	100 Unit /MI Solution, 70 Unit, Qd	Not Reported
Lyrica	C	Oral	(150 Mg) 1 Capsule, Qd (Once In Evening)	Not Reported
Lyrica	C	Oral	(75 Mg) 1 Capsule, Qd (Once In Morning)	Not Reported
Acetaminophen	C	Oral	1 Tablet As Needed Upto Twice Daily	Not Reported
Vitamin B 12	C		Unk, Monthly	Not Reported
Coumadin /00014802/	C	Oral	1 Tablet, Qd	Not Reported
Zofran /00955301/	C	Oral	1 Df, Q8hr Prn	Not Reported
Emla /00675501/	C		2.5 % Externally	Not Reported
Potassium Chloride	C	Oral	1 Packet (20 Meq), Qd	Not Reported
Losartan Potassium	C			Not Reported
Simvastatin	C	Oral	1 Tablet, Qd	Not Reported
Lexapro	C	Oral	1 Tablet, Qd	Not Reported
Furosemide	C	Oral	1 Tablet Qd	Not Reported
Pepcid /00706001/	C	Oral	1 Tablet, Qd (Prn)	Not Reported
Doxazosin Mesylate	C	Oral	1 Tablet, Qd	Not Reported
Biotin	C	Oral	1 Capsule, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11487858	EXPEDITED (15-DAY)		DE	IN-PFIZER INC-2015298011			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Doxycycline Monohydrate			S		200 Mg, 2x/Day		Pfizer	
	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Chloramphenicol			S	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11487861	EXPEDITED (15-DAY)		DE	IN-PFIZER INC-2015298010			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Doxycycline Monohydrate			S		200 Mg, 2x/Day		Pfizer	
	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Chloramphenicol			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11487871	EXPEDITED (15-DAY)		DE	IN-PFIZER INC-2015297953			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Doxycycline Monohydrate			S		200 Mg, 2x/Day		Pfizer	
	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Chloramphenicol			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2015	11489503	NON-EXPEDITED			US-JAZZ-2015-US-005584		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Bronchitis; Drug Ineffective; Feeling Abnormal; Malaise; Migraine; Muscle Tightness; Myalgia; Vomiting	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Xyrem			S	Oral	6 G, First Dose		Jazz	
	Xyrem			S	Oral	3 G, Second Dose		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Zithromax			S				Not Reported	
	Percocet			S				Not Reported	
	Alpha Lipoic Acid			C		Unk		Not Reported	
	Calcium Carbonate			C		Unk		Not Reported	

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

Coq-10	C	Unk	Not Reported
Estradiol	C	Unk	Not Reported
N-Acetylcysteine	C	Unk	Not Reported
Progesterone	C	Unk	Not Reported
Vitamin D Nos	C	Unk	Not Reported
Seroquel	C	Unk	Not Reported
Cymbalta	C	Unk	Not Reported
Ibuprofen	C	Unk	Not Reported
Imitrex	C	Unk	Not Reported
Naltrexone	C	Unk	Not Reported
Clonazepam	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11334089	EXPEDITED (15-DAY)		HO, OT	PHHY2015BR090842		53 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Fluctuation; Erythema; Eye Swelling; Fatigue; Hot Flush; Pruritus; Urticaria; Wound	Azithromycin Sandoz Cerazette (Desogestrel)			S C	Oral Unknown	500 Mg, Qd		Novartis Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11437861	NON-EXPEDITED			US-PFIZER INC- 2015285958		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Therapeutic Response Unexpected	Azithromycin Azithromycin Azithromycin			S S S	Oral Oral	Unk (Five Daily Doses) 250mg (250mg 2 Tablets By Mouth First Day Then 1 Tablet For 4 Day Took For 5 Days Total)		Pfizer Pfizer Pfizer	

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

	Rifamycin	S		Unk (Five Daily Doses)	Not Reported
	Coumadin	S		Unk	Not Reported
	Protonix	C		200 Mg, 1x/Day	Not Reported
	Enalapril	C		Unk	Not Reported
	Requip	C		8 Mg, 1x/Day (4mg 2 Tablets At Bedtime)	Not Reported
	Oxygen	C		Unk	Not Reported
	Enalapril Maleate	C		5 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11487081	NON-EXPEDITED			US-PFIZER INC-2015298852			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cleocin			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11487085	NON-EXPEDITED			US-PFIZER INC-2015296398		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S	Unknown	Unk		Pfizer	
	Tequin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11487128	NON-EXPEDITED			US-PFIZER INC-2015298719		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	

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

Toradol	S	Unk	Not Reported
Aspirin /00002701/	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11487154	NON-EXPEDITED			US-PFIZER INC-2015298931		45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Coumadin /00014802/			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2015	11490768	EXPEDITED (15-DAY)		OT	US-BAYER-2015-413686		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Vascular Compression; Venous Thrombosis Limb	Cipro			S	Oral			Bayer
	Azithromycin			S				Not Reported
	Coumadin			S				Not Reported
	Rifamycin			S				Not Reported
	Protonix			C				Not Reported
	Enalapril			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2015	9713556	NON-EXPEDITED			US-PFIZER INC-2013333245		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Keflex /00145501/			S		Unk		Not Reported
	Clinoril			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2015	11227503	EXPEDITED (15-DAY)		HO, LT, OT	JP-PFIZER INC-2015211670		67 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cardiac Failure Congestive; Hepatic Failure	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
	Sunrythm			S	Oral	100 Mg, Daily		Not Reported	
	Xarelto			C	Oral	15 Mg, Daily		Not Reported	
	Herbesser			C	Oral	100 Mg, Daily		Not Reported	
	Maintate			C	Oral	2.5 Mg, Daily		Not Reported	
	Diart			C	Oral	15 Mg, Daily		Not Reported	
	Feburic			C	Oral	20 Mg, Daily		Not Reported	
	Lipidil			C	Oral	80 Mg, Daily		Not Reported	
	Nexium			C	Oral	20 Mg, Daily		Not Reported	
	Vasolan [Verapamil Hydrochloride]			C	Oral	80 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2015	11448980	NON-EXPEDITED			US-PFIZER INC-2015291281			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Product Label Issue	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2015	11493351	EXPEDITED (15-DAY)		OT	IE-LUPIN PHARMACEUTICALS INC.-2015-02727		20 YR	Male	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Oral			Not Reported	
	Ceftriaxone			C	Intramuscular			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2015	11495763	NON-EXPEDITED			US-PFIZER INC-2015297014		33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2015	11496642	NON-EXPEDITED		HO, OT	US-JNJFOC-20150901533		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pericardial Haemorrhage	Rivaroxaban			S	Oral			Not Reported	
	Rivaroxaban			S	Oral			Not Reported	
	Acetylsalicylic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2015	11499265	NON-EXPEDITED			US-TEVA-591688USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain; Pruritus; Urticaria	Proair Hfa			S	Respiratory (inhalation)	2 Puffs		Ivax	
	Zithromax Z-Pack			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2015	11500445	NON-EXPEDITED			US-PFIZER INC-2015302074			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Doxycycline Monohydrate	S	Unk	Pfizer
	Phenytoin	S	Unk	Pfizer
	Hydroxyzine Pamoate	S	Unk	Pfizer
	Hydrocodone	S	Unk	Not Reported
	Biaxin	S	Unk	Not Reported
	Buspar	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Erythromycin	S	Unk	Not Reported
	Levofloxacin	S	Unk	Not Reported
	Tizanidine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2015	11500581	NON-EXPEDITED			US-PFIZER INC-2015302334		31 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2015	11503861	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK072885			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coordination Abnormal; Diarrhoea; Drug Hypersensitivity; Headache; Muscular Weakness; Palpitations; Rash; Somnambulism	Fluticasone			S				Glaxosmithkline
	Propionate+Salmeterol							
	Xinafoate							
	Amoxicillin + Clavulanate K			S				Glaxosmithkline
	Levaquin			S				Glaxosmithkline
	Lidocaine			S				Glaxosmithkline
	Atorvastatin			S				Glaxosmithkline
	Clonazepam			S				Glaxosmithkline
	Doxycycline			S				Glaxosmithkline

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

Azithromycin			S			Glaxosmithkline			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2015	11503999	NON-EXPEDITED			US-PFIZER INC-2015303271			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2015	11507788	DIRECT		OT			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Laryngitis	Z Pack			S	Oral	3 Pills First Day, Three Times Daily Taken By Mouth		Not Reported	
	Lisinopril			C				Not Reported	
	Fenofibrate			C				Not Reported	
	Valacyclovir			C				Not Reported	
	Multi Vitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2015	11504281	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-1630572		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Bone Pain; Chromaturia; Drug Ineffective; Feeling Abnormal; Liver Disorder; Loss Of Consciousness; Memory Impairment; Myalgia; Overdose; Renal Impairment; Self-Medication; Suicidal Ideation; Thinking Abnormal; Vision Blurred	Diazepam			S	Unknown			Not Reported	
	Pregabalin			S	Other	3 Or 4 Times A Day		Not Reported	
	Lyrica			S	Other			Not Reported	
	Oxycontin			S	Other			Not Reported	
	Hydromorphone			S	Other			Not Reported	
	Morphine			S	Other			Not Reported	
	Propranolol			S	Other			Not Reported	
	Azithromycin			S	Unknown	One In The Morning And		Not Reported	

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

					One At Night				
	Gabapentin		S	Unknown					Not Reported
	Oxycodone		S	Unknown					Not Reported
	Methadone		C						Not Reported
	Subutex		C						Not Reported
	Demerol		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2015	11506664	NON-EXPEDITED			US-PFIZER INC-2015304852		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Bleph			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2015	11511223	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2015301718		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Methylprednisolone			S		Unk		Pfizer	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Rifampicin			S		Unk		Unknown	
	Vancomycin Hcl			S		Unk		Pfizer	
	Cefepime			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2015	11512563	EXPEDITED (15-DAY)		HO, LT, OT	US-VIIV HEALTHCARE LIMITED-US2015131913		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Abdominal Pain Upper; Hunger; Intentional Product Misuse; Middle Insomnia; Mycobacterium Avium Complex Infection; Vomiting	Triumeq	S	Oral	600mg Abacavir/50mg Dolutegravir/And 300mg Lamivudine, 1 Tablet Qd	Viiv
	Atovaquone	S		Unk	Glaxosmithkline
	Rifampin	S		Unk	Glaxosmithkline
	Azithromycin	S		Unk	Glaxosmithkline
	Ethambutol	S		Unk	Not Reported
	Atripla	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2015	11514415	NON-EXPEDITED			US-PFIZER INC-2015305353		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Dizziness; Fatigue; Flatulence; Nausea; Reaction To Excipient; Vomiting	Azithromycin			S	Oral	2 Df, Unk		Pfizer
	Lactose			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2015	11514494	EXPEDITED (15-DAY)		HO, LT, OT	US-GLAXOSMITHKLINE-US2015131913		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Hunger; Intentional Product Misuse; Middle Insomnia; Mycobacterium Avium Complex Infection; Vomiting	Triumeq			S	Oral	600mg Abacavir/50mg Dolutegravir/And 300mg Lamivudine, 1 Tablet Qd		Viiv
	Atovaquone			S		Unk		Glaxosmithkline
	Rifampin			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Ethambutol			S		Unk		Not Reported
	Atripla			S				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2015	11515483	EXPEDITED (15-DAY)		OT	PHHY2015IT110205		22 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Nausea; Vomiting	Paracetamol		Y	S	Oral	500 Mg, Once/Single		Novartis	
	Zitromax			S	Oral	1 Df, Once/Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2015	11459118	NON-EXPEDITED		OT	US-PFIZER INC-2015290452		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia; Drug Ineffective; Pneumonia; Tendonitis	Azithromycin			S		250 Mg, Stopped At Day Two Of Five		Pfizer	
	Amoxicillin			S	Oral	500mg Tablet, Three Times Daily		Not Reported	
	Levaquin			S		250 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2015	11516456	NON-EXPEDITED			US-PFIZER INC-2015308789		93 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2015	11516467	NON-EXPEDITED			US-PFIZER INC-2015307149		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Sinus Congestion; Therapeutic Product Effect Incomplete	Zithromax			S		6 Df, Daily		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2015	11520969	DIRECT	Y	OT			55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Tinnitus	Zithromax			S	Oral			Pfizer	
	Gabapentin			C				Not Reported	
	Clofazimine			C				Not Reported	
	Aspirin 81 Mg			C				Not Reported	
	Nitroglycerin Ointment			C				Not Reported	
	Amlodipine			C				Not Reported	
	Cyclobenzaprine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2015	11528479	EXPEDITED (15-DAY)	Y	HO, OT	US-ZYDUS-009029		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Pulmonary	Levofloxacin (Levofloxacin)			S				Not Reported	
Histoplasmosis; Drug	Azithromycin (Azithromycin)			S				Not Reported	
Ineffective	Prednisone (Prednisone)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2015	7812183	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2011027887		34 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Potentiating Drug	Azithromycin			S		250 Mg, 1x/Day		Pfizer	
Interaction;	Cyclosporin A			S		170 Mg, 2x/Day		Not Reported	
Rhabdomyolysis; Toxicity	Cyclosporin A			S				Not Reported	
To Various Agents	Pravastatin			S		20 Mg, 1x/Day		Not Reported	
	Colchicine			S		1 Mg, 3x/Day		Not Reported	
	Colchicine			S		1 Mg, 2x/Day		Not Reported	
	Colchicine			S		1 Mg, 1x/Day		Not Reported	
	Hydrocortisone			C		20 Mg, 1x/Day		Not Reported	

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

Everolimus	C	1 Mg, 1x/Day	Not Reported
Colimycin	C		Not Reported
Nicorandil	C	10 Mg, 1x/Day	Not Reported
Irbesartan	C	150 Mg, 1x/Day	Not Reported
Acetylsalicylate Lysine	C	75 Mg, 1x/Day	Not Reported
Ferrous Ascorbate	C	66 Mg, 1x/Day	Not Reported
Co-Trimoxazole	C		Not Reported
Calcium	C	1 G, 1x/Day	Not Reported
Vitamin D Nos	C	880 Iu, 1x/Day	Not Reported
Pancreatin	C	250000 Iu, 1x/Day	Not Reported
Tocopherol	C	500 Mg, 1x/Day	Not Reported
Esomeprazole	C	20 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2015	11183466	NON-EXPEDITED		OT	US-AMGEN- USASP2015056347		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Leukopenia; Liver Function Test Increased; Weight Increased	Enbrel			S	Unknown	25 Mg/0.5ml, Unk		Amgen	
	Xeljanz			S	Oral	5 Mg, Twice Daily		Not Reported	
	Xeljanz			S				Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Oxycodone			S	Unknown	Unk		Not Reported	
	Reglan /00041901/			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Actemra			S	Unknown	162 Mg, Qwk		Not Reported	
	Codeine Sulfate			S	Unknown	Unk		Not Reported	
	Chloroquine			S	Unknown	Unk		Not Reported	
	Keflex /00145501/			S	Unknown	Unk		Not Reported	
	Arava			S	Unknown	Unk		Not Reported	
	Metamucil /00029101/			C		Unk		Not Reported	

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

Vitamin D /00107901/	C	Unk	Not Reported
Bayer	C	81 Mg, Unk	Not Reported
Orencia	C	Unk	Not Reported
Metamucil /00029101/	C	0.52 G, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2015	11520267	EXPEDITED (15-DAY)		DE, HO, OT	US-GLENMARK PHARMACEUTICALS INC, USA.- 2015GMK01946		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Condition Aggravated; Legionella Infection	Levofloxacin			S		Unk		Glenmark
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S				Not Reported
	Rifampin			S		Unk		Not Reported
	Antiretrovirals			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2015	11432106	NON-EXPEDITED		HO	US-PFIZER INC- 2015283981		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Oral	500 Mg, Daily (Two 250 Mg Tabs Day 1)		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily (1 Tablet For 4 Days)		Pfizer
	Prednisone			S	Oral	60 Mg, Unk (Three 20 Mg Tabls)		Not Reported
	Prednisone			S	Oral	40 Mg, Daily (Two 20 Mg Tabs For 2 Day)		Not Reported
	Robitussin Ac (Codeine Phosphate\Guaifenesin)			S	Oral	10 MI, As Needed (Codeine: 10 Mg/MI, Guaifenesin: 100 Mg/MI)Tid		Not Reported

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

	Robitussin Ac (Codeine Phosphate/Guaifenesin)	S							Not Reported
	Solunedrol	S	Intravenous (not otherwise specified)	125 Mg, Single					Not Reported
	Solunedrol	S							Not Reported
	Lasix	S		Unk					Not Reported
	Levaquin	S	Oral	750 Mg, 1x/Day					Not Reported
	Levaquin	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2015	11528817	NON-EXPEDITED			US-PFIZER INC-2015303309			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Musculoskeletal Stiffness	Azithromycin			S	Oral	500 Mg, 1x/Day For Three Days.		Pfizer	
	Azithromycin			S	Oral	250 Mg, Two Tablets By Mouth		Pfizer	
	Azithromycin			S		250 Mg, Daily		Pfizer	
	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day Until Completed		Pfizer	
	Enbrel			C		1 Df, Weekly		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2015	11531710	NON-EXPEDITED			US-TAKEDA-2015TUS012678		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pruritus; Rash	Dexilant			S	Oral	60 Mg, Qd		Takeda	
	Z-Pack			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2015	11532296	NON-EXPEDITED			US-PFIZER INC-2015306474			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Azithromycin			S		500 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2015	8889497	EXPEDITED (15-DAY)		HO	US-JNJFOC-20121016988		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Calcinosis; Coma; Drug Interaction; Generalised Tonic-Clonic Seizure; Total Lung Capacity Decreased; Weight Decreased	Topamax			S	Oral			Not Reported	
	Seroquel			S	Oral	2-4 Times A Day Started Around 2004-2005		Not Reported	
	Lorazepam			S	Oral			Not Reported	
	Lorazepam			S	Oral			Not Reported	
	Promethazine			S	Oral			Not Reported	
	Azithromycin			S	Oral	10 Day Dose Started Before 30-Dec-2005		Not Reported	
	Meclizine			S	Oral			Not Reported	
	Furosemide			S	Oral	Started Around 2004-2005		Not Reported	
	Prilosec			S	Oral	Started Around 2004-2005		Not Reported	
	Hydrocodone			S	Oral			Not Reported	
	Thyroid Therapy			S	Oral			Not Reported	
	Potassium Chloride			S	Oral	Started Around 2004-2005		Not Reported	
	An Unknown Medication			S	Oral			Not Reported	
	Hydrocortisone			S	Oral			Not Reported	
	Zoloft			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2015	11051927	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015130197		67 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Zitromax			S	Oral	1 Df, Daily		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2015	11382727	EXPEDITED (15-DAY)		DE	PH-PFIZER INC-2015268305			Unknown	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2015	11537669	EXPEDITED (15-DAY)		DE, HO, OT	JP-PFIZER INC-2015192845		87 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Zithromac Sr			S	Oral	2 G, Single		Pfizer	
	Clarith			C	Oral	200 Mg, 2x/Day		Not Reported	
	Ceftriaxone			C	Intravenous drip	1 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2015	11537986	NON-EXPEDITED			US-PFIZER INC-2015304128			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Calten			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2015	11189862	NON-EXPEDITED			US-PFIZER INC-2015194282			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Not Reported	
	Aspirin			S		Unk		Not Reported	

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

	Leflunomide		S		Unk			Not Reported	
	Meperidine		S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2015	11492296	NON-EXPEDITED			US-PFIZER INC-2015299474			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Intentional Product Use Issue	Azithromycin			S		500 Mg, Unk (Two Tablets)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2015	11539428	NON-EXPEDITED			US-TEVA-567613USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Gastrooesophageal Reflux Disease; Glossitis; Oral Disorder	Hydroxychloroquine			S	Unknown	400 Milligram Daily;		Teva	
	Minocycline\Minocycline Hydrochloride			S	Unknown	100 Milligram Daily;		Not Reported	
	Metoclopramide			S	Unknown	20 Milligram Daily;		Not Reported	
	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported	
	Valaciclovir			S	Unknown	2 Bid		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2015	11542393	EXPEDITED (15-DAY)			US-WATSON-2015-03176			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Alendronate Sodium (Watson Laboratories)			S	Unknown	Unk, Unknown		Watson	
	Doxycycline Hyclate (Actavis Laboratories FI)			S	Unknown	Unk, Unknown		Actavis	
	Oxycodone Hydrochloride (Aellic)			S	Unknown	Unk, Unknown		Watson	
	Ciprofloxacin Hydrochloride (Watson Laboratories)			S	Unknown	Unk, Unknown		Watson	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Zithromax	S	Not Reported
Ceftin /00454603/	S	Not Reported
Ciprocinonide	S	Not Reported
Cataflam /00372302/	S	Not Reported
Erythromycin Base	S	Not Reported
Fluocinonide	S	Not Reported
Savella	S	Not Reported
Procinonide	S	Not Reported
Vioxx	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2015	11423167	EXPEDITED (15-DAY)	CA, HO, OT		US- GLAXOSMITHKLINE- US2015GSK121793		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection;	Pravachol			S		Unk		Glaxosmithkline
Constipation; Cough;	Advair			S				Glaxosmithkline
Depression; Dermatitis;	Ciprofloxacin			S				Glaxosmithkline
Diarrhoea; Dizziness;	Augmentin			S				Glaxosmithkline
Drug Interaction; Drug	Zosyn			S				Not Reported
Level Increased;	Azithromycin			S				Glaxosmithkline
Dyspnoea; Enterovirus	Tagamet			S				Glaxosmithkline
Test Positive;	Vfend			S	Oral	200 Mg, Bid		Not Reported
Hallucination; Headache;	Vfend			S		200 Mg, Qd		Not Reported
Human Rhinovirus Test	Oseltamivir			C		Unk		Glaxosmithkline
Positive; Hypertension;	Vibramycin			C		Unk		Not Reported
Hypomagnesaemia;	Lorazepam			C				Not Reported
Mental Status Changes;	Promethazine			C				Not Reported
Nausea; Palpitations;	Proventil			C				Not Reported
Presyncope; Pyrexia;	Ecotrin			C				Not Reported
Rash; Respiratory Tract	Zyrtec			C				Not Reported
Infection; Viraemia;	Flonase			C				Not Reported
Vomiting	Novolin N			C				Not Reported
	Humulin R			C				Not Reported
	Levothyroxine			C				Not Reported
	Metformin			C				Not Reported
	Nitroglycerine			C				Not Reported
	Vitamin B 12			C				Not Reported
	Cozaar			C				Not Reported

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

		Mobic		C					Not Reported
		Morphine		C					Not Reported
		Omeprazole		C					Not Reported
		Azulfidine		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2015	11544448	NON-EXPEDITED			US-PFIZER INC-2015317625			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Topamax			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2015	11545152	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2015R1-103592		25 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Vulvovaginal Mycotic Infection	Azithromycin			S	Oral	500mg Pro Tabeltte		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2015	11546794	NON-EXPEDITED			US-PFIZER INC-2015317796		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Wellbutrin XI			C		Unk		Not Reported	
	Diazepam			C		5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2015	11550281	EXPEDITED (15-DAY)		OT	US-HOSPIRA-3018035		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity; Leukopenia; Liver Function Test Increased; Weight Increased	Xeljanz	S	Oral	Twice Daily	Not Reported
	Codeine Sulfate	S	Unknown		Not Reported
	Chloroquine	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Enbrel	S	Unknown	25 Mg/0.5ml	Not Reported
	Azithromycin	S	Unknown		Not Reported
	Keflex /00145501/	S	Unknown		Not Reported
	Reglan /00041901/	S	Unknown	Unk	Not Reported
	Bayer Aspirin	C			Not Reported
	Orencia	C			Not Reported
	Arava	S	Unknown		Not Reported
	Oxycodone	S	Unknown		Not Reported
	Vitamin D /00107901/	C			Not Reported
	Actemra	S	Unknown		Not Reported
	Metamucil /00029101/	C			Not Reported
	Metamucil /00029101/	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2015	11552543	NON-EXPEDITED			US-PFIZER INC- 2015310944		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S	Oral	500 Mg, (250mg Tablets 2 Tablets By Mouth And 1 Tablet Daily For 4 Days)		Pfizer
	Zithromax			S	Oral	250 Mg, (250mg Tablets 2 Tablets By Mouth And 1 Tablet Daily For 4 Days)		Pfizer
	Zantac			S		150 Mg, Daily (75mg Started With 2 Tablets A Day For A Week And Went Down To 1)		Not Reported
	Zantac			S		75 Mg, Daily (75mg Started With 2 Tablets A Day For A Week And		Not Reported

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

		Claritin		S	Went Down To 1)				Not Reported
		Cefadroxil		S	10 Mg, 1x/Day				Not Reported
					10 Mg, 2x/Day				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2015	11552811	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-103640			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Nausea; Vomiting	Paracetamol		Y	S	Oral	500 Mg, Total		Ohm Lab	
	Zitromax			S	Oral	1 Df, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2015	11554870	EXPEDITED (15-DAY)		HO, LT, OT	US-BMSGILMSD-2015- 0173910		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Hunger; Middle Insomnia; Mycobacterium Avium Complex Infection; Treatment Noncompliance; Vomiting	Atripla			S	Unknown			Gilead	
	Atovaquone			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2015	11556410	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2015318266		35 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Diarrhoea; Hiatus Hernia; Malaise; Medication Error; Umbilical Hernia; Vomiting	Zithromax			S	Oral	2 G, Single		Pfizer	
	Nexiam			C	Oral	40 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2015	11292332	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015241329		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Paraesthesia; Paraesthesia Oral; Pruritus	Zithromax			S	Oral	Three Or Four Courses At A Tapered Dose Every Day For About Six Days		Pfizer	
	Zithromax			S				Pfizer	
	Ativan			C	Oral	2.5 Mg, As Needed		Not Reported	
	Bentyl			C	Oral	10 Mg, Unk		Not Reported	
	Tums			C		Unk		Not Reported	
	Gas X			C		Unk		Not Reported	
	Pepcid			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2015	11561538	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015318462		24 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Eye Swelling; Localised Oedema; Pruritus; Rash	Azithromycin			S	Oral	500 Mg, Total		Pfizer	
	Oki			S	Oral	80 Mg, Total		Not Reported	
	Tachipirina			S	Oral	500 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2015	11569939	DIRECT	Y	HO			72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Zithromax			S	Oral	2 On Day One Then 1 Qd X4 Qd Oral		Not Reported	
	Zestril			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2015	11574621	DIRECT					20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2015	8875712	EXPEDITED (15-DAY)		DE	US-ROCHE-1129779			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Appetite Disorder; Chills; Conjunctivitis; Contusion; Death; Emotional Disorder; Fatigue; Haemorrhage; Macrocytosis; Nausea; Neuropathy Peripheral; Off Label Use; Pain; Pyrexia; Rash; Respiratory Disorder; Vomiting	Rituxan			S	Intravenous (not otherwise specified)				Not Reported
	Rituxan			S	Unknown				Not Reported
	Rituxan			S	Unknown				Not Reported
	Rituxan			S	Unknown				Not Reported
	Bactrim Ds			S	Unknown				Not Reported
	Azithromycin			S	Oral				Not Reported
	Tylenol			C	Unknown				Not Reported
	Benadryl (United States)			C	Unknown				Not Reported
	Solu-Medrol			C	Unknown				Not Reported
	Famotidine			C	Unknown				Not Reported
	Acyclovir			C	Oral				Not Reported
	Entocort			C	Unknown				Not Reported
	Ergocalciferol			C	Unknown				Not Reported
	Levaquin			C	Unknown				Not Reported
	Prednisone			C	Unknown				Not Reported
	Advair Diskus			C	Unknown	250/50 Mcg One Puff			Not Reported
	Tacrolimus			C	Unknown				Not Reported
	Voriconazole			C	Unknown				Not Reported

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

	Coumadin (United States)	C	Unknown	Not Reported
	Pred Forte	C		Not Reported
	Restasis	C		Not Reported
	Aquasite	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2015	10154397	NON-EXPEDITED			US-PFIZER INC-2014121987			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Atarax			S		Unk		Pfizer	
	Oxycodone			S		Unk		Not Reported	
	Benadryl			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
	Z-Pack			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Asa			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
	Darvon			S		Unk		Not Reported	
	Darvocet			S		Unk		Not Reported	
	Citalopram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2015	11574700	NON-EXPEDITED			US-PFIZER INC-2015314743			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort	Azithromycin			S		500 Mg, Unk (Took 2 Tablets)		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2015	11455997	EXPEDITED (15-DAY)		OT	US-TEVA-582372USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dizziness;	Azithromycin			S	Unknown			Not Reported	
Drug Hypersensitivity;	Cimetidine			S	Unknown			Teva	
Extrasystoles; Mental	Ciprofloxacin			S	Unknown			Barr	
Status Changes; Nausea;	Hydroxychloroquine			S	Unknown			Teva	
Pyrexia; Ventricular	Meperidine Hydrochloride			S	Unknown			Barr	
Tachycardia; Vomiting									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2015	11584560	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2014US-87906			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Anger; Coma;	Azithromycin			S	Unknown	10 Day Dose		Not Reported	
Craniocerebral Injury;	Lorazepam			S	Unknown	10 Mg		Sun	
Hypersensitivity;	Promethazine			S	Unknown	Unk		Sun	
Hypertension; Overdose;	Zoloft			S	Oral	Unk Unk, Qd		Not Reported	
Pain; Post-Traumatic	Seroquel			S	Oral	25 Mg 2 Or 4 Times A Day		Not Reported	
Stress Disorder; Seizure;	Meclizine			S	Unknown	Unk		Not Reported	
Total Lung Capacity	Potassium Chloride			S	Unknown	Unk		Not Reported	
Decreased; Vertigo	Prilosec			S	Unknown	Unk		Not Reported	
	Furosemide			S	Unknown	Unk		Sun	
	Pristine			S	Unknown	Unk		Not Reported	
	Topamax			S	Unknown	Unk		Not Reported	
	Hydrocortone			S	Unknown	Unk		Not Reported	
	Ranoxyl			S	Unknown	Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2015	11586631	NON-EXPEDITED			US-PFIZER INC-2015318884			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2015	11184163	NON-EXPEDITED			US-PFIZER INC-2015193704		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Liver Function Test Increased	Azithromycin			S		Unk		Pfizer	
	Enbrel			S		Unk (25 Mg/0.5 MI)		Pfizer	
	Oxycodone			S		10 Mg, Unk		Pfizer	
	Codeine Sulfate			S		15 Mg, Unk		Not Reported	
	Keflex			S		250 Mg, Unk		Not Reported	
	Reglan			S		10 Mg, Unk		Not Reported	
	Chloroquine			S		Unk		Not Reported	
	Actemra			S		162 Mg, Weekly		Not Reported	
	Bactrim			S		Unk (400 Mg Sulfamethoxazole-800mg Trimethoprim)		Not Reported	
	Oxycontin			S		10 Mg, Unk		Not Reported	
	Oxycodone Hcl			S		10 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2015	11588522	EXPEDITED (15-DAY)		LT	US-FRESENIUS KABI-FK201504696		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Cardiac Tamponade; Drug	Azithromycin (Manufacturer Unknown) (Azithromycin)			S	Unknown			Fresenius Medical Care	

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

Interaction; Pericardial Effusion; Pericardial Haemorrhage; Pericarditis	Azithromycin (Manufacturer Unknown) (Azithromycin) (Azithromycin) Rivaroxaban	S						Fresenius Medical Care
		S	Unknown					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2015	11588953	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP013122		88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Tamponade; Drug Interaction; Pericardial Haemorrhage; Pericarditis	Azithromycin			S	Unknown			Apotex
	Azithromycin			S				Apotex
	Rivaroxaban			S	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Leukopenia; Liver Function Test Increased; Weight Increased	Oxycodone Hydrochloride			S		Unk		Egalet
	Enbrel			S		25 Mg/0.5ml,Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Xeljanz			S		1 Df, Daily		Not Reported
	Xeljanz			S	Oral	5 Mg, Twice Daily		Not Reported
	Methotrexate			S		Unk		Not Reported
	Reglan /00041901/			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Actemra			S		162 Mg, Qwk		Not Reported
	Codeine Sulphate			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported

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

Keflex /00145501/	S	Unk	Not Reported
Arava	S	Unk	Not Reported
Metamucil /00029101/	C	Unk	Not Reported
Metamucil /00029101/	C	0.52 G, Unk	Not Reported
Vitamin D /00107901/	C	Unk	Not Reported
Bayer Aspirin	C	81 Mg, Unk	Not Reported
Orencia	C	Unk	Not Reported
Multivitamins	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2015	11589898	EXPEDITED (15-DAY)		HO	US-TEVA-598163USA		88 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Tamponade; Drug Interaction; Pericardial Haemorrhage; Pericarditis	Azithromycin			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2015	11590271	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2015M1033065			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Tamponade; Drug Interaction; Pericardial Haemorrhage; Pericarditis	Azithromycin			S	Unknown			Not Reported
	Rivaroxaban			S	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Levothyroxine Sodium			C	Unknown			Not Reported
	Aspirin /00002701/			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2015	11591238	EXPEDITED (15-DAY)		HO	IT-TEVA-596039ACC		24 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Eye Swelling; Localised Oedema; Ocular Hyperaemia; Pruritus; Rash	Azithromycin			S	Oral	500 Mg Total		Not Reported	
	Oki - 80 Mg Granulato Per Soluzione Orale - Dompe Farmaceutici S.P.A .			S	Oral	80 Mg Total		Not Reported	
	Tachipirina - 500 Mg Compresse - Aziende Chimiche Riunite Angelini Fra			S	Oral	500 Mg Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2015	11592181	NON-EXPEDITED		OT	US-DRREDDYS- USA/USA/15/0049122		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Body Temperature Fluctuation; Clonus; Generalised Tonic-Clonic Seizure; Hot Flush; Neuralgia; Neuropathy Peripheral; Sinusitis; Tinnitus; Wrong Technique In Product Usage Process	Sumatriptan Succinate Tablets			S	Oral	Started Taking 1/4 Of A Tablet (12.5 Mg) For Very First Dose. For Subsequent Doses, Took 1/2 Of A Ta		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2015	11593734	EXPEDITED (15-DAY)			US- GLAXOSMITHKLINE- US2015GSK109035			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Drug Hypersensitivity; Muscular Weakness; Temporal Arteritis; Urinary Tract	Zantac			S		Unk		Glaxosmithkline	
	Lyrica			S	Oral	50 Mg, Tid		Not Reported	
	Zithromax			S				Not Reported	

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

Infection	Pregabalin			S					Not Reported
	Cipro			S					Glaxosmithkline
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2015	11594218	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2015M1032604			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Azithromycin			S	Oral	500 Mg, Total			Not Reported
Erythema; Eye Oedema;	Oki			S	Oral	80 Mg, Total			Not Reported
Localised Oedema; Ocular	Tachipirina			S	Oral	500 Mg, Total			Not Reported
Hyperaemia; Rash Pruritic									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2015	11498268	NON-EXPEDITED			US-PFIZER INC-2015302340		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zolof			S		Unk			Pfizer
	Zithromax			S		Unk			Pfizer
	Vibramycin			S		Unk			Pfizer
	Inderal			S		Unk			Pfizer
	Verapamil Hcl			S		Unk			Pfizer
	Epinephrine			S		Unk			Unknown
	Elavil			S		Unk			Not Reported
	Suprax			S		Unk			Not Reported
	Keflex			S		Unk			Not Reported
	Depakote			S		Unk			Not Reported
	Pamelor			S		Unk			Not Reported
	Bactrim			S		Unk			Not Reported
	Imitrex			S		Unk			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2015	11598038	NON-EXPEDITED			US-ROCHE-1522149			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Malaise; Pruritus; Rash; Sinusitis; Urticaria	Erivedge			S	Unknown			Not Reported
	Zithromycin			S	Unknown			Not Reported
	Metformin			C	Unknown	500/15mg		Not Reported
	Atenolol			C	Unknown			Not Reported
	Aspirin			C				Not Reported
	Cinnamon			C	Unknown			Not Reported
	Tamsulosin			C	Unknown			Not Reported
	Simvastatin			C	Unknown			Not Reported
	Glipizide XI			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported
	Triamterene/Hctz			C	Unknown	37.5/25		Not Reported
	Enalapril			C	Unknown			Not Reported
	Pioglitazone			C	Unknown	500/15		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2015	11598278	NON-EXPEDITED		HO, OT	US-PFIZER INC- 2015331083		30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transaminases Increased	Heparin Sodium			S	Intravenous (not otherwise specified)	2500units In 250 Saline; 18units Per Kg/Hour		Unknown
	Lovenox			S	Subcutaneous	80mg Every 12 Hours		Not Reported
	Arixtra			S	Subcutaneous	75 Mg, 1x/Day		Not Reported
	Z-Pack			S		First Day He Took Two		Not Reported
	Z-Pack			S		One Every Day For Four Days		Not Reported
	Rocephin			S	Intravenous (not	1gm Once A Day		Not Reported

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

		otherwise specified)		
Percocet	S		Unk	Not Reported
Oxycodone	S		Unk	Not Reported
Warfarin	S	Oral	5 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2015	11599008	NON-EXPEDITED			US-PFIZER INC-2015329808			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2015	11605078	NON-EXPEDITED			US-PFIZER INC-2015322494			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2015	11605361	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015330076		78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Oxygen Therapy; Product Prescribing Error	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2015	11607286	NON-EXPEDITED			US-PFIZER INC-2015322728			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2015	11610809	EXPEDITED (15-DAY)		DE	US-ACTAVIS-2015-21401		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Incorrect Dose Administered; Sudden Cardiac Death	Azithromycin (Unknown)			S	Unknown	Unk		Not Reported	
	Omeprazole (Actavis Laboratories FI)			S	Unknown	20 Mg, Daily		Actavis	
	Potassium Chloride			S	Unknown	2 Meq/L (Instead Of 3 Meq/L)		Aptalis	
	Magnesium (Unknown)			S	Unknown	Unk		Not Reported	
	Sodium Bicarbonate			S	Unknown	High Bicarbonate Bath		Not Reported	
	Acetate Ringers			S	Unknown	Unk		Not Reported	
	Calcium Acetate			S	Unknown	3 Df, Unk		Not Reported	
	Calcium			S	Unknown	Unk		Not Reported	
	Cinacalcet			C	Unknown	30 Mg, Qhs		Not Reported	
Nifedipine			C	Unknown	90 Mg, Qhs		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2015	11610955	NON-EXPEDITED			US-PFIZER INC-2015332641			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2015	11613671	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015332577		70 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Altered State Of Consciousness	Zithromac	S	Oral	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2015	8837880	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-PFIZER INC-2012249138		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Zolof			S	Oral	50 Mg, 1x/Day		Pfizer
Abnormal Behaviour;	Furosemide			S	Oral	Two Tablets Of 20 Mg Daily		Unknown
Brain Injury; Coma; Drug Hypersensitivity; Fluid Retention; Generalised Tonic-Clonic Seizure;	Hydrocortisone			S		Unk		Pfizer
Head Injury; Lung Disorder; Oedema;	Lorazepam			S		10 Mg, Unk		Not Reported
Overdose; Post-Traumatic Stress Disorder; Product Prescribing Error;	Azithromycin			S	Oral	250 Mg, Unk		Not Reported
Sinusitis; Stasis Dermatitis	Potassium Chloride			S	Oral	Unk		Not Reported
	Promethazine			S		25 Mg, Unk		Not Reported
	Seroquel			S	Oral	4 Mg, Unk		Not Reported
	Prilosec			S	Oral	Two Capsules Of 20 Mg Daily		Not Reported
	Prilosec			S				Not Reported
	Meclizine			S	Oral	25 Mg, Unk		Not Reported
	Hydrocodone			S		5 Mg, Unk		Not Reported
	Topamax			S		25 Mg, Unk		Not Reported
	Ranoxyl			C		Unk		Not Reported
	Pristine			C		Unk		Not Reported
	Agarol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2015	11443087	NON-EXPEDITED			US-PFIZER INC-2015289975		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

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

Penicillin G Benzathine			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2015	11593762	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2015330021		85 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Function Abnormal; Multiple Organ Dysfunction Syndrome	Zithromac			S		500 Mg, Daily		Pfizer	
	Recomodulin			S	Unknown	25600 U		Not Reported	
	Meropenem			C		0.5 G 3x/Day		Not Reported	
	Elaspol			C		300 Mg		Not Reported	
	Methylprednisolone			C		1 G/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2015	11614776	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2015-03118		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Tamponade; Drug Level Increased; Pericardial Effusion	Azithromycin			S	Unknown			Not Reported	
	Rivaroxaban			S	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
	Aspirin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2015	11615235	NON-EXPEDITED			US-PFIZER INC-2015333947			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2015	8456965	EXPEDITED (15-DAY)		DS, HO, OT	BR-ROCHE-720062		64 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
Anaemia; Arthralgia;	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
Arthralgia; Arthropathy;	Mabthera			S	Intravenous (not otherwise specified)	Route: Endovenous; Dose: 100mg/10ml, Frequency: 1000 Mg, Second Infusion Was Given On 01 Oct 2012.		Not Reported	
Arthropathy; Arthropathy;	Mabthera			S	Intravenous (not otherwise specified)	Latest Infusion Was Given On 14/Aug/2013		Not Reported	
Asthenia; Asthma;	Mabthera			S	Intravenous (not otherwise specified)	Other Indication: Asthma		Not Reported	
Asthmatic Crisis; Back Disorder; Back Pain;	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
Bacterial Infection; Blood Cholesterol Increased;	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
Blood Pressure Decreased; Body Height Decreased; Bronchitis;	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
Bronchitis; Bronchitis;	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
Bursitis; Chills; Chronic Gastritis; Coccydynia;	Azithromycin			S	Unknown			Not Reported	
Constipation; Decreased Immune Responsiveness;	Diclofenac			C	Unknown			Not Reported	
Dizziness; Drug Ineffective;	Cyclobenzaprine			C	Unknown			Not Reported	
Encephalopathy;	Lyrica			C	Unknown			Not Reported	
Erythema; Exostosis; Fall;	Tramal			C	Unknown			Not Reported	
Fibromyalgia; Headache;	Penicillamine			C	Unknown			Not Reported	
Hepatic Encephalopathy;	Omeprazole			C	Unknown			Not Reported	
Hepatitis C;	Omeprazole			C	Unknown			Not Reported	
Hyperaesthesia;	Tylenol			C	Unknown			Not Reported	
Hypersensitivity;	Tylenol			C	Unknown			Not Reported	
Hypertension;	Tylenol			C	Unknown			Not Reported	
Hypotension;	Celebra			C	Unknown			Not Reported	
Immunodeficiency;	Losartan			C	Unknown	Drug: Losartana		Not Reported	
Influenza; Insomnia; Joint Prosthesis User; Limb Injury; Mass; Memory Impairment; Muscle Rigidity; Muscular Weakness;	Diurisa			C	Unknown			Not Reported	
Nasopharyngitis;	Pentalac			C	Unknown	3 Or 4 Times/Day, Other Indication Stomach Crisis		Not Reported	
	Pentalac			C	Unknown			Not Reported	



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

Nasopharyngitis; Nausea;	Neomycin	C	Unknown	When Necessary	Not Reported
Osteoarthritis; Pain;	Domperidone	C	Unknown		Not Reported
Palpitations; Pelvic Pain;	Amlodipine	C	Unknown		Not Reported
Peripheral Swelling;					
Platelet Count Decreased;	Aceclofenac	C	Unknown		Not Reported
Pneumonia; Protein Total	Lipless	C	Unknown	Indication: Stomach Crisis	Not Reported
Decreased; Rash;	Domperidone	C	Unknown		Not Reported
Rheumatoid Arthritis;	Cortisone	C	Unknown		Not Reported
Sciatica; Spinal Disorder;	Bamifix	C			Not Reported
Spinal Fracture; Swelling;	Avamys	C			Not Reported
Urinary Tract Infection;	Losartan	C	Unknown		Not Reported
Varicose Vein; Vascular	Diupress	C	Unknown		Not Reported
Rupture; Vitamin D	Acetaminophen	C			Not Reported
Decreased; Weight	Pregabalin	C	Unknown		Not Reported
Decreased	Furosemide	C	Unknown		Not Reported
	Higroton	C		Not Reported	
	Lactulona	C		Not Reported	
	Prednisone	C	Unknown	Not Reported	
	Prednisone	C	Unknown	Not Reported	
	Neomycin	C		Not Reported	
	Diupress	C		Not Reported	
	Losartan	C		Not Reported	
	Omeprazole	C		Not Reported	
	Nexium	C		Not Reported	
	Tylex (Brazil)	C	Unknown	Not Reported	
	Aldactone (Brazil)	C	Unknown	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2015	11619929	NON-EXPEDITED			US-PFIZER INC-2015336065			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	

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

Azithromycin	S	Unk	Pfizer
Flonase	S	Unk	Not Reported
Cyclobenzaprine Hcl	S	Unk	Not Reported
Amitriptyline	S	Unk	Not Reported
Pravastatin	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Flexeril	S	Unk	Not Reported
Lisinopril Hydrochlorothiazide	S	Unk	Not Reported
Aspirin Ec	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2015	11619960	NON-EXPEDITED		OT	US-PFIZER INC-2015336209			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2015	11620021	NON-EXPEDITED			US-PFIZER INC-2015328196			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2015	11620650	NON-EXPEDITED			US-PFIZER INC-2015329707			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2015	11620661	NON-EXPEDITED			US-PFIZER INC-2015330650		4 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11392498	EXPEDITED (15-DAY)		DS, OT	PHEH2015US015733		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Basophil Count Decreased; Bone Cancer; Bone Disorder;	Afinitor			S	Oral	10 Mg, Qd		Novartis	
Carbohydrate Antigen 15-3 Increased;	Afinitor			S	Oral	5 Mg, Qd		Novartis	
Chondropathy; Dyspnoea; Epistaxis; Erythema Nodosum; Gastrointestinal Melanosis; Haematocrit Decreased; Hypercholesterolaemia; Hypothyroidism; Lymphocyte Count Decreased; Mean Cell Haemoglobin Concentration Decreased; Menopausal Symptoms; Metastases To Liver; Metastases To Lymph Nodes; Oedema; Oedema Peripheral; Osteomyelitis; Osteopenia; Pneumonitis; Pneumonitis; Rash; Red Blood Cell Count Decreased; Red Cell Distribution Width Increased; Second	Z-Pack			S	Unknown			Not Reported	

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

Primary Malignancy; Skin
Disorder; Stomatitis;
Toothache; White Blood
Cell Count Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11624345	EXPEDITED (15-DAY)		HO, LT	US-LUPIN PHARMACEUTICALS INC.-2015-03135		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11624971	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015333926		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Body Height Decreased; Disorientation; Mental Disorder	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11625380	NON-EXPEDITED			US-PFIZER INC- 2015341964			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Asa			S		Unk		Not Reported	
	Citalopram			S		Unk		Not Reported	
	Elavil			S		Unk		Not Reported	
	Paxil			S		Unk		Not Reported	
	Prozac			S		Unk		Not Reported	
	Serzone			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Trazodone		S			Unk			Not Reported
	Zyrtec		S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11626374	NON-EXPEDITED			US-ROCHE-1539029			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Naprosyn			S	Oral	Prn		Not Reported	
Dizziness;	Neurontin (United States)			S	Oral			Not Reported	
Hypersensitivity;	Zithromax			S	Unknown			Not Reported	
Myoclonus	Erythromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11626865	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015339151			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Pneumonia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2015	11628180	DIRECT		DE, HO			57 YR	Female	LBN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Quality Issue	Azithromycin			S	Oral	2 Tablets Days One, 1x 2-5 Days Once Daily Taken By Mouth		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	10671990	NON-EXPEDITED			US-PFIZER INC-2014350694			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

Amlodipine Besilate	S	Unk	Pfizer
Paxil	S	Unk	Not Reported
Iodine	S	Unk	Not Reported
Norco	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11254727	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015223611		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Haematoma	Zithromax			S	Oral	Unk		Pfizer
	Previscan (Fluindione)			S	Oral	Alternating 20 Mg And 25 Mg Daily		Not Reported
	Previscan (Fluindione)			S	Oral	Alternating 20 Mg And 25 Mg Daily		Not Reported
	Furosemide			C		40 Mg, 1x/Day		Not Reported
	Spironolactone			C		50 Mg, 1x/Day		Not Reported
	Letrozole			C		2.5 Mg, 1x/Day		Not Reported
	Verapamil			C		40 Mg, 2x/Day		Not Reported
	Digoxin			C		0.125 Mg, 1x/Day		Not Reported
	Esomeprazole			C		40 Mg, 1x/Day		Not Reported
	Fosavance			C		70 Mg Once Weekly		Not Reported
	Calcidose Vitamine D			C		1 Df, 2x/Day (In Mornings And Evenings)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11383042	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015268337		41 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Zithromac			S	Oral	500 Mg, Daily		Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11583255	EXPEDITED (15-DAY)		OT	US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-077		4 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Disturbance In Attention; Psychomotor Hyperactivity; Unresponsive To Stimuli	Delsym Suspension Adult			S	Unknown	2.5 MI, Bid		Not Reported	
	Grapedelsym Suspension Pediatric Grape			S	Unknown	16.7 MI, Single		Not Reported	
	Delsym Suspension Adult Grapedelsym Suspension Pediatric Grape Zithromax			S	Unknown	2 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11611563	EXPEDITED (15-DAY)		DE	US-PFIZER INC- 2015329570		59 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Fluconazole			S		Unk		Pfizer	
	Rifampicin			S		Unk		Unknown	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Amphotericin			S		Unk		Not Reported	
	Pentamidine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11630441	NON-EXPEDITED			US-PFIZER INC- 2015332784			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Benadryl			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	

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

Phenothiazine			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2015	11630593	NON-EXPEDITED			US-PFIZER INC-2015333826			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2015	11632951	EXPEDITED (15-DAY)		OT	NZ-APOTEX-2015AP013244		84 YR	Male	NZL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Azithromycin			S	Oral			Apotex	
	Amoxicillin W/Clavulanic Acid			S	Oral			Not Reported	
	Atorvastatin			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2015	11633424	EXPEDITED (15-DAY)		OT	PHHY2015GB124495		24 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Expired Product Administered; Vomiting	Azithromycin Sandoz			S	Oral	1 G, Once/Single		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2015	11633918	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK144560			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flonase			S				Glaxosmithkline	
	Amitriptyline			S				Glaxosmithkline	
	Pravastatin			S				Not Reported	

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

Amoxicillin	S	Glaxosmithkline
Azithromycin	S	Glaxosmithkline
Bactrim	S	Glaxosmithkline
Aspirin Ec	S	Glaxosmithkline
Cyclobenzaprine Hydrochloride	S	Not Reported
Dilantin	S	Not Reported
Flexeril	S	Not Reported
Lisinopril Hctz	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2015	11634567	EXPEDITED (15-DAY)		HO, OT	FR-GILEAD-2015-0176564		35 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Truvada			S	Oral	Unk		Gilead
	Bactrim			S	Oral	Unk		Not Reported
	Isentress			S	Oral	Unk		Not Reported
	Eupantol			S	Oral	Unk		Not Reported
	Azadose			S	Oral	Unk		Not Reported
	Cymevan			C		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported
	Ceftriaxone Kabi			C		Unk		Not Reported
	Rovamycine /00074401/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2015	11637061	DIRECT					20 YR	Female	PAK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Urine Present; Urine Abnormality	Azotek (Azithromycin) 250mg Saffron			S	Oral	2 Pills Twice Daily Taken By Mouth		Saffron Pharma

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11635499	EXPEDITED (15-DAY)		HO	FR-ABBVIE-15K-056-1481140-00		52 YR	Female	FRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Albumin Decreased;	Humira			S	Unknown			Not Reported
C-Reactive Protein	Humira			S	Unknown			Not Reported
Increased; Cough;	Humira			S	Unknown			Not Reported
Folliculitis; Inflammation;	Humira			S	Unknown			Not Reported
Metastases To	Humira			S	Unknown			Not Reported
Peritoneum; Neutrophilia;	Humira			S	Unknown			Not Reported
Night Sweats; Ovarian	Humira			S	Unknown			Not Reported
Cancer; Peristalsis Visible;	Humira			S	Unknown			Not Reported
Pyrexia; Rash Papular;	Humira			S	Unknown			Not Reported
Red Blood Cell	Humira			S	Unknown			Not Reported
Sedimentation Rate	Humira			S	Unknown			Not Reported
Increased;	Humira			S	Unknown			Not Reported
Thrombocytosis	Humira			S	Unknown			Not Reported
	Imeth			S	Oral			Not Reported
	Novatrex			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11635579	NON-EXPEDITED			US-PFIZER INC- 2015340938			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S	Unknown	Unk		Pfizer
	Augmentin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11635608	NON-EXPEDITED			US-PFIZER INC- 2015332751		16 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		2 Pills First Day, Taking The Product Around Lunch Time		Pfizer
	Azithromycin			S		One Pill For The Remaining Days, Taking		Pfizer

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

Azithromycin			S			The Product Around Lunch Time			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
16-Oct-2015	11635613	NON-EXPEDITED			US-PFIZER INC-2015335800			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer		
	Doxycycline Hyclate			S		Unk		Pfizer		
	Vicodin			S		Unk		Not Reported		
	Acetaminophen\Hydrocodone Bitartrate			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
16-Oct-2015	11636755	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-600286ACC		60 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Kidney Injury; Blood Thyroid Stimulating Hormone Decreased; Cytomegalovirus Infection; Drug Reaction With Eosinophilia And Systemic Symptoms; Euthyroid Sick Syndrome; Haemophagocytic Lymphohistiocytosis; Hepatitis Cholestatic; Infection Reactivation; Lip Haemorrhage; Mouth Ulceration; Mucosal Erosion; Pancytopenia; Rash; Respiratory Failure; Stevens-Johnson Syndrome	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported		
	Calcium			C				Not Reported		
	Colace			C				Not Reported		
	Lantus			C	Subcutaneous			Not Reported		
	Norvasc Tab 10mg			C				Not Reported		
	Novorapid			C				Not Reported		
	Prednisone			C				Not Reported		
	Salbutamol			C				Not Reported		
	Travatan Z			C	Ophthalmic			Not Reported		
	Valsartan/Hctz			C				Not Reported		
	Vitamin D Nos			C				Not Reported		
	Zantac			C				Not Reported		

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11636873	EXPEDITED (15-DAY)		DE	CA-TEVA-600293ACC		65 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea; Pulmonary Congestion; Respiratory Failure; Tachypnoea	Azithromycin			S	Unknown			Not Reported	
	Aspirin			C				Not Reported	
	Gabapentin			C				Not Reported	
	Metoprolol			C				Not Reported	
	Quetiapine			C				Not Reported	
	Valproic Acid			C				Not Reported	
	Zeldox			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11637782	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2015347698		30 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chills; Dyspnoea; Hypoaesthesia; Palpitations	Zithromax			S	Intravenous drip	0.5 G, Plus 5% Gs 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11637921	EXPEDITED (15-DAY)		OT	US-TEVA-600998USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gait Inability; Gout; Pain In Extremity	Azithromycin			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Prednisone			C	Unknown	For 3 Days Then Gradually Taper Back Down To Maintenance Dose		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2015	11638775	EXPEDITED (15-DAY)		HO	US-ABBVIE-15P-163-1477545-00		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Hepatic Enzyme Increased; Hyperhidrosis; Pharyngeal Swelling; Pneumonia Haemophilus; Pneumonia Klebsiella; Retching	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Oral	7 Pills, Every Sunday Night		Not Reported	
	Ampicillin			S	Unknown			Not Reported	
	Ampicillin			S				Not Reported	
	Zithromax			S	Intravenous (not otherwise specified)			Not Reported	
	Zithromax			S				Not Reported	
	Lisinopril			C				Not Reported	
	Ibuprofen			C	Oral	Three In One Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2015	11639967	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2015R1-104372		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Diarrhoea; Hypersensitivity	Azithromycin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2015	10792440	EXPEDITED (15-DAY)		HO, OT	US-TEVA-539969USA		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Craniocerebral Injury; Generalised Tonic-Clonic Seizure; Hypersensitivity; Post-Traumatic Stress Disorder;	Azithromycin			S	Unknown			Not Reported	
	Furosemide			S	Unknown			Ivax	
	Seroquel			S	Unknown			Not Reported	

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

Seizure	Lasix	S	Unknown	Not Reported
	Prilosec	S	Unknown	Not Reported
	Zoloft	S	Unknown	Not Reported
	Lorazepam	S	Unknown	Not Reported
	Meclizine	S	Unknown	Not Reported
	Potassium	S	Unknown	Not Reported
	Hydrocortisone	S	Unknown	Not Reported
	Promethazine	S	Unknown	Not Reported
	Hydrocodone	S	Unknown	Not Reported
	Topamax	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2015	11642782	EXPEDITED (15-DAY)		OT	FR-ROCHE-1647425		68 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Squamous Cell Carcinoma	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Sixth Cycle		Not Reported
	Cortancyl			S	Oral	5 Mg		Not Reported
	Novatrex			S	Oral	2.5 Mg		Not Reported
	Alendronic Acid			C	Oral			Not Reported
	Speciafoldine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2015	11643182	NON-EXPEDITED			US-PFIZER INC-2015345245			Female	USA

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

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11643199	NON-EXPEDITED			US-PFIZER INC-2015346705			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Inflammation	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11645163	EXPEDITED (15-DAY)		OT	JP-AKORN PHARMACEUTICALS-2015AKN00600		48 YR	Male	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased	Azasite			S	Ophthalmic	1 Gtt, Odd		Akorn	
	Depakene-R			C		Unk		Not Reported	
	Serenace			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2015	11645884	NON-EXPEDITED			US-PFIZER INC-2015340246			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11649178	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2015355422		39 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dermatitis Exfoliative Generalised; Pruritus; Rash	Zithromax			S	Oral	0.2 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2015	11650848	NON-EXPEDITED			US-PFIZER INC-2015348865			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Drunk	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Oct-2015	11653511	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2015355199		40 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pharyngeal Oedema	Azithromycin			S	Oral	1 Df, Daily		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11049318	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1011578			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Haematemesis; Urticaria; Vertigo	Azithromycin Mylan			S	Oral	500 Mg Daily		Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11642225	NON-EXPEDITED			US-PFIZER INC-2015340444		13 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dermatitis Contact; Eye Swelling; Rash; Swelling Face	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11656806	EXPEDITED (15-DAY)		HO, OT	TR-WATSON-2015-22272		35 YR	Female	TUR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Drug Interaction; Peripheral Ischaemia; Vasospasm		Ergotamine Azithromycin (Unknown)		S S	Unknown Unknown		Unk 1 G, Single		Watson Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11657069	EXPEDITED (15-DAY)		OT	JP-MYLANLABS- 2015M1036113			Unknown	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Oral	2.0 G Extended-Release Formulation		Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Oct-2015	11659833	DIRECT		OT			57 YR	Female	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Back Pain; Gait Inability; Impaired Work Ability; Pain	Azithromycin			S	Oral	2 First Day, 1/ Day 4 Days		Greenstone	
	Wellbutrin			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Acidophilus			C				Not Reported	
	Fish Oil			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11659217	NON-EXPEDITED			US-PFIZER INC- 2015355067			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Product Residue Present	Azithromycin			S		250 Mg, Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2015	11659218	NON-EXPEDITED			US-PFIZER INC- 2015354869		39 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2015	11659910	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2015AP013897		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Bronchiolitis; Drug-Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2015	11660526	EXPEDITED (15-DAY)		LT	US-KNIGHT THERAPEUTICS (USA) INC.-1043373		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Ineffective For Unapproved Indication; Multi-Organ Disorder; Neurological Decompensation; Off Label Use; Toxicity To Various Agents	Impavido (Miltefosine) Capsules			S				Knight Therapeutics	
	Dexamethasone Sodium Phosphates			S				Not Reported	
	Fosphenytoin Sodium			S				Not Reported	
	Azithromycin			S				Not Reported	
	Fluconazole			S				Not Reported	
	Fluorocytosine			S				Not Reported	
	Sulfadiazine			S				Not Reported	
	Levetiracetam			S				Not Reported	
	Phenobarbital			S				Not Reported	
	Valproate Sodium			S				Not Reported	
	Lorazepam			S				Not Reported	
	Metronidazole Sodium			S				Not Reported	
	Thioridazine Hydrochloride			S				Not Reported	
	Methylprednisolone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2015	11661216	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2015357347		42 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cyanosis;	Zithromax			S	Intravenous drip	500 Mg, 1x/Day		Pfizer	

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

Hypotension; Pyrexia;
Restlessness;
Somnolence;
Supraventricular
Tachycardia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2015	11661613	NON-EXPEDITED			US-PFIZER INC- 2015356648			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2015	11661823	NON-EXPEDITED			US-BAUSCH-BL-2014- 011365		52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia; Nausea; Vision Blurred; Visual Impairment	Ativan			S				Not Reported
	Ultram Er			S				Not Reported
	Wellbutrin Sr			S	Oral			Not Reported
	Wellbutrin Sr			S	Oral			Not Reported
	Align			S				Not Reported
	Azithromycin			S				Not Reported
	Fiorinal			S				Not Reported
	Fluticasone			S				Not Reported
	Imodium			S				Not Reported
	Inderal			S				Not Reported
	Lisinopril			S				Not Reported
	Miralax			S				Not Reported
	Motrin			S				Not Reported
	Mucinex D			S				Not Reported
	Nexium			S				Not Reported
	Robaxin			S				Not Reported
	Tylenol			S				Not Reported
	Zofran			S				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11445530	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2015267898		88 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Gastric Cancer; Pyrexia; Upper Respiratory Tract Inflammation	Lipitor			S	Oral	Unk, 1x/Day		Pfizer	
	Zithromac			S	Oral	500 Mg, 1x/Day		Pfizer	
	Berizym			S	Oral	Unk, 3x/Day		Not Reported	
	Camostat			S	Oral	Unk, 3x/Day		Not Reported	
	Teprenone			S	Oral	Unk, 3x/Day		Not Reported	
	Ranitidine			S	Oral	Unk, 1x/Day		Not Reported	
	Reticolan			S	Oral	Unk, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11637812	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2015344916		44 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Blood Cholesterol Increased; Blood Triglycerides Increased; Chills; Condition Aggravated; High Density Lipoprotein Increased; Hypertransaminasaemia; Myositis; Pyrexia	Methotrexate			S		10 Mg, Weekly		Pfizer	
	Azithromycin			S		500 Mg Persistent 1 Months		Pfizer	
	Prednisone			S		15 Mg, 1x/Day		Not Reported	
	Prednisone			S		25 Mg, 1x/Day		Not Reported	
	Mercaptopurine			S	Intravenous (not otherwise specified)	125 Mg For 3 Days		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	Infusion		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	Infusion 480 Mg Once In A Month		Not Reported	
	Lansoprazole			C	Oral	30 Mg		Not Reported	
	Deltacortene			C	Oral	5 Mg, Cyclic		Not Reported	
	Eutirox			C	Oral	75 Mg		Not Reported	

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

	Cardioaspirin	C	Oral	100 Mg				Not Reported	
	Natecal D3	C	Oral	Unk				Not Reported	
	Forsteo	C	Subcutaneous	20 Mg				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11668891	NON-EXPEDITED			US-PFIZER INC-2015359101			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11668953	NON-EXPEDITED			US-PFIZER INC-2015360747			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Interaction	Dilantin			S		200 Mg, 2x/Day		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11669043	NON-EXPEDITED			US-PFIZER INC-2015360896		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression	Zithromax			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2015	11673461	DIRECT		DS			67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Tendonitis; Weight Bearing Difficulty	Z Pack (Azithromycin)	S	Oral	4 Pills; 1 Per Day Once Daily	Not Reported
	Losartan-Hctz	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2015	11665877	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK152643			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Interaction	Valtrex			S				Glaxosmithkline	
	Zithromax			S				Glaxosmithkline	
	Bactrim			S				Glaxosmithkline	
	Cipro			S				Glaxosmithkline	
	Dilantin			S				Not Reported	
	Polycitra-K (Nos)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2015	11675158	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP013898		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxic Epidermal Necrolysis; Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown			Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	9687099	EXPEDITED (15-DAY)		OT	PHHY2013IT126677		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Reaction; Conjunctival Hyperaemia; Eyelid Oedema	Voltaren Ofta			S	Ophthalmic	1 Drp, Qid		Novartis	
	Azyter			S		1 Drp, Tid		Not Reported	
	Monofloxofta			S	Ophthalmic	1 Drp, Qid		Not Reported	
	Oftaquix			S	Ophthalmic	Unk Drp, Every Day		Not Reported	
	Hyalistil			C		Unk Ukn, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11543727	EXPEDITED (15-DAY)		HO, OT	IT-ROCHE-1635164		52 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Blood Cholesterol Increased; Blood Triglycerides Increased; Chills; High Density Lipoprotein Increased; Hypertransaminasaemia; Myositis; Oropharyngitis; Fungal; Pyrexia; Pyrexia; Upper Respiratory Tract Infection; Urinary Tract Infection	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Roactemra			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous drip			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Weekly For 4 Weeks		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mercaptopurine			S	Intravenous (not otherwise specified)			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Methotrexate			S	Intramuscular			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Azithromycine			S	Unknown			Not Reported
	Deltacortene			S	Oral			Not Reported
	Deltacortene			S				Not Reported
	Sandimmun Neoral			S	Oral			Not Reported
	Sandimmun Neoral			S				Not Reported
	Lansoprazole			C	Oral	Hard Capsule		Not Reported
	Deltacortene			C	Oral	Period 8 Years		Not Reported
	Eutirox			C	Oral			Not Reported
	Cardioaspirin			C	Oral	Period 6 Years		Not Reported

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

	Natecal D3	C	Oral	Orodispersible Tablet	Not Reported
	Forsteo	C	Subcutaneous		Not Reported
	Actonel	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11574745	NON-EXPEDITED			US-PFIZER INC-2015323983			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hyperhidrosis	Ciprofloxacin			S		Unk		Not Reported	
	Doxycycline Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11603315	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-08798		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Micturition Urgency; Nausea; Oedema Peripheral; Vomiting	Metoprolol Tartrate Tablets Usp 25 Mg			S	Oral	25 Mg,1 Tablet Two Times A Day		Aurobindo	
	Norvasc			S	Oral	5 Mg, 1 Tablet Daily		Not Reported	
	Azasite			S	Ophthalmic	Twice Daily 8 To 12 Hours		Not Reported	
	Aspirin			C	Oral	1 Tablet Daily		Not Reported	
	Albuterol Sulfate			C		2.5 Mg/3ml, 1 Vial 4 Time A Day		Not Reported	
	Albuterol Sulfate			C		0.63 Mg/3ml, Every 4 To 6 Hour Needed		Not Reported	
	Amlodipine Besylate			C	Oral	5 Mg, Daily, 1 Tablet Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11681604	NON-EXPEDITED			US-PFIZER INC-2015359981		65 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vision Blurred; Visual Impairment	Zithromax			S		Unk		Pfizer	
	Synthroid			C		Unk, Daily (0.88 Per Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11682018	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1036698			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxic Epidermal Necrolysis; Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11682025	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2015M1036720			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Bronchiolitis; Drug-Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11682461	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP013910			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
	Levofloxacin Tablets			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11682576	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP013911			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11682754	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP013912			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11684019	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP013913			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11684482	NON-EXPEDITED			US-PFIZER INC-2015364440			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Hydroxyzine Pamoate			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Erythromycin			S		Unk		Not Reported	
	Ultram			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2015	11684656	NON-EXPEDITED			US-THE RITEDOSE CORPORATION-2014RIT000068		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Choking; Cough; Drug Ineffective; Dry Mouth; Dyspnoea; Insomnia; Off Label Use	Ipratropium Bromide And Albuterol Sulfate Inhalation Solution	S	Respiratory (inhalation)	The Ritedose
	Ipratropium Bromide And Albuterol Sulfate Inhalation Solution	S	Respiratory (inhalation)	The Ritedose
	Losartan	C		Not Reported
	Furosemide	C		Not Reported
	Garlic	C		Not Reported
	Klor-Con	C		Not Reported
	Advair	C		Not Reported
	Guaifenesin\Pseudoephedrine Hydrochloride	C	Oral	Not Reported
	Carvedilol	C		Not Reported
	Multivitamins	C		Not Reported
	Prednisone	S		Not Reported
	Azithromycin	S		Not Reported
	Azithromycin	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2015	11414217	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015276134		74 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pollakiuria; Urinary Retention; Urine Flow Decreased	Zithromac			S	Oral	500 Mg, Daily		Pfizer
	Zithromac			S				Pfizer
	Allegra			S	Oral	1 Df, 2x/Day		Not Reported
	Tamsulosin			C	Oral	Unk		Not Reported
	Avolve			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2015	11415919	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2015274699		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Electrolytes Abnormal; Cardiac Arrest; Cough; Electrocardiogram Qt	Azithromycin			S		Unk		Pfizer
	Zyrtec			S				Not Reported
	Imbruvica			S	Oral	420 Mg, 1x/Day		Not Reported

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

Prolonged; Hypoxic-Ischaemic Encephalopathy; Leukocytosis; Rib Fracture; Ventricular Fibrillation	Synthroid	C	Unk	Not Reported
	Losartan/Hydrochlorothiazide	C	Unk	Not Reported
	Metformin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2015	11682142	EXPEDITED (15-DAY)		HO	PT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015R1-105260		35 YR	Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Kaposi'S Sarcoma	Azithromycin			S	Unknown	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported
	Everolimus			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Mutual

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2015	11686180	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI- FK201505440		20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Toxic Epidermal Necrolysis	Azithromycin (Manufacturer Unknown) (Azithromycin)			S	Unknown			Fresenius Medical Care

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2015	11686184	EXPEDITED (15-DAY)		DE, LT, OT	US-FRESENIUS KABI- FK201505439		11 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis; Bronchiolitis; Drug-Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin (Manufacturer Unknown) (Azithromycin)			S	Unknown			Fresenius Medical Care

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2015	11689093	EXPEDITED (15-DAY)		DE, OT	US-TEVA-605289USA		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Bronchiolitis; Drug- Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2015	11689622	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2015365425		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Zithromax			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2015	11690201	EXPEDITED (15-DAY)		OT	PHHY2015DE137823			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Complications Of Transplanted Lung; Diarrhoea; Drug Interaction; Erythema; Metastases To Bone; Metastases To Central Nervous System; Metastases To Liver; Metastases To Lung; Metastases To Skin; Metastases To The Mediastinum; Metastatic Malignant Melanoma; Skin Lesion; Taste Disorder	Ciclosporin			S	Unknown			Not Reported	
	Ciclosporin			S				Not Reported	
	Everolimus			S	Unknown			Not Reported	
	Everolimus			S				Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S				Not Reported	
	Prednisolone			S	Unknown			Novartis	
	Prednisolone			S				Novartis	
	Itraconazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Vemurafenib			S	Unknown	480 Mg, Bid		Not Reported	
	Vemurafenib			S	Unknown	960 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Vemurafenib			S		Unknown		720 Mg, Bid		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
02-Nov-2015	11690286	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1036367			Unknown	ITA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Palatal Oedema; Pharyngeal Oedema	Azithromycin			S	Oral	1 Df, Qd			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
02-Nov-2015	11690564	NON-EXPEDITED			US-PFIZER INC-2015366378		76 YR	Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Nightmare; Palpitations	Zithromax			S		Unk Unk, 1x/Day			Pfizer	
	Xtandi			S		160 Mg, 1x/Day			Not Reported	
	Desonide			C		Unk			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
02-Nov-2015	11691346	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015366552			Unknown	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Diffuse Large B-Cell Lymphoma	Azithromycin			S		Unk			Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
02-Nov-2015	11693293	DIRECT		OT			51 YR	Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Abdominal Pain Upper; Dyspepsia; Dysuria; Fungal Infection; Pruritus; Vaginal Discharge	Azithromycin			S	Oral	Azithromycin 2 Pills One Time Taken By Mouth			Not Reported	
	Janumet			C					Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2015	8494552	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2012078806		58 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autonomic Nervous System Imbalance; Erythema Multiforme; Peripheral Sensory Neuropathy	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2015	11693356	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015283893		16 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Duodenitis; Eosinophilia; Hepatic Function Abnormal; Nausea; Pyrexia; White Blood Cell Count Increased	Zithromac			S	Oral	250 Mg, Daily		Pfizer	
	Flomox [Cefcapene Pivoxil Hydrochloride]			S	Oral	100 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2015	11693363	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015368179		21 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
	Pa			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2015	11693604	NON-EXPEDITED			US-PFIZER INC-2015370216			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2015	11694374	EXPEDITED (15-DAY)		OT	US-TEVA-605315USA		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxic Epidermal Necrolysis; Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2015	11696060	DIRECT		DE			39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Zithromax			S	Oral	X 5 Days Once Daily Taken By Mouth		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2015	11695732	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2015-03395		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2015	11696056	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015US-105313			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anger; Brain Injury; Coma; Craniocerebral Injury; Drug Hypersensitivity;	Lorazepam			S	Unknown	Unk		Sun	
	Azithromycin			S	Unknown	Unk		Not Reported	

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

Generalised Tonic-Clonic Seizure; Lung Disorder; Oedema; Overdose; Peripheral Swelling; Post-Traumatic Stress Disorder; Sinusitis; Stasis Dermatitis	Furosemide	S	Unknown	Unk	Not Reported
	Potassium Chloride	S	Unknown	Unk	Not Reported
	Promethazine Hydrochloride	S	Unknown	Unk	Not Reported
	Seroquel	S	Unknown	Unk	Not Reported
	Prilosec	S	Unknown	Unk	Not Reported
	Meclozine	S	Unknown	Unk	Not Reported
	Hydrocodone	S	Unknown	Unk	Not Reported
	Topamax	S	Unknown	Unk	Not Reported
	Hydrocortisone	S	Unknown	Unk	Not Reported
	Zoloft	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2015	11696365	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015368117			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Empyema; Rhinalgia; Sinus Headache	Zithromac			S	Oral	Unk, 1x/Day		Pfizer	
	Clarith			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2015	11697606	EXPEDITED (15-DAY)		OT	PHHY2015CA142931		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2015	11698287	NON-EXPEDITED			US-PFIZER INC-2015369985			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

Tetracycline Hcl			S		Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2015	11702713	NON-EXPEDITED			US-PFIZER INC-2015370322			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2015	11704570	DIRECT	Y				22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystic Fibrosis; Disease Complication	Azithromycin			S	Oral			Teva	
	Pancreaze			C				Not Reported	
	Aquadeus			C				Not Reported	
	Ursodiol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2015	11489790	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015296847		12 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothermia	Zithromac			S	Oral			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2015	11611752	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015332730		21 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Azithromycin			S	Oral	Unk		Pfizer	
	Sodium Valproate			C	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2015	11319752	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-100804			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Haemorrhagic Oedema Of Infancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2015	11714396	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC- 2015375467		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2015	11716513	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2015AP014262		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Vasculitis; Drug Reaction With Eosinophilia And Systemic Symptoms	Apo-Azithromycin Tablets 250 Mg			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2015	11719385	DIRECT		LT, OT			5 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Nausea; Poisoning; Product Preparation Issue; Pyrexia	Azithromycin 200/5ml Elsa Pharmacy			S	Oral	1 Teaspoonful Once Daily Taken By Mouth		Unknown	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2015	11719625	DIRECT					66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Skin Irritation	Azithromycin			S	Oral	2 Pills, 1 Pills, 2, Then 1x5days		Sandoz	
	Atenolol			C				Not Reported	
	Aspirin			C				Not Reported	
	Acidophilus			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2015	11719653	DIRECT		OT			52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Deafness; Diarrhoea	Azithromycin			S	Oral	2 Pills 1st Day Then 1 Pill		Teva	
	Benzonate			S	Oral			Ascend	
	Naproxen			C				Not Reported	
	Benzonatate			C				Not Reported	
	Benadryl			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11599428	EXPEDITED (15-DAY)		OT	US-TEVA-598175USA		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Drug Hypersensitivity; Headache; Hypersensitivity; Lip Swelling; Mouth Swelling; Musculoskeletal Pain; Myocardial Infarction; Swollen Tongue	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Crestor			C				Not Reported	
	Xarelto			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11719386	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2015M1038555			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Vasculitis; Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11720425	EXPEDITED (15-DAY)		HO, LT	BE-PFIZER INC-2015371463		87 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Torsade De Pointes	Efexor Exel			S	Oral	75 Mg, 1x/Day		Pfizer	
	Zitromax			S	Oral	500 Mg, 3x/Day		Pfizer	
	Cordarone			S	Oral	200 Mg, Daily		Pfizer	
	Isoten			C	Oral	2.5 Mg, Daily		Not Reported	
	Prolopa			C	Oral	250 Mg, 3x/Day		Not Reported	
	Prolopa Hbs			C	Oral	125 Mg, Daily		Not Reported	
	Mirapexin			C		0.18 Mg, Daily		Not Reported	
	Pantomed (Pantoprazole Sodium)			C	Oral	40 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11720763	NON-EXPEDITED			US-PFIZER INC-2015374425			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Augmentin /00852501/			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11722319	DIRECT		LT, OT			66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Cough; Dyspnoea; Heart Rate Increased; Vomiting	Azithromycin 250 Mg			S	Oral	250 Mg - 6 Tablets - 2 Tab 5 DAY Day One; 1 Tablet Daily - Daily 1 Tab For 4 Days		Pliva	
	Albuterol Sulfate (Pro Air - Hfa) 90mcg			S	Oral	1-2 Puffs As Needed By Mouth		Teva	
	Enalapril			C				Not Reported	
	Amlodipine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2015	11723226	DIRECT		OT			87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Yellow Skin	Azithromycin			S	Oral	2 Pills Then 1 A Day For 4 5days		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2015	11723220	EXPEDITED (15-DAY)			US- GLAXOSMITHKLINE- US2015GSK158499			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Ceftin			S		Unk		Glaxosmithkline	
Anxiety; Crying;	Effexor Prolonged-Release			S		Unk		Glaxosmithkline	
Diarrhoea; Drug	Capsule								
Ineffective; Dysphemia;	Effexor Prolonged-Release			S				Glaxosmithkline	
Gastrointestinal Pain; Hot	Capsule								
Flush; Product	Effexor Prolonged-Release			S				Glaxosmithkline	
Substitution Issue; Rash;	Capsule								
Skin Disorder; Social	Effexor Prolonged-Release			S				Glaxosmithkline	
Avoidant Behaviour;	Capsule								
Therapeutic Response	Azithromycin			S				Glaxosmithkline	
Decreased; Tremor	Xanax			C				Glaxosmithkline	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11723289	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015308712		16 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Atypical Pneumonia	Zithromac			S	Oral	Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11723691	EXPEDITED (15-DAY)		HO, OT	PHHY2015US145801		34 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Drospirenone,Ethinylestradiol			S	Unknown			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11723694	EXPEDITED (15-DAY)		DE, OT	PHHY2015US145810		76 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury; Multiple Organ Dysfunction Syndrome	Azithromycin			S	Unknown			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2015	11725783	EXPEDITED (15-DAY)		OT	CA-HOSPIRA-3068082		46 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2015	11728292	NON-EXPEDITED			US-PFIZER INC-2015378494			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Prednisone			S		Unk		Pfizer	
	Cefaclor			S		Unk		Not Reported	
	Ciprofloxacin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2015	11728653	EXPEDITED (15-DAY)		OT	US-TEVA-608500	USA	53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Trimethoprim			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2015	11728716	EXPEDITED (15-DAY)		DE, OT	US-TEVA-608507	USA	11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Respiratory Failure; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2015	11728896	EXPEDITED (15-DAY)		OT	US-TEVA-608510	USA	20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Drug-Induced Liver Injury; Multi-Organ Disorder; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2015	11729209	NON-EXPEDITED			US-PFIZER INC-2015382923			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	
	Phenergan			S		Unk		Not Reported	
	Lortab			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Invanz			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2015	11729911	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014362		19 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2015	11730066	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014365		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11732880	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014358		365 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11733175	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2015AP014359		11 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury; Respiratory Failure; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11733505	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP014361		13 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11733683	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014360		8 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11733911	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014364		45 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11734658	EXPEDITED (15-DAY)		OT	CA-FRESENIUS KABI-FK201505815		46 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Central Nervous System Vasculitis; Drug Reaction With Eosinophilia And Systemic Symptoms; Pericardial Effusion	Azithromycin (Manufacturer Unknown) (Azithromycin)	S	Unknown	Fresenius Medical Care

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11734803	NON-EXPEDITED			US-PFIZER INC-2015380541			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Toradol			S		Unk		Not Reported	
	Iron			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11734871	NON-EXPEDITED			US-PFIZER INC-2015379528			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11734975	EXPEDITED (15-DAY)		CA, HO	PHHY2015US146254			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Aqueductal Stenosis; Congenital Hydrocephalus; Foetal Exposure During Pregnancy; Premature Baby	Influenza Virus Vaccine - Unknown Inn			S	Transplacental			Not Reported	
	Prednisone			S	Transplacental			Novartis	
	Salbutamol			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental	Unk		Not Reported	
	Azithromycin			S	Transplacental			Not Reported	
	Ceftriaxone			S	Transplacental			Not Reported	
	Vancomycin			S	Transplacental			Not Reported	

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

Oseltamivir			S		Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11734976	EXPEDITED (15-DAY)		HO	PHHY2015US143897		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Breech Presentation; Caesarean Section; Chills; Cough; Dyspnoea; Hypotension; Influenza A Virus Test Positive; Malaise; Maternal Exposure During Pregnancy; Premature Delivery; Premature Rupture Of Membranes; Productive Cough; Pulmonary Oedema; Pyrexia; Respiratory Syncytial Virus Test Positive; Respiratory Tract Congestion; Secretion Discharge; Sputum Discoloured; Tachycardia	Influenza Virus Vaccine - Unknown Inn			S	Unknown	1 Df		Not Reported	
	Prednison			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	For 10 Days		Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown	For 5 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11735284	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014366		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
	Trimethoprim			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11735451	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2015M1039199			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Acute Respiratory Distress Syndrome; Drug-Induced Liver Injury; Multi-Organ Disorder; Toxic Epidermal Necrolysis	Azithromycin	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11735453	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2015M1039204			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury; Respiratory Failure; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11737386	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014367		22 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11738183	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014363		20 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Respiratory Distress Syndrome; Drug-Induced Liver Injury; Multi-Organ Disorder; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Apotex
	Ibuprofen			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11738245	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2015381995			Unknown	CHN

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Cholestasis; Drug-Induced Liver Injury		Azithromycin		S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11738369	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014368		25 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11738397	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014376		54 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11738541	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014375		60 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury; Hepatitis Acute	Azithromycin			S	Unknown			Apotex	
	Repaglinide			C	Unknown			Not Reported	
	Hydrochlorothiazide\Triamterene			C	Unknown			Not Reported	
	Insulin			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2015	11738624	NON-EXPEDITED			US-PFIZER INC-2015378419		60 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Drug Ineffective	Azithromycin		S			Unk		Pfizer	
	Azithromycin		S					Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11738706	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2015AP014374		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Multiple Organ Dysfunction Syndrome	Azithromycin			S		Unknown			Apotex
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11738827	NON-EXPEDITED		OT	US-APOTEX-2015AP014373		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Hepatic Failure	Azithromycin			S		Unknown			Apotex
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11739127	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014372		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury	Azithromycin			S		Unknown			Apotex
	Trimethoprim Sulfamethoxazole			S		Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11739373	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014370		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury	Azithromycin			S		Unknown			Apotex
	Trimethoprim Sulfamethoxazole			S		Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11739435	EXPEDITED (15-DAY)		OT	US-APOTEX-2015AP014369		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
	Ethinylestradiol, Drospirenone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2015	11741912	DIRECT		OT			48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Azithromycin 250mg			S	Oral			Not Reported	
	Ventolin			C				Not Reported	
	Lorazepam			C				Not Reported	
	Lithium			C				Not Reported	
	Seriquel Xr			C				Not Reported	
	Sertraline			C				Not Reported	
	Hydrocortisone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2015	11227428	EXPEDITED (15-DAY)		OT	CH-TEVA-574019ISR		41 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Erysipelas; Hepatitis; Hepatosplenic T-Cell Lymphoma; Hyperhidrosis; Transaminases Increased; Weight Decreased	Azithromycin			S	Unknown			Not Reported	
	Amoxicillin/Clavulanic Acid			S	Unknown			Teva	
	Ciprofloxacin			S	Unknown	Administered Temporarily		Barr	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2015	11741195	EXPEDITED (15-DAY)		LT	US-HOSPIRA-3079620		47 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome; Sudden Cardiac Death	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2015	11744608	NON-EXPEDITED			US-PFIZER INC- 2015386854			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lamictal			S		Unk		Not Reported	
	Seroquel			S		Unk		Not Reported	
	Tegretol			S		Unk		Not Reported	
	Trileptal			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2015	11744626	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-078128		80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Ocular Hyperaemia; Productive Cough; Skin Exfoliation; Swollen Tongue	Opdivo			S	Intravenous (not otherwise specified)	Unk		Bristol Myers Squibb	
	Opdivo Z-Pack			S S	Unknown	Unk		Bristol Myers Squibb Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11091121	NON-EXPEDITED			US-PFIZER INC- 2015148477			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11528843	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015313758		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Product Use In Unapproved Indication; Upper Respiratory Tract Infection	Sirolimus			S	Oral	1.5 Mg, 1x/Day		Pfizer	
	Sirolimus			S	Oral	2 Mg, 1x/Day (Every Morning)		Pfizer	
	Zithromax			S		250 Mg, 1x/Day (For A Week)		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	250 Mg, Unk (Three Times A Week)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11745247	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-02851			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus	Azithromycin			S	Unknown			Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11745485	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/15/0053969		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Complications Of Transplanted Lung; Fungal Infection; Organising Pneumonia; Periostitis; Respiratory Distress; Rheumatoid Arthritis	Tacrolimus			S	Unknown			Not Reported	
	Valganciclovir			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Voriconazole			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11745696	EXPEDITED (15-DAY)		HO, LT, OT	US-WATSON-2015-24727		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Respiratory Failure	Lorazepam (Watson Laboratories)			S	Unknown	Unk		Watson	
	Azithromycin (Unknown)			S	Oral	Unk		Not Reported	
	Suboxone			S	Sublingual	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11745986	NON-EXPEDITED			US-PFIZER INC-2015389695			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Macrodantin			S		Unk		Not Reported	
	Parafon Forte			S		Unk		Not Reported	
	Celexa /00582602/			S		Unk		Not Reported	
	Trilipix			S		Unk		Not Reported	
	Ciprofloxacin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Flexeril /00428402/			S		Unk		Not Reported	
	Fluorouracil			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Niaspan			S		Unk		Not Reported	
	Percocet /00446701/			S		Unk		Not Reported	
	Paxil /00830802/			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11746031	NON-EXPEDITED			US-PFIZER INC-2015387793		54 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Augmentin /00756801/			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11746374	EXPEDITED (15-DAY)		OT	ES-TEVA-609756ISR		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11747768	NON-EXPEDITED			US-PFIZER INC-2015386747			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Malaise	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2015	11748426	NON-EXPEDITED			US-PFIZER INC-2015385998			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	9938724	NON-EXPEDITED			US-PFIZER INC-2014056092			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity; Palpitations		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	10539155	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2014287554			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hallucination	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11723293	EXPEDITED (15-DAY)		DE	NL-PFIZER INC- 2015379006		83 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulation Time Prolonged; Drug Interaction; Nausea; Vomiting	Azithromycin			S	Oral	500 Mg, Unk		Pfizer	
	Acenocoumarol			S	Oral	According To The Schedule Of The Thrombosis Service		Not Reported	
	Acenocoumarol			S				Not Reported	
	Oxycodon			C	Oral	10 Mg, Unk		Not Reported	
	Rabeprazol Sodico			C	Oral	20 Mg, Unk		Not Reported	
	Carbamazepine A			C	Oral	400 Mg, Unk		Not Reported	
	Pregabalin			C	Oral	75 Mg, Unk		Not Reported	
	Colecalciferol			C	Oral	800 Iu, Unk		Not Reported	
	Etoricoxib			C	Oral	60 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11749485	NON-EXPEDITED			US-PFIZER INC- 2015387670		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Feeling Abnormal; Headache; Loss Of Personal	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Norco			S	Oral	5-325, One To Two One		Not Reported	

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

Independence In Daily Activities; Nausea; Pain In Jaw	Diphenhydramine Hydrochloride Mucinex D	C C	Oral	To Two Tablets 4-6 Hours 25 Mg, One Only At Night 600mg Guaifenesin, 60mg Pseudoephedrine, Daily	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11749656	EXPEDITED (15-DAY)		CA, HO, LT, OT	US-GLAXOSMITHKLINE-K201305216			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastroesophageal Reflux Disease	Sumatriptan Succinate			S	Transplacental			Glaxosmithkline
	Cetirizine Hydrochloride			S	Transplacental			Glaxosmithkline
	Topamax			S	Transplacental			Not Reported
	Flexeril			S	Transplacental			Not Reported
	Cheracol			S	Transplacental			Not Reported
	Prenatal Vitamins			S	Transplacental			Not Reported
	Nitrofurantoin			S	Transplacental			Not Reported
	Olopatadine Hydrochloride			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Fluticasone Propionate			S	Transplacental			Glaxosmithkline
	Vicodin			S	Transplacental			Not Reported
	Amoxycillin			S	Transplacental			Not Reported
	Naproxen			S	Transplacental			Not Reported
	Ibuprofen			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11749813	NON-EXPEDITED			US-PFIZER INC-2015386472			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11749824	NON-EXPEDITED			US-PFIZER INC-2015386431			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11750670	NON-EXPEDITED			US-PFIZER INC-2015385975			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11752126	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015389758			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Pfizer	
	Vancomycin			S	Transplacental	Unk		Unknown	
	Ceftriaxone			S	Transplacental	Unk		Not Reported	
	Albuterol			S	Transplacental	Unk		Not Reported	
	Oseltamivir			S	Transplacental	Unk		Not Reported	
	Prednisone			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2015	11752127	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015389757			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Pfizer	
	Amoxicillin			S	Transplacental	Unk		Pfizer	

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

	Vancomycin	S	Transplacental	Unk		Unknown
	Vancomycin	S				Unknown
	Piperacillin/Tazobactam	S	Transplacental	Unk		Unknown
	Oseltamivir	S	Transplacental	Unk		Not Reported
	Ceftriaxone	C	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11540057	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015314077		34 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Zithromac			S	Oral	500 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11619877	NON-EXPEDITED			US-PFIZER INC-2015330649		7 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin			S		1200mg Suspension, 200mg/5mls		Pfizer	
	Prednisolone			S	Oral	1 Teaspoon, Daily For Five Days		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11753691	NON-EXPEDITED			US-PFIZER INC-2015385350			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective	Azithromycin			S		250 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11753702	NON-EXPEDITED			US-PFIZER INC-2015384419			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Augmentin	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11753750	NON-EXPEDITED			US-PFIZER INC-2015389161			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11755363	EXPEDITED (15-DAY)		OT	HR-TEVA-609091ISR		52 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Headache	Sumamed			S	Oral	500 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11755763	EXPEDITED (15-DAY)		HO, OT	ZW-GILEAD-2015-0182856		36 YR	Female	ZWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pruritus; Vomiting	Tenofovir Disoproxil Fumarate			S	Unknown	Unk		Gilead	
	Emtricitabine			S	Unknown	Unk		Gilead	
	Efavirenz			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Isoniazid			S	Unknown	Unk		Not Reported	
	Co Trimoxazole			C	Unknown	Unk		Not Reported	
	Fluconazole			C	Unknown	Unk		Not Reported	
	Albendazole			C	Unknown	Unk		Not Reported	
	Pyridoxine			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2015	11756015	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2015384501		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Drug Interaction; Respiratory Distress	Azithromycin			S				Pfizer	
	Lorazepam			S	Sublingual	Unk		Not Reported	
	Suboxone			S	Sublingual	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11744087	EXPEDITED (15-DAY)		DE	PHHY2015NL145481		83 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; International Normalised Ratio Abnormal	Acenocoumarol			S	Oral	1 Df, (Scheduled Thrombosis) (Weekly Schedule 3-2-2-2-2-2mg)		Not Reported	
	Azithromycin			S	Oral	1 Df, Unk		Novartis	
	Oxycodon			C	Oral	1 Df, Unk		Not Reported	
	Rabeprazol			C	Oral	1 Df, Unk		Not Reported	
	Carbamazepin			C	Oral	1 Df, Unk		Not Reported	
	Pregabalin			C	Oral	1 Df, Unk		Not Reported	
	Colecalciferol			C	Oral	1 Df, Unk		Not Reported	
	Etoricoxib			C	Oral	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11756856	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-106378		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Lung Infiltration; Respiratory	Azithromycin			S	Oral	Unk		Sun	

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

Failure	Lorazepam	S	Unknown	Unk	Sun
	Suboxone	S	Sublingual	Unk	Not Reported
	Cocaine	C	Unknown	Unk	Not Reported
	Tramadol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11757307	EXPEDITED (15-DAY)		DE, OT	PHHY2015US151881		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Drug Level Increased	Metoprolol			S	Unknown			Not Reported
	Diclofenac			S	Unknown			Novartis
	Ibuprofeno			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Cyclobenzaprine			S	Unknown			Not Reported
	Nitroglycerin Sandoz			S	Unknown	Unk		Not Reported
	Clonidine			S	Unknown			Not Reported
	Lisinopril			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Doxycycline			S	Unknown			Not Reported
	Cefalexin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11757369	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2015-10626			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased;	Azithromycin			S	Unknown			Aurobindo

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Bronchiectasis;
Bronchiolitis; Drug-
Induced Liver Injury;
Stevens-Johnson
Syndrome

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11757920	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03627		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Mrc-6			S	Unknown			Not Reported	
	Drospirenone And Ethinyl Estradiol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11758341	NON-EXPEDITED			US-PFIZER INC- 2015388367			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11758352	NON-EXPEDITED			US-PFIZER INC- 2015388405			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Urticaria	Azithromycin			S				Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2015	11758674	NON-EXPEDITED			US-PFIZER INC- 2015392243			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	6725938	EXPEDITED (15-DAY)		HO, LT, OT	US-ASTRAZENECA-2008UW15622		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Prilosec			S	Oral			Not Reported	
Abnormal Behaviour;	Prilosec			S	Oral			Not Reported	
Adverse Drug Reaction;	Prilosec Otc			S	Oral	Approximately For 10 Days		Not Reported	
Auditory Disorder; Blood Potassium Decreased;	Seroquel			S	Oral			Not Reported	
Calcinosis; Cardiac Failure; Coma;	Seroquel			S	Oral			Not Reported	
Craniocerebral Injury;	Seroquel			S	Oral			Not Reported	
Dermatitis; Diverticulitis;	Seroquel			S	Oral			Not Reported	
Diverticulum; Dizziness;	Seroquel			S	Oral			Not Reported	
Drug Hypersensitivity;	Seroquel			S	Oral			Not Reported	
Drug Interaction;	Seroquel			S	Oral			Not Reported	
Electroencephalogram Abnormal; Fall; Fungal Infection;	Seroquel			S	Oral			Not Reported	
Gastrooesophageal Reflux Disease; Generalised Tonic-Clonic Seizure;	Seroquel			S	Oral	25 Mg, 2 Or 4 Times A Day,		Not Reported	
Haemorrhoids; Head Injury; Hypersensitivity; Hypertension;	Seroquel			S	Oral	25 Mg, 2 Or 4 Times A Day,		Not Reported	
Inflammation; Nausea; Neuroleptic Malignant Syndrome; Oedema;	Zoloft			S	Oral			Not Reported	
Oedema Peripheral; Off Label Use; Overdose;	Zoloft			S	Oral			Not Reported	
Pain; Pain In Extremity; Post-Traumatic Stress Disorder; Product Use In Unapproved Indication;	Hydrocortisone			S	Oral	Non Az Product		Not Reported	
Seizure; Sinusitis; Total Lung Capacity Decreased; Vertigo; Vomiting; Weight Decreased	Potassium Chloride			S	Oral	10 Med		Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Furosemide			S	Oral			Not Reported	
	Topamax			S	Oral			Not Reported	
	Meclizine			S	Oral			Not Reported	

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

Erythromycin	S	Oral	Not Reported
Thyroid	S	Oral	Not Reported
Nasonex	S	Oral	Not Reported
Lorazepam	S	Oral	Not Reported
Lorazepam	S	Oral	Not Reported
Promethazine	S	Unknown	Not Reported
Hydrocodone	S	Oral	Not Reported
Augmentin	S	Oral	Not Reported
Bactrim	S	Oral	Not Reported
Macrobid	S	Oral	Not Reported
Magnesium	S	Oral	Not Reported
Penicillin	S	Oral	Not Reported
Sulfanilamide	S	Oral	Not Reported
Compazine	S	Oral	Not Reported
Synthroid	S	Oral	Not Reported
Levothyroxine	S	Oral	Not Reported
Ranoxyl	C		Not Reported
Pristine	C		Not Reported
Agarol	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	11767236	NON-EXPEDITED			US-PFIZER INC-2015390440			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swollen Tongue; Vision Blurred	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	11767239	NON-EXPEDITED			US-PFIZER INC-2015391045			Male	USA

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

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

Lacrimation Increased; Rhinorrhoea; Swollen Tongue		Zithromax	S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	11767387	NON-EXPEDITED			US-PFIZER INC- 2015394116		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	11769937	EXPEDITED (15-DAY)		LT	PHHY2015US148978		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Novartis	
	Azithromycin			S				Novartis	
	Promethazine Hydrochloride			C	Unknown			Not Reported	
	Promethazine Hydrochloride			C				Not Reported	
	Dextromethorphan Hydrobromide			C	Unknown			Not Reported	
	Dextromethorphan Hydrobromide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	11769952	EXPEDITED (15-DAY)		OT	PHHY2015US148981		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Cyanosis; Drug Interaction; Hypoxia; Respiratory Distress	Azithromycin			S	Oral			Novartis	
	Lorazepam			S	Unknown			Not Reported	
	Suboxone			S	Sublingual			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2015	11770774	EXPEDITED (15-DAY)		DE, OT	US-VALIDUS PHARMACEUTICALS		48 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

LLC-US-
2015VAL000770

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death; Drug Level Increased	Metoprolol Tartrate			S		Unk		Validus
	Diclofenac			S		Unk		Not Reported
	Ibuprofeno (Ngx)			S		Unk		Not Reported
	Oxycodone Hydrochloride (Ngx)			S		Unk		Not Reported
	Cyclobenzaprine (Ngx)			S		Unk		Not Reported
	Nitroglycerin Sandoz (Ngx)			S		Unk		Not Reported
	Clonidine (Ngx)			S		Unk		Not Reported
	Lisinopril (Ngx)			S		Unk		Not Reported
	Escitalopram (Ngx)			S		Unk		Not Reported
	Azithromycin (Ngx)			S		Unk		Not Reported
	Methylprednisolone (Ngx)			S		Unk		Not Reported
	Doxycycline (Ngx)			S		Unk		Not Reported
	Cefalexin (Ngx)			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	10618511	NON-EXPEDITED		OT	US-TEVA-492613USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Diarrhoea Haemorrhagic	Azithromycin			S		3000mg Or 1000mg/Day For Three Days		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11771869	NON-EXPEDITED			US-PFIZER INC-2015403851			Male	USA

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

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

Drug Hypersensitivity	Zithromax	S	Subcutaneous	Unk	Pfizer
	Cefuroxime	S		Unk	Not Reported
	Biaxin	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772151	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2015M1041519			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Mental Disorder; Pneumonia; Respiratory Failure; Transaminases Increased	Buprenorphine			S	Sublingual			Mylan	
	Lorazepam			S	Sublingual			Not Reported	
	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772183	NON-EXPEDITED			US-TEVA-523119USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hypersensitivity; Nausea; Swollen Tongue	Azithromycin			S	Unknown	1200 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772184	NON-EXPEDITED			US-TEVA-530444USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Pruritus; Throat Tightness	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772187	NON-EXPEDITED			US-TEVA-523898USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Taste Disorder	Azithromycin			S		Frequency Not Provided		Not Reported	

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772188	NON-EXPEDITED			US-TEVA-522870USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772190	NON-EXPEDITED			US-TEVA-525298USA		88 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity; Nasopharyngitis; Ventricular Extrasystoles; Viral Infection	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772196	NON-EXPEDITED			US-TEVA-526872USA		7 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyskinesia; Dyskinesia	Azithromycin			S	Unknown	200 Mg/5 MI			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772197	NON-EXPEDITED			US-TEVA-522701USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772199	NON-EXPEDITED			US-TEVA-529368USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Azithromycin			S					Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772200	NON-EXPEDITED			US-TEVA-567742USA		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue; Pruritus	Azithromycin			S	Oral	250 Milligram Daily; 1 Tablet Daily For 4 Days		Not Reported	
	Singulair			C	Unknown			Not Reported	
	Flovent			C	Unknown			Not Reported	
	Albuterol			C	Unknown			Not Reported	
	Metaclopramide			C	Unknown			Not Reported	
	Lovenox			C	Unknown			Not Reported	
	Norco			C	Unknown			Not Reported	
	Fiorinal			C	Unknown			Not Reported	
	Chlorphenaramine			C	Unknown			Not Reported	
	Apap			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772201	NON-EXPEDITED			US-TEVA-521768USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Palpitations	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772202	NON-EXPEDITED			US-TEVA-528252USA			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown			Not Reported	

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772203	NON-EXPEDITED			US-TEVA-529078USA		16 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Diarrhoea; Nausea	Azithromycin			S		2 Teaspoons		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772204	NON-EXPEDITED			US-TEVA-533113USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Creatinine Increased	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772205	NON-EXPEDITED			US-TEVA-535769USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Diarrhoea; Dysgeusia	Azithromycin			S	Oral	200 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772206	NON-EXPEDITED			US-TEVA-528386USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Product Blister Packaging Issue	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772207	NON-EXPEDITED			US-TEVA-534213USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Dysbiosis	Azithromycin		S		Unknown		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772208	NON-EXPEDITED			US-TEVA-520284USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Taste Abnormal; Vomiting	Azithromycin			S	Unknown	200 Mg/5 MI			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772210	NON-EXPEDITED			US-TEVA-532773USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Screen False Positive	Azithromycin			S		Frequency Not Provided			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772211	NON-EXPEDITED			US-TEVA-537823USA		6 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Product Quality Issue	Azithromycin			S	Unknown	200 Mg / 5ml			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772215	NON-EXPEDITED		OT	US-TEVA-537886USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Distension; Abdominal Pain; Abdominal Pain; Abdominal Pain; Abdominal Tenderness; Asthenia; Constipation; Nausea; Rectal	Azithromycin			S	Oral				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Haemorrhage; Screaming;
Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772216	NON-EXPEDITED			US-TEVA-538284USA		6 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash Erythematous	Azithromycin			S	Unknown				Not Reported
	Azithromycin			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772217	NON-EXPEDITED			US-TEVA-550207USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Taste Disorder	Azithromycin			S	Unknown	200 Mg/5ml			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772218	NON-EXPEDITED			US-TEVA-545539USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vision Blurred	Azithromycin			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772219	NON-EXPEDITED			US-TEVA-543281USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash	Azithromycin			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772220	NON-EXPEDITED			US-TEVA-550330USA		25 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Azithromycin			S	Unknown			Not Reported	
	Tylenol With Codeine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772221	NON-EXPEDITED			US-TEVA-555510USA		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772222	NON-EXPEDITED			US-TEVA-566428USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772223	NON-EXPEDITED			US-TEVA-549558USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772224	NON-EXPEDITED			US-TEVA-545542USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hiccups	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772225	NON-EXPEDITED		OT	US-TEVA-550926USA		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash Vesicular	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772226	NON-EXPEDITED			US-TEVA-553207USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Diarrhoea; Vomiting	Azithromycin			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772227	NON-EXPEDITED			US-TEVA-561994USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eczema; Rash	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772229	NON-EXPEDITED			US-TEVA-548210USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Substitution Issue; Regressive Behaviour	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772230	NON-EXPEDITED			US-TEVA-545888USA		62 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Muscular Weakness;	Azithromycin			S	Oral	250 Milligram Daily;			Not Reported

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

Vision Blurred		Azithromycin		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772231	NON-EXPEDITED			US-TEVA-549483USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Headache; Liquid Product Physical Issue; Pruritus; Rash	Azithromycin			S	Oral	200 Mg/5 MI Daily X 5 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772232	NON-EXPEDITED			US-TEVA-538886USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Fatigue; Fatigue	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772233	NON-EXPEDITED			US-TEVA-566817USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Taste Abnormal; Vomiting	Azithromycin			S		Product Strength Was Not Available		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772234	NON-EXPEDITED			US-TEVA-558681USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Somnolence; Somnolence	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772235	NON-EXPEDITED			US-TEVA-548704USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Taste Abnormal; Tongue Discomfort	Azithromycin			S	Oral	200mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772236	NON-EXPEDITED			US-TEVA-582409USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Oral Discomfort	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772237	NON-EXPEDITED			US-TEVA-559109USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper	Azithromycin			S	Unknown	Units And Frequency Not Provided		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772238	NON-EXPEDITED			US-TEVA-590160USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Reconstitution Quality Issue; Vomiting	Azithromycin			S		200 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772239	NON-EXPEDITED			US-TEVA-560389USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Urticaria		Azithromycin		S		Form Strength: 200/5		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772240	NON-EXPEDITED			US-TEVA-558940USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S	Unknown	Dose And Frequency Not Provided			Not Reported
	Lisinopril			S	Unknown	Dose And Frequency Not Provided			Ivax
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772241	NON-EXPEDITED			US-TEVA-563460USA		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue; Nausea	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772242	NON-EXPEDITED			US-TEVA-557609USA		8 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Headache; Pyrexia	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772243	NON-EXPEDITED			US-TEVA-555509USA		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S	Unknown				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772246	NON-EXPEDITED			US-TEVA-567920USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Taste Abnormal; Vomiting	Azithromycin			S		Product Strength Was Not Available		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772247	NON-EXPEDITED			US-TEVA-561299USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772248	NON-EXPEDITED			US-TEVA-556254USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysgeusia; Product Taste Abnormal	Azithromycin			S	Oral	200 Mg/5 MI 22.5 Package Size		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772249	NON-EXPEDITED			US-TEVA-555843USA		73 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Oral	400 Mg, Then 200 Mg For 3 Additional Days		Not Reported	
	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772250	NON-EXPEDITED			US-TEVA-569487USA		73 YR	Female	USA

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeding Disorder; Nausea	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772251	NON-EXPEDITED			US-TEVA-577227	USA		Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Oral Discomfort; Paraesthesia Oral; Taste Disorder	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772252	NON-EXPEDITED			US-TEVA-572256	USA	4 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Gastrointestinal Tract Mucosal Discolouration; Rash; Stomatitis	Azithromycin			S		5 MI Daily;		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772253	NON-EXPEDITED			US-TEVA-595691	USA		Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardiac Discomfort; Dizziness; Drug Ineffective; Pruritus; Rhinorrhoea	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772254	NON-EXPEDITED			US-TEVA-587091	USA		Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Drug Ineffective		Azithromycin		S		250 Milligram Daily;		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772255	NON-EXPEDITED			US-TEVA-579825USA			Male	IND
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772256	NON-EXPEDITED			US-TEVA-600118USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Product Formulation Issue; Product Taste Abnormal	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772257	NON-EXPEDITED			US-TEVA-571743USA		10 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Urticaria; Vomiting	Azithromycin			S		Frequency Not Provided			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772258	NON-EXPEDITED			US-TEVA-570903USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anosmia; Hypogeusia	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772259	NON-EXPEDITED			US-TEVA-568760USA			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Gastrointestinal Disorder; Nausea	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772261	NON-EXPEDITED			US-TEVA-576496USA		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772263	NON-EXPEDITED			US-TEVA-576195USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Dysgeusia; Parosmia; Product Formulation Issue; Product Substitution Issue	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772264	NON-EXPEDITED			US-TEVA-588340USA			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Product Reconstitution Quality Issue; Product Taste Abnormal	Azithromycin			S	Oral	200mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772265	NON-EXPEDITED			US-TEVA-575471USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Ageusia; Anosmia		Azithromycin		S	Unknown		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772266	NON-EXPEDITED			US-TEVA-587291USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Therapeutic Response Unexpected	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772267	NON-EXPEDITED			US-TEVA-567169USA		53 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Back Pain; Fatigue; Nausea	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772268	NON-EXPEDITED			US-TEVA-578048USA		54 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Rash	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772269	NON-EXPEDITED			US-TEVA-598744USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772273	NON-EXPEDITED			US-TEVA-570795USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Dysgeusia; Product Reconstitution Quality Issue; Vomiting		Azithromycin		S	Unknown	250/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772274	NON-EXPEDITED			US-TEVA-576110USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity; Rash; Viral Rash	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772275	NON-EXPEDITED			US-TEVA-599603USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Hypophagia; Pyrexia; Vomiting	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772276	NON-EXPEDITED			US-TEVA-579818USA		60 DAY	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash; Viral Rash	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Nov-2015	11772277	NON-EXPEDITED			US-TEVA-594038USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Taste Abnormal; Throat Irritation	Azithromycin			S	Oral	200mg/5ml			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772278	NON-EXPEDITED			US-TEVA-580117USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Malaise	Azithromycin Azithromycin			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772280	NON-EXPEDITED		OT	US-TEVA-588089USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Tinnitus	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11772281	NON-EXPEDITED			US-TEVA-591472USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11774286	EXPEDITED (15-DAY)		HO	US-JNJFOC-20151122293		3 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Stoma Complication	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Humira			C	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Chlorhexidine			C	Unknown			Not Reported	
	Ferrous Sulfate			C	Unknown			Not Reported	

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

	Folic Acid	C	Unknown	Not Reported
	Amoxicillin	C	Unknown	Not Reported
	Ondansetron	C	Unknown	Not Reported
	Nystatin	C	Unknown	Not Reported
	Clindamycin	C	Unknown	Not Reported
	Methotrexate	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2015	11777330	DIRECT	Y				43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin 250 Mg			S	Oral	2 Tabs Day 1, 1 Tab Daily		Not Reported	
	Metoprolol Succinate			C				Not Reported	
	Nasonex			C				Not Reported	
	Tylenol			C				Not Reported	
	Zyrtec			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	7623481	EXPEDITED (15-DAY)		DE, HO, LT	PHHO2010AU15115		28 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Acute	Everolimus			S	Oral	5 Mg, Daily		Novartis	
Kidney Injury; Alveolitis;	Everolimus			S	Oral	2.5 Mg, Unk		Novartis	
Anaphylactic Reaction;	Everolimus			S	Oral	5 Mg, Daily		Novartis	
Atrial Fibrillation;	Azacididine			S	Unknown	128 Mg, Unk		Not Reported	
Bronchiolitis; Cardiac	Azacididine			S	Unknown	128 Mg, Unk		Not Reported	
Arrest; Cardiac Failure;	Azacididine			S	Unknown	Unk		Not Reported	
Coagulopathy; Delirium;	Azithromycin			S	Unknown	Unk		Not Reported	
Depressed Level Of	Adriamycin			S	Unknown			Not Reported	
Consciousness; Dilatation	Cyclophosphamide			S	Unknown			Not Reported	
Atrial; Dyspnoea; Ejection	Idarubicin			S	Unknown			Not Reported	
Fraction Decreased; Fluid									
Overload; Hypotension;									
Left Ventricular Dilatation;									
Left Ventricular									

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

Dysfunction; Left	Vitamin K	C	Not Reported
Ventricular End-Diastolic	Ciclosporin	C	Not Reported
Pressure Increased; Left	Mtx	C	Not Reported
Ventricular Failure; Liver	Irradiation	C	Not Reported
Abscess; Liver Function	Palifermin	C	Not Reported
Test Abnormal; Liver	Atgam	C	Not Reported

Injury; Mitral Valve
Incompetence;
Mucormycosis; Multiple
Organ Dysfunction
Syndrome; Mycoplasma
Test Positive; Myocarditis
Bacterial; Necrotising
Gastritis; Neutropenia;
Oedema; Orthopnoea;
Pleural Effusion;
Pneumonia; Pyrexia;
Respiratory Distress;
Sepsis; Thrombosis;
Ventricular Hypokinesia;
Viral Infection; Weight
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11392636	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015270889		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Decreased Appetite; Drug Ineffective; Dysphonia; Dyspnoea; Pharyngeal Haemorrhage; Pyrexia; Retching; Throat Irritation; Weight Decreased	Azithromycin			S	Oral	500 Mg Day 1 And Then 250 Mg Once A Day For 4 Days		Pfizer
	Azithromycin			S	Oral	500 Mg Day 1 And Then 250 Mg Once A Day For 4 Days		Pfizer
	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11751095	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2015394310			Male	JPN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Nasopharyngitis; Pyrexia; Seizure; Wheezing	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
	Finasteride Pfizer			S		Unk, 1x/Day (After Breakfast)		Not Reported	
	Tranexamic Acid			S				Not Reported	
	Ibuprofen			S			Not Reported		
	Placode			S	Unk, 3x/Day After Every Meal		Not Reported		
	Biofermin			C	Taken After Every Meal		Not Reported		
	Coreminal			C		Taken After Every Meal		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11776353	EXPEDITED (15-DAY)		HO, LT	US-HOSPIRA-3089184		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Respiratory Failure	Cocaine			C	Sublingual			Not Reported	
	Tramadol			C				Not Reported	
	Suboxone			S				Not Reported	
	Lorazepam			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11777206	NON-EXPEDITED			US-PFIZER INC- 2015391297		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11778974	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2015405879		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Interaction; Epistaxis; Hypocoagulable State	Azithromycin	S	Oral	500 Mg, Daily	Pfizer
	Sintrom	S	Oral	1 Mg, As Needed	Not Reported
	Luvion /00252501/	C	Oral	50 Mg, Unk	Not Reported
	Folina /00024201/	C		Unk	Not Reported
	Ferro-Grad	C	Oral	105 Mg, Unk	Not Reported
	Spiriva	C	Nasal	1 Df, Unk	Not Reported
	Mirapexin	C		Unk	Not Reported
	Trittico	C		Unk	Not Reported
	Bisoprolol Hemifumarate	C	Oral	2.5 Mg, Unk	Not Reported
	Cetirizine	C	Oral	10 Mg, Unk	Not Reported
	Allopurinol	C	Oral	300 Mg, Unk	Not Reported
	Repaglinide	C	Oral	1.5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11779408	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2015402632		49 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cellulitis; Drug Ineffective For Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer
	Toprec			S	Oral	Unk		Not Reported
	Flagyl /00012501/			S	Oral	Unk		Not Reported
	Klipal /00116401/			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11784988	DIRECT		OT			7 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Nausea; Product Complaint; Product Taste Abnormal; Tremor; Vomiting	Azithromycin 200mg Teva			S	Oral	5 MI Day One And 2.5 Day 2 - 5		Teva

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2015	11785099	DIRECT		DE			64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Cardiomegaly; Chest Pain; Circulatory Collapse; Diarrhoea; Fatigue; Hepatic Fibrosis; Hepatic Steatosis; Hyperhidrosis; Movement Disorder; Nausea; Pneumonia; Pulmonary Oedema; Sudden Death; Thirst; Ventricular Hypertrophy; Vomiting	Azithromycin 250mg Dose Pack Pfizer			S	Oral	2 Pills Day 1, 1 Pill Days 2-5		Pfizer	
	Eye Glasses Frame (Metal)			C				Not Reported	
	Canagliflozin			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Clonazepam			C				Not Reported	
	Aspirin			C				Not Reported	
	Fluvoxamine			C				Not Reported	
	Gabapentin			C				Not Reported	
	Glipizide			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Metformin			C				Not Reported	
	Mirtazapine			C				Not Reported	
	Topiramate			C				Not Reported	
	Azithromycine			C				Not Reported	
	Hydrocodone			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Diovan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11771077	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03419		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780714	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2015-02719		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Chills; Chills; Dry Throat; Nausea		Azithromycin		S	Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780720	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2015-02808		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Azithromycin			S	Unknown	1 Gram		Not Reported	
	Azithromycin			S	Unknown	500 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780721	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03418		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780726	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03721		8 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780728	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03720		1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780729	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03722		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780730	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03723		19 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780731	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03724		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780734	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03726		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
	Trimethoprim/Sulfamethoxazole			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780739	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS		45 YR	Male	USA

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

INC.-2015-03727

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780740	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03725		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780741	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03728		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780743	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03729		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Trimethoprim			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780744	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03730		54 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780748	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03731		60 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780749	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03732		60 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown				Not Reported
	Repaglinide			C	Unknown				Not Reported
	Hydrochlorothiazide/Triamterene			C	Unknown				Not Reported
	Insulin			C	Unknown				Not Reported
	Esomeprazole			C	Unknown				Not Reported
	Metoprolol			C	Unknown				Not Reported
	Acetaminophen			C	Unknown	<2.5 G/Day			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Nov-2015	11780751	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-03733		65 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Drug-Induced Liver Injury	Azithromycin	S	Unknown	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2015	11780832	NON-EXPEDITED		DE	US-LUPIN PHARMACEUTICALS INC.-2015-03734		76 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2015	11782431	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA- 2015SF19037			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Disease Progression; Insomnia	Faslodex			S	Intramuscular			Astrazeneca
	Ibrance			S	Oral			Not Reported
	Ibrance			S	Oral			Not Reported
	Zithromax			S	Unknown	250 Mg, As Directed		Not Reported
	Xanax			S	Oral			Not Reported
	Zometa			C				Not Reported
	Zoladex			C				Not Reported
	Xgeva			C				Not Reported
	Caltrate			C				Not Reported
	Compazine			C				Not Reported
	Letrozole			C				Not Reported
	Venlafaxine			C				Not Reported
	Vitamin B Complex			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2015	11783860	EXPEDITED (15-DAY)		OT	US-BAXTER- 2015BAX061338		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During	Ceftriaxone Injection, Usp (In			S	Intravenous (not			Baxter

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

Pregnancy; Hypotension; Premature Rupture Of Membranes; Pulmonary Oedema; Secretion Discharge; Tachycardia	Dextrose) Vancomycin Injection, Usp Azithromycin Azithromycin Oseltamivir Prednisone Albuterol	S S S C C	otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown	Baxter Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11727492	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015374464		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Flutter; Chest Pain; Drug Ineffective; Drug Interaction; Heart Rate Increased; Palpitations	Advil			S		Three Tablets, Six Hours Apart		Pfizer	
	Advil			S		Took Six For The Day		Pfizer	
	Advil			S		Had Five Tablets		Pfizer	
	Advil			S		Had Two		Pfizer	
	Doxycycline			S		100 Mg, One In Morning And One In Afternoon With Food		Not Reported	
	Augmentin			S		125 Mg, 2x/Day		Not Reported	
	Azithromycin			S		250 Mg 2 First Day, Unk		Not Reported	
	Azithromycin			S		250 Mg (1 For Remaining 3 Days), Unk		Not Reported	
	Zyrtec			S		10 Mg, One A Day		Not Reported	
	Turmeric Root			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11784757	EXPEDITED (15-DAY)		OT	US-JNJFOC- 20151117055		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Cardiac Flutter; Heart Rate Increased; Pain; Product Packaging Issue; Pulse Absent	Zyrtec 10mg Ir Tablet	Y	S	Oral		Not Reported
	Zyrtec 10mg Ir Tablet		S	Oral		Not Reported
	Advil		S	Unknown	Five Tablets	Not Reported
	Advil		S	Unknown	Six For The Day	Not Reported
	Advil		S	Unknown	Three Tablets Six Hours Apart	Not Reported
	Advil		S	Unknown	Two Tablets	Not Reported
	Advil		S	Unknown	Three Tablets Six Hours Apart	Not Reported
	Advil		S	Unknown	Six For The Day	Not Reported
	Advil		S	Unknown	Two Tablets	Not Reported
	Advil		S	Unknown	Five Tablets	Not Reported
	Doxycycline		S	Unknown	One In Morning And One In Afternoon With Food	Not Reported
	Zithromax Z-Pack		S	Unknown		Not Reported
	Zithromax Z-Pack		S	Unknown	For 4 Days	Not Reported
	Augmentin		C	Unknown	6 Days	Not Reported
	Turmeric		C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11785219	NON-EXPEDITED			US-PFIZER INC-2015374400		53 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Protonix			S		Unk		Pfizer
	Naproxen			S		Unk		Not Reported
	Zpack			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Zestril			S		Unk		Not Reported
	Ultracet			S		Unk		Not Reported

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

Talwin	S	Unk	Not Reported
Codeine	S	Unk	Not Reported
Fish Oil	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11785869	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1040883			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Urea Increased; Toxic Epidermal Necrosis	Azithromycin			S	Oral	Unk Unk, Qd		Not Reported
	Allopurinol			S	Oral	Unk Unk, Qd		Not Reported
	Urorec			C	Oral	Unk		Not Reported
	Karvezide			C	Oral	Unk		Not Reported
	Pariet			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11787372	EXPEDITED (15-DAY)		OT	US-TEVA-612392USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Juvenile Idiopathic Arthritis; Product Use In Unapproved Indication	Azithromycin			S				Not Reported
	Clarinet			C				Not Reported
	Magnesium			C				Not Reported
	Nucynta			C				Not Reported
	Buprenorphine			C				Not Reported
	Advil			C				Not Reported
	Allegra			C				Not Reported
	Caffeine			C				Not Reported
	B-Complex			C				Not Reported
	Ginseng			C				Not Reported
	Bilberry			C				Not Reported
	Cranberry			C				Not Reported
	Vitamin D3			C				Not Reported
	Calcium W/Magnesium			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2015	11789923	DIRECT					42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Swollen Tongue; Throat Tightness	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2015	11788407	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/15/0054247		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Antinuclear Antibody Positive; Drug-Induced Liver Injury; Toxic Epidermal Necrolysis	Ibuprofen			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2015	11788492	EXPEDITED (15-DAY)		OT	CH-009507513-1511CHE015113		37 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome	Noxafil			S	Oral	300 Mg, Qd		Merck	
	Quetiapine Fumarate			S	Oral	25 Mg, Qd		Not Reported	
	Zithromax			S	Oral	500 Mg, Qd		Not Reported	
	Tavanic			S	Oral	500 Mg, Qd		Not Reported	
	Zyprexa			S	Oral	5 Mg, Qd		Not Reported	
	Prograf			S	Intravenous (not otherwise specified)	0.5 Mg, Qd		Not Reported	
	Lasix (Furosemide)			C		20 Mg, Qd		Not Reported	
	Beloc (Metoprolol Succinate)			C		25 Mg, Qd		Not Reported	
	Beloc [Metoprolol Tartrate]			C		25 Mg, Qd		Not Reported	
	Nexium			C		40 Mg, Qd		Not Reported	

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

Prednisone	C	40 Mg, Qd	Merck
Valtrex	C	500 Mg, Qd	Not Reported
Rituximab	C	Unk	Not Reported
Rituximab	C	Unk	Not Reported
Rituximab	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2015	11789172	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201506128		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Potentiating Drug Interaction; Respiratory Failure	Azithromycin (Manufacturer Unknown)			S	Oral			Fresenius Medical Care	
	Lorazepam (Manufacturer Unknown)			S	Unknown			Not Reported	
	Suboxone			S	Sublingual			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2015	11793856	DIRECT		OT			56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Lung Disorder; Pulmonary Mass	Zithromax			S			5 DAY	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11129319	NON-EXPEDITED			US-PFIZER INC-2015168914			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cefepime Hcl			S		Unk		Not Reported	
	Vancomycin			S		Unk		Unknown	
	Zosyn			S		Unk		Pfizer	
	Oseltamivir			S		Unk		Not Reported	

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

	Restoril		S		Unk		Not Reported		
	Pegaspargase		S		Unk		Not Reported		
	Zofran		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11267564	NON-EXPEDITED			GXBR2015US001572			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Recurrence; Dysphonia; Productive Cough; Sneezing; Throat Irritation	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	
	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	
	Azithromycin 250 Mg			S				Novartis	
	Azithromycin 250 Mg			S				Novartis	
	Azithromycin 250 Mg			S				Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11285336	NON-EXPEDITED			GXBR2015US001601		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Skin Reaction	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11383303	NON-EXPEDITED		LT, OT	GXBR2015US000746		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Azithromycin 250 Mg			S	Unknown	500 Mg, Once/Single		Novartis	
Anal Incontinence;	Tylenol			C	Unknown	1 Df, Prn At Bedtime		Not Reported	
Anaphylactic Shock;	Ibuprofen			C	Unknown	1 Df, Prn At Bedtime		Not Reported	
Dizziness; Dyspepsia;									
Headache; Hyperhidrosis;									
Loss Of Consciousness;									
Pain									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11413131	NON-EXPEDITED			GXBR2015US001743			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Expired Product Administered	Azithromycin 250 Mg			S	Unknown	Unk Df, Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11684547	NON-EXPEDITED			GXBR2015US002187			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fatigue; Hypersensitivity; Nausea	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11686729	NON-EXPEDITED			GXBR2015US002192			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper	Azithromycin 250 Mg			S	Oral	250 Mg, Once2sdo		Novartis	
	Azithromycin 250 Mg			S	Oral	250 Mg, Qd		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11793050	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-10839		43 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Drug-Induced Liver Injury	Azithromycin			S	Unknown			Aurobindo	
	Trimethoprim+Sulfamethoxazole			S	Unknown			Aurobindo	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11793394	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-11181		1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Drug-Induced Liver Injury; Liver Injury	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11793406	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2015-11192		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Drug-Induced Liver Injury; Jaundice; Multiple Organ Dysfunction Syndrome; Nausea	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11794098	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-11186		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Drug-Induced Liver Injury	Azithromycin			S	Unknown			Aurobindo	
	Trimethoprim+Sulfamethoxazole			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11794406	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2015-11183		11 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Bilirubin Increased; Drug-Induced Liver Injury; Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795648	NON-EXPEDITED			GXBR2015US000586		37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin 250 Mg			S	Oral	500 Mg, Day One		Novartis	
	Azithromycin 250 Mg			S	Oral	250 Mg, Qd For Four Days		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795649	NON-EXPEDITED			GXBR2015US000933			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Burning Sensation; Head Discomfort; Insomnia; Joint Lock; Joint Noise; Limb Discomfort; Muscle Tightness; Neuralgia; Paraesthesia; Reaction To Excipient; Superficial Vein Prominence	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795651	NON-EXPEDITED			GXBR2014US002545			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Rash Erythematous		Azithromycin 250 Mg		S	Unknown	250 Mg, Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11795652	NON-EXPEDITED			GXBR2015US000560			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Chest Pain; Ear Pain; Headache; Insomnia; Myalgia; Palpitations; Throat Irritation	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11795654	NON-EXPEDITED			GXBR2014US002609		43 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cough; Dyspnoea; Headache; Lacrimation Increased; Laryngospasm; Nausea; Pruritus; Rhinorrhoea	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11795655	NON-EXPEDITED		OT	GXBR2015US000584			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea; Hypersensitivity	Azithromycin 250 Mg			S	Oral	500mg Qdx1 Day, 250mg Qd X4 Days		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Dec-2015	11795656	NON-EXPEDITED			GXBR2014US002415		71 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Blood Glucose Increased	Azithromycin 250 Mg	S	Oral	250 Mg, Once2sdo	Novartis
	Azithromycin 250 Mg	S	Oral	250 Mg, Qd	Novartis
	Azithromycin 250 Mg	S			Novartis
	Novolog Mix	C		Unk Df, Unk	Not Reported
	Atorvastatin	C		80 Mg, Qhs	Not Reported
	Vagifem	C		Unk Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795665	NON-EXPEDITED			GXBR2015US001082			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Nervousness; Tic	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	
	Azithromycin 250 Mg			S				Novartis	
	Azithromycin 250 Mg			S				Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795666	NON-EXPEDITED			GXBR2015US001405			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795667	NON-EXPEDITED			GXBR2015US000585		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin 250 Mg			S	Oral	500 Mg, Day One		Novartis	
	Azithromycin 250 Mg			S	Oral	250 Mg, Qd For Four Days		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11795786	NON-EXPEDITED			GXBR2015US000973			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Activity; Drug Ineffective; Dysstasia; Malaise; Pain; Product Quality Issue	Azithromycin 600 Mg			S	Oral	600 Mg, Bid		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2015	11798026	DIRECT		OT			16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Anger; Intentional Self-Injury	Azithromycin			S	Oral	2 First Day 1 For 4 Days Follow, 2 1 Day 1 Day Flw		Greenstone	
	Keppra			C				Not Reported	
	Birth Control			C				Not Reported	
	B Complex			C				Not Reported	
	Magnesium			C				Not Reported	
	Multivitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	10585522	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2014M1010233			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disseminated Intravascular Coagulation; Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Promethazine			C	Unknown			Not Reported	
	Dextromethorphan			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	11796339	NON-EXPEDITED			US-PFIZER INC-2015398732			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	11796428	EXPEDITED (15-DAY)		HO	NL-MYLANLABS-2015M1041165			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S		500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	11797288	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015413178		19 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Tazocilline			S		Unk		Pfizer	
	Tazocilline			S	Intravenous (not otherwise specified)	1 Df, 3x/Day		Pfizer	
	Vancomycine			S		Unk		Pfizer	
	Vancomycine			S	Intravenous (not otherwise specified)	1 G, 2x/Day		Pfizer	
	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Gentamicin			S	Intravenous (not otherwise specified)	240 Mg, 1x/Day		Not Reported	
	Alprazolam			C	Oral	0.5 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	11797326	EXPEDITED (15-DAY)		LT, OT	GB-PFIZER INC-2015415374		72 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Flushing; Pruritus; Rash Macular	Azithromycin			S	Oral	250 Mg 3x/Week		Pfizer	
	Aspirin			C		Unk		Not Reported	
	Amitriptyline			C		Unk		Not Reported	
	Prednisolone			C		Unk		Not Reported	
	Rituximab			C		Unk		Not Reported	

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

	Co-Trimoxazole			C		Unk			Not Reported
	Lansoprazole			C		Unk			Not Reported
	Bisoprolol			C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	11797910	EXPEDITED (15-DAY)		OT	US-TEVA-614511USA		8 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Pain Upper; Coeliac Disease; Cough; Diarrhoea	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2015	11798089	NON-EXPEDITED			US-PFIZER INC- 2015394991			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Oropharyngeal Pain; Stomatitis	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2015	11779447	EXPEDITED (15-DAY)		OT	US-APOTEX- 2015AP014819			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Azithromycin			S	Unknown	Unk			Apotex
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2015	11800574	EXPEDITED (15-DAY)		OT	CH-ASTRAZENECA- 2015SF19303		37 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome	Quetiapine			S	Oral				Not Reported

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

Zithromax	S	Oral	Not Reported
Tavanic	S	Oral	Not Reported
Zyprexa	S	Oral	Not Reported
Noxafil	S	Oral	Not Reported
Prograf	S	Intravenous drip	Not Reported
Lasix	C		Not Reported
Beloc-Zok	C	Oral	Not Reported
Nexium	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Valtrex	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2015	11801076	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2015-03859		44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Not Reported
	Promethazine Hydrochloride			C	Unknown			Not Reported
	Dextromethorphan Hydrobromide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2015	11801096	EXPEDITED (15-DAY)		HO, LT	US-LUPIN PHARMACEUTICALS INC.-2015-03906		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Respiratory Failure	Azithromycin			S	Oral			Not Reported
	Lorazepam			S	Unknown			Not Reported
	Suboxone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2015	11805229	EXPEDITED (15-DAY)		HO	IT-MYLANLABS- 2015M1042203			Unknown	ITA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epistaxis; Hypocoagulable State; Labelled Drug-Drug Interaction Medication Error	Azitromicina			S	Oral	500 Mg, Qd		Mylan	
	Sintrom			S	Oral	1 Mg, Prn		Not Reported	
	Luvion /00839101/			C	Oral	50 Mg, Unk		Not Reported	
	Folina /00024201/			C				Not Reported	
	Ferro-Grad			C	Oral	1 Df, Unk		Not Reported	
	Spiriva			C		1 Df, Unk		Not Reported	
	Trittico			C				Not Reported	
	Mirapexin			C				Not Reported	
	Bisoprolol Hemifumarate			C	Oral	2.5 Mg, Unk		Not Reported	
	Cetirizine			C	Oral	10 Mg, Unk		Not Reported	
	Allopurinol			C	Oral	300 Mg, Unk		Not Reported	
Repaglinide			C	Oral	1.5 Mg, Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2015	11806639	NON-EXPEDITED			US-PFIZER INC-2015419617			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2015	11806643	NON-EXPEDITED			US-PFIZER INC-2015427762		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Diclofenac Epolamine			S		Unk		Unknown	
	Cymbalta			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	

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

	Reglan		S		Unk			Not Reported	
	Toradol		S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2015	11807288	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015422246			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Chest Pain; Hypersensitivity; Myocardial Infarction	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2015	11807787	EXPEDITED (15-DAY)		HO	IT-TEVA-613078ACC		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Epistaxis; Hypocoagulable State	Azithromycin			S	Oral	500 Milligram Daily; 500 Mg Daily		Not Reported	
	Sintrom - 1 Mg Compresse - Novartis Farma S.P.A.			S	Oral	1 Mg As Necessary		Not Reported	
	Luvion - 50 Mg Compresse			C	Oral	50 Mg		Not Reported	
	Folina - 5 Mg Capsule Molli			C				Not Reported	
	Ferro-Grad - 105 Mg Compresse			C	Oral	1 Df		Not Reported	
	A Rilascio Prolungato								
	Spiriva Respimat - 2.5 Mcg			C		1 Df		Not Reported	
	Soluzione Per Inalazione								
	Trittico - 60 Mg/MI Gocce Orali			C				Not Reported	
	Soluzione								
	Mirapexin			C				Not Reported	
	Bisoprolol Hemifumarate			C	Oral	2.5 Mg		Not Reported	
	Cetirizine			C	Oral	10 Mg		Not Reported	
	Allopurinol			C	Oral	300 Mg		Not Reported	
	Repaglinide			C	Oral	1.5 Mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2015	11807990	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015422889			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Interval Abnormal	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2015	11620648	NON-EXPEDITED			US-PFIZER INC-2015330730			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Codeine Phosphate			S		Unk		Not Reported	
	Zocor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2015	11779451	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2015AP014822		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Pneumonia; Respiratory Failure	Azithromycin			S	Oral			Apotex	
	Suboxone			S	Sublingual			Not Reported	
	Suboxone			S				Not Reported	
	Lorazepam			S	Sublingual			Not Reported	
	Macrolides			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2015	11810010	EXPEDITED (15-DAY)		OT	JP-SA-2015SA199052		74 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Pollakiuria; Urinary Retention; Urine Flow Decreased	Allegra	S	Oral	Not Reported
	Zithromac	S	Oral	Not Reported
	Zithromac	S	Oral	Not Reported
	Tamsulosin	C	Oral	Not Reported
	Avolve	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11812261	EXPEDITED (15-DAY)		LT, OT	PHHY2015GB156774		72 YR	Female	GBR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eosinophilia; Flushing; Pruritus; Rash Macular	Azithromycin			S	Oral	250 Mg,Qw3		Novartis
	Aspirin			C	Unknown			Not Reported
	Amitriptyline			C	Unknown			Not Reported
	Prednisolone			C	Unknown			Not Reported
	Rituximab			C	Unknown			Not Reported
	Co-Trimoxazole /Unk/			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported
	Bisoprolol			C	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2015	11812605	EXPEDITED (15-DAY)		OT	BR-MYLANLABS-2015M1043340			Unknown	BRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Azithromycin			S		500 Mg, Qd		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Dec-2015	11813241	NON-EXPEDITED			US-HOSPIRA-2867545		93 YR	Female	USA

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

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

Erythema; Infusion Site Pain; Infusion Site Rash; Peripheral Swelling; Poor Quality Product	Sodium Chloride	S	Intravenous drip		Not Reported
Administered; Product Colour Issue	Azithromycin	S	Intravenous drip	Daily	Not Reported
	Warfarin	C	Oral	Variable Dose, Daily	Not Reported
	Norvasc	C	Oral	Daily	Not Reported
	Losartan	C	Oral	Daily	Not Reported
	Imdur	C	Oral	Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2015	11813252	NON-EXPEDITED			US-HOSPIRA-2867539		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Erythema; Infusion Site Pain; Injection Site Pruritus; Poor Quality Product	Sodium Chloride			S	Intravenous drip			Not Reported
Administered; Product Colour Issue; Rash Macular	Azithromycin			S	Intravenous drip	Daily		Not Reported
	Oxycodone			C	Oral			Not Reported
	Nexium /01479302/			C	Oral	Hs		Not Reported
	Bactrim			C	Oral	0.5 Unit Not Provided		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2015	11814181	EXPEDITED (15-DAY)		LT, OT	GB-TEVA-613562ACC		72 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia; Flushing; Pruritus; Rash Macular	Azithromycin			S	Oral			Not Reported
	Aspirin			C				Not Reported
	Amitriptyline			C				Not Reported
	Prednisolone			C				Not Reported
	Rituximab			C				Not Reported
	Co-Trimoxazole			C				Not Reported
	Lansoprazole			C				Not Reported
	Bisoprolol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2015	11816371	EXPEDITED (15-DAY)		LT, OT	GB-MYLANLABS-2015M1042699			Unknown	GBR

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia; Flushing; Pruritus; Rash Macular	Azithromycin			S	Oral	250 Mg, 3xw		Not Reported
	Aspirin /00002701/			C		Unk		Not Reported
	Amitriptyline			C		Unk		Not Reported
	Prednisolone			C		Unk		Not Reported
	Rituximab			C		Unk		Not Reported
	Co-Trimoxazole			C		Unk		Not Reported
	Lansoprazole			C		Unk		Not Reported
	Bisoprolol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2015	11818897	DIRECT		LT			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Asthenia; Blood Pressure Increased; Nausea; Paraesthesia	Azithromycin			S	Oral	3 Pills		Greenstone
	Levothyroxin			C				Not Reported
	Vitamin D3			C				Not Reported
	Ranitidine			C				Not Reported
	Vitamin A			C				Not Reported
	Vitamin B6			C				Not Reported
	Vitamin Womens 50+ Multi			C				Not Reported
	Vitamin B12			C				Not Reported
	Glucosamine Maximum Strength			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2015	11793759	EXPEDITED (15-DAY)		HO, OT	PHHY2015IT153401		73 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Epistaxis; Hypocoagulable State; International Normalised Ratio Increased	Sintrom			S	Oral	1 Mg, Prn (As Needed)		Not Reported
	Sintrom			S	Oral	1 Mg, Bid (Scheme 0 Mg- 1 Mg-0 Mg-1 Mg)		Not Reported
	Azitromicina			S	Oral	500 Mg, Qd		Novartis

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

	Bisoprolol	C	Oral	2.5 Mg, Unk	Not Reported
	Cetirizine	C	Oral	10 Mg, Unk	Not Reported
	Allopurinol	C	Oral	300 Mg, Unk	Not Reported
	Repaglinide	C	Oral	1.5 Mg, Unk	Not Reported
	Luvion (Canrenone)	C	Oral	50 Mg, Unk	Not Reported
	Folina [Folic Acid]	C	Oral		Not Reported
	Ferro-Grad	C	Oral	1 Df, Unk	Not Reported
	Spiriva	C	Respiratory (inhalation)	1 Df, Unk	Not Reported
	Trittico	C	Unknown		Not Reported
	Mirapexin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2015	11821444	NON-EXPEDITED		OT	US-PFIZER INC-2015427467			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cyclic			S		Unk		Not Reported
	Cialis			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2015	11822568	EXPEDITED (15-DAY)		OT	CH-ASTELLAS-2015JP024305		37 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Long Qt Syndrome	Quetiapine			S	Oral			Not Reported
	Tacrolimus			S	Intravenous drip	0.5 Mg, Once Daily		Astellas
	Zithromax			S	Oral			Not Reported
	Tavanic			S	Oral			Not Reported
	Zyprexa			S	Oral			Not Reported
	Noxafil			S	Oral			Not Reported

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

Lasix /00032601/	C	Unknown	Not Reported
Metoprolol Succinate	C	Oral	Not Reported
Nexium /01479302/	C	Oral	Not Reported
Prednisone	C	Oral	Not Reported
Valtrex	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2015	11823601	NON-EXPEDITED			US-PFIZER INC-2015436449			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Tamiflu			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2015	11650205	NON-EXPEDITED			US-PFIZER INC-2015348084		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder; Nausea	Azithromycin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2015	11654647	NON-EXPEDITED			US-PFIZER INC-2015348779		69 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Pruritus; Rash	Zithromax			S	Oral	Unk		Pfizer
	Dexilant			S	Oral	60 Mg, 1x/Day		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2015	11749223	EXPEDITED (15-DAY)		OT	US-TEVA-608651USA		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Flutter; Chest Pain; Drug Ineffective; Drug Interaction; Heart Rate Increased; Neck Pain; Pain; Palpitations; Sinus Congestion; Sinus Headache; Tooth Disorder	Azithromycin			S	Unknown	250 Mg 2 First Day And 1 For Remaining 4 Days		Not Reported	
	Advil			S	Unknown	On 01nov2015 Had 5 Tablets For The Entire Day		Not Reported	
	Doxycycline			S	Unknown	200 Milligram Daily;		Not Reported	
	Zyrtec			S	Unknown			Not Reported	
	Augmentin			S	Unknown	250 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2015	11826333	NON-EXPEDITED			US-PFIZER INC-2015406960			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2015	11826337	NON-EXPEDITED			US-PFIZER INC-2015403578		5 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Oedema; Reaction To Excipient; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2015	11828146	NON-EXPEDITED			US-PFIZER INC-2015405191			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Lisinopril	S		Not Reported
	Naproxen	S	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11828148	NON-EXPEDITED			US-PFIZER INC-2015407637			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Incorrect Route Of Product Administration; Injection Site Erythema; Injection Site Infection; Injection Site Swelling	Zithromax			S	Intramuscular	Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2015	11831723	DIRECT		HO			35 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholelithiasis; Drug-Induced Liver Injury; Hepatic Cirrhosis; Hepatic Encephalopathy; Hepatic Fibrosis; Steatohepatitis; Varices Oesophageal; Vascular Pseudoaneurysm	Azithromycin			S			4 DAY	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2015	11835896	DIRECT	Y	HO			37 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption; Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema Multiforme	Azithromycin			S				Not Reported
	Cephalexin			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11816254	NON-EXPEDITED			US-AMGEN- USASL2015130172		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Body Temperature Abnormal; Chills; Conjunctivitis; Contusion; Decreased Appetite; Feeling Hot; Injection Site Pain; Malaise; Nausea; Viral Upper Respiratory Tract Infection	Enbrel			S	Unknown	Unk		Amgen	
	Enbrel			S				Amgen	
	Enbrel			S				Amgen	
	Z-Pack			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11824325	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2015M1043459			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diabetes Mellitus; Hypertensive Crisis; Liver Disorder	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
	Deflan			S	Oral	1 Df, Qd		Mylan	
	Torvast			C	Oral	20 Mg, Unk		Mylan	
	Triatec /00885601/			C	Oral	5 Mg, Unk		Mylan	
	Norvasc			C	Oral	5 Mg, Unk		Mylan	
	Cardura			C	Oral	1 Df, Unk		Mylan	
	Cardioaspirin			C		100 Mg, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11837040	EXPEDITED (15-DAY)		OT	PHHY2015BR161159		18 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S		500 Mg, Qd		Novartis	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2015	11837281	NON-EXPEDITED			US-PFIZER INC-2015441934			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax Lisinopril			S S		Unk		Pfizer Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2015	11841300	EXPEDITED (15-DAY)		OT	BR-PFIZER INC-2015411058			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Disease Recurrence; Drug Ineffective; Feeling Abnormal; Nausea; Off Label Use; Tuberculosis	Zitromax Zitromax			S S	Oral	500 Mg, 1x/Day		Pfizer Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2015	11844799	DIRECT	Y	HO			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Failure Congestive; Pulmonary Oedema	Zithromax Z-Pack			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	10875072	EXPEDITED (15-DAY)		OT	US-JAZZ-2015-US-002766			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bronchitis; Rash	Xyrem Xyrem Xyrem			S S S	Oral Oral Oral	2.5 G, Bid 3.5 G, Bid 4.5 G, Bid		Jazz Jazz Jazz	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

		Tessalon		S					Not Reported
		Zithromax		S					Not Reported
		Amoxicillin		S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	11844223	EXPEDITED (15-DAY)		HO	US-FRESENIUS KABI-FK201506599		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Tubular Necrosis; Tubulointerstitial Nephritis	Azithromycin (Manufacturer Unknown)			S	Oral			Fresenius Medical Care	
	Azithromycin (Manufacturer Unknown)			S	Oral			Fresenius Medical Care	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	11845232	NON-EXPEDITED			US-PFIZER INC-2015419913			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	11845234	NON-EXPEDITED			US-PFIZER INC-2015419397			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
	Fentanyl			S		Unk		Not Reported	
	Scopolamine			S		Unk		Not Reported	
	Requip			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	11845261	NON-EXPEDITED			US-PFIZER INC-2015412110			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Dilaudid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	11847306	NON-EXPEDITED			US-ROCHE-307737		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Dyspepsia; Headache; Nausea	Tamiflu			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2015	11848123	NON-EXPEDITED			US-PFIZER INC- 2015419952		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2015	11849716	EXPEDITED (15-DAY)		OT	US-APOTEX- 2015AP015258			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2015	11852485	NON-EXPEDITED			US-PFIZER INC- 2015453590			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

	Levaquin		S		Unk			Not Reported	
	Biaxin		S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2015	11852574	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK175565			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Advair			S	Unknown	Unk Unk, U		Glaxosmithkline	
	Azithromycine Capsule			S	Unknown	Unk, U		Glaxosmithkline	
	Clindamycine Cutaneous Solution			S	Unknown	Unk, U		Glaxosmithkline	
	Feldene			S	Unknown	Unk, U		Glaxosmithkline	
	Indocin			S	Unknown	Unk, U		Glaxosmithkline	
	Flexeril			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11669115	NON-EXPEDITED			US-PFIZER INC-2015359739		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Product Administration Duration; Vision Blurred; Visual Impairment	Zithromax			S		500 Mg, 1x/Day On Day 1		Pfizer	
	Zithromax			S		250 Mg, 1x/Day (Days 2 - 5)		Pfizer	
	Aspirin			C		Unk, Daily		Not Reported	
	Synthroid			C		88 Ug, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11856268	EXPEDITED (15-DAY)		HO	JP-AKRON, INC.-1045720		95 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Pyrexia; Urinary Tract Infection	Azasite			S	Ophthalmic			Akorn	
	Exforge			C				Not Reported	

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

Amlodipine	C	Not Reported
Protecadin	C	Not Reported
Zetia	C	Not Reported
Nifedipine	C	Not Reported
Ferromia	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11856330	EXPEDITED (15-DAY)		HO, OT	JP-AKRON, INC.- 1045722		48 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Creatine Phosphokinase Increased; Blood Lactate Dehydrogenase Increased; Contusion; Keratitis; Schizophrenia	Azasite® (Azithromycin Ophthalmic Solution)			S	Ophthalmic			Akorn	
	Depakene-R (Sodium Valproate)			C				Not Reported	
	Serenace (Haloperidol)			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11857182	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2015AP015326		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Tubular Necrosis; Tubulointerstitial Nephritis	Azithromycin			S	Oral	500 Mg On Day 1		Apotex	
	Azithromycin			S	Oral	250 Mg/Day For 4 Days		Apotex	
	Aspirin /00002701/			C	Oral	81mg/Day		Not Reported	
	Atorvastatin			C	Oral	20mg/Day		Not Reported	
	Ezetimibe			C	Oral	10mg/Day		Not Reported	
	Insulin Glargine			C	Subcutaneous	40units/Day		Not Reported	
	Insulin Aspart			C	Subcutaneous	According To A Sliding Scale		Not Reported	
	Irbesartan			C	Oral	75mg/Day		Not Reported	
	Metoprolol Succinate			C	Oral	50mg/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11857199	NON-EXPEDITED			US-PFIZER INC-2015422191			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11857246	NON-EXPEDITED			US-PFIZER INC-2015422658			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11857295	NON-EXPEDITED			US-PFIZER INC-2015453275			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Amlodipine Besilate			S		Unk		Pfizer	
	Metformin			S		Unk		Not Reported	
	Simvastatin			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	
	Erythromycin Base			S		Unk		Not Reported	
	Influenza Vaccine			S		Unk		Not Reported	
	Moxifloxacin			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
	Welchol			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2015	11857347	NON-EXPEDITED			US-PFIZER INC-2015422613			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sinusitis	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2015	11856830	EXPEDITED (15-DAY)		DE, OT	FR-009507513-1512FRA008761		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Noxafil			S	Oral	Unk		Merck	
	Candidas			S		Unk		Merck	
	Oracilline (Penicillin V Benzathine)			S		Unk		Not Reported	
	Oracilline (Penicillin V Benzathine)			S		Unk		Not Reported	
	Ciloxan			S	Ophthalmic	Unk		Not Reported	
	Azyter			S	Ophthalmic	Unk		Not Reported	
	Ramipril			S	Oral	Unk		Not Reported	
	Amlodipine			S	Oral	Unk		Not Reported	
	Eupressyl			S		Unk		Not Reported	
	Furosemide			S		Unk		Not Reported	
	Furosemide			S		Unk		Not Reported	
	Vancomycin			C		Unk		Not Reported	
	Vancomycin			C		Unk		Not Reported	
	Ganciclovir			C		Unk		Not Reported	
	Nefopam			C		Unk		Not Reported	
	Nefopam			C		Unk		Not Reported	
	Nefopam			C		Unk		Not Reported	
	Nefopam			C		Unk		Not Reported	

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

Nefopam	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Morphine	C	Unk	Not Reported
Dexamethasone	C	Unk	Merck
Insulin	C	Unk	Not Reported
Alfuzosin Hydrochloride	C	Unk	Not Reported
Valacyclovir Hydrochloride	C	Unk	Not Reported
Prednisone	C	Unk	Merck
Acetaminophen	C	Unk	Not Reported
Clairyg	C	Unk	Not Reported
Rimexolone	C	Unk	Not Reported
Acyclovir	C	Unk	Not Reported
Entecavir	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2015	11858528	EXPEDITED (15-DAY)		HO, OT	CH-009507513-1512CHE009151		75 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Chromaturia; Chromaturia; Decreased Appetite; Drug Interaction; Fatigue; Myalgia; Prescribed Overdose; Rhabdomyolysis	Zocor			S	Oral	40 Mg, 1 Per Day		Merck
	Zocor 80mg			S	Oral	80 Mg, 1 Per Day		Merck
	Azithromycin			S	Oral	250 Mg, Frequency Reported As 1 Per 2 Days		Not Reported
	Ezetrol			C	Oral	10 Mg, 1 Per Day		Merck
	Torem			C	Oral	5 Mg, 1 Per Day		Not Reported
	Surmontil (Trimipramine Maleate)			C	Oral	100 Mg, 1 Per Day		Not Reported
	Alvesco			C	Buccal	160 Microgram, 1 Per Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2015	11861560	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2015449320		75 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Chromaturia; Drug Interaction; Fatigue; Myalgia; Prescribed Overdose; Rhabdomyolysis	Azithromycin			S	Oral	250 Mg, Alternate Day		Pfizer	
	Zocor Heart			S	Oral	40 Mg, 1x/Day		Not Reported	
	Zocor Heart			S	Oral	80 Mg, 1x/Day		Not Reported	
	Ezetrol			C	Oral	10 Mg, 1x/Day		Not Reported	
	Torem /01036501/			C	Oral	5 Mg, 1x/Day		Not Reported	
	Surmontil /00051802/			C	Oral	100 Mg, 1x/Day		Not Reported	
	Alvesco			C	Buccal	160 Ug, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11271626	EXPEDITED (15-DAY)		HO	FR-MERCK-1507FRA005778		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eczema; Pruritus; Rash Maculo-Papular	Aerius (Desloratadine)			S	Oral	1 Df, Qd/5 Mg In The Evening		Merck	
	Azithromycin			S	Oral	Unk		Not Reported	
	Rhinocort (Budesonide)			S	Nasal	1 Df, Qd/0.06mg On Spray In The Morning In Each Nostril		Not Reported	
	Chondrosulf			S	Oral	1 Df, Tid/3 Capsules In The Morning		Not Reported	
	Urbanyl			S	Oral	1 Df, Qd/10mg In The Evening		Not Reported	
	Lasilix			S	Oral	20 Mg Daily		Not Reported	
	Onbrez			C	Respiratory (inhalation)	1 Df, Qd		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11293148	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2015M1024149			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Face Oedema; Hypersensitivity	Azithromycin			S		Unk		Not Reported	
	Oki			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11864802	EXPEDITED (15-DAY)		DE	ALCN2015FR007832		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Ciloxan			S	Ophthalmic	Unk		Novartis	
	Oracilline			S	Ophthalmic	Unk		Not Reported	
	Oracilline			S	Unknown	Unk		Not Reported	
	Azyter			S	Ophthalmic	Unk		Not Reported	
	Noxafil			S	Oral	Unk		Not Reported	
	Ramipril Mylan			S	Oral	Unk		Not Reported	
	Amlodipine Arrow			S	Oral	Unk		Not Reported	
	Eupressyl			S	Unknown	Unk		Not Reported	
	Cancidas			S	Unknown	Unk		Not Reported	
	Furosemide Renaudin			S	Unknown	Unk		Not Reported	
	Furosemide Renaudin			S	Unknown	Unk		Not Reported	
	Aciclovir			C	Unknown	Unk		Not Reported	
	Vancomycine			C	Unknown	Unk		Not Reported	
	Vancomycine			C	Unknown	Unk		Not Reported	
	Ganciclovir			C	Unknown	Unk		Not Reported	
	Nefopam			C	Unknown	Unk		Not Reported	
	Nefopam			C	Unknown	Unk		Not Reported	
	Nefopam			C	Unknown	Unk		Not Reported	

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

Nefopam	C	Unknown	Unk	Not Reported
Nefopam	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Dexametason//Dexamethasone	C	Ophthalmic	Unk	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Ursodeoxycholic Acid	C	Unknown	Unk	Not Reported
Alfuzosine	C	Unknown	Unk	Not Reported
Valaciclovir	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	1 Df, Prn	Not Reported
Clairyg	C	Unknown	1 Df, Once/Single	Not Reported
Rimexolone	C	Ophthalmic	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11865750	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015459629		63 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Amnesia; Feeling Abnormal; Panic Disorder; Respiratory Distress; Therapeutic Response Decreased	Zithromac			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2015	11865925	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015420695		84 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Delirium; Hallucination;	Zithromac			S		500 Mg, Daily		Pfizer

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

Mental Disorder	Tamsulosin Hydrochloride	C	0.2 Mg, Daily, In The Morning	Not Reported
	Ambroxol Hydrochloride	C	45 Mg, Daily, After Each Meal	Not Reported
	Gascon	C	240 Mg, Daily, After Each Meal	Not Reported
	Midodrine Hydrochloride	C	4 Mg, Daily, In The Morning And Evening	Not Reported
	Xyzal	C	5 Mg, Daily, In The Evening	Not Reported
	Lansoprazole	C	15 Mg, Daily, In The Evening	Not Reported
	Maglax	C	500 Mg, Daily, In The Morning And Evening	Not Reported
	Miya Bm	C	3 G, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2015	11870763	DIRECT	Y	HO			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Cardiac Arrest; Syncope; Torsade De Pointes	Ondansetron			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2015	11873132	NON-EXPEDITED			US-PFIZER INC-2015468772			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Losartan Potassium			S		Unk		Not Reported
	Suprax /00497602/			S		Unk		Not Reported
	Enalapril			S		Unk		Not Reported

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

	Keflexin	S	Unk	Not Reported
	Vasotec	S	Unk	Not Reported
	Fercayl	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2015	11873200	EXPEDITED (15-DAY)		HO	FR-SA-2015SA104372		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eczema; Pruritus; Rash Maculo-Papular	Urbanyl			S	Oral	Dose:10mg In The Evening		Not Reported	
	Furosemide			S	Oral	Discontinued On 10 April By The Treating Doctor For Suspicion Of Link With Skin Eruption		Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Chondrosulf			S	Oral	Dose:3 Capsule In The Morning		Not Reported	
	Rhinocort			S	Nasal	Rhinocort 0.06 Mg: 1 Spray In The Morning In Each Nostril.		Not Reported	
	Aerius (Desloratadine)			S	Oral	Dose:5mg In Evening		Not Reported	
	Onbrez Breezhaler			C	Respiratory (inhalation)	150 Micrograms, Powder For Day(S)) Inhalation In Capsule Every Morning		Not Reported	
	Macrogol			C		10: 1 Sachet In The Morning, 3x/Week		Not Reported	
	Proctolog			C		1 Suppository The Evening 1x/Week		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2015	11873326	EXPEDITED (15-DAY)		DS	NL-PFIZER INC-2015464238		62 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Neuropathy Peripheral	Azithromycin		S	Oral	500 Mg, 1x/Day		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2015	11841807	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2015441863		2 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Neutropenia; Toxicity To Various Agents	Azithromycin			S	Oral	10 Mg/Kg, Daily		Pfizer	
	Rifabutin			S		5 Mg/Kg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2015	11852456	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2015419551		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cough; Diarrhoea; Dyspnoea; Nausea; Vomiting	Azithromycin			S	Oral	500 Mg, The First Day		Pfizer	
	Lamotrigine			C		150 Mg, 1x/Day		Not Reported	
	Lamotrigine			C		Unk		Not Reported	
	Fioricet			C		1 Df, 2x/Day		Not Reported	
	Fioricet			C		Unk		Not Reported	
	Buspirone			C		15 Mg, 2x/Day		Not Reported	
	Proair			C		Unk		Not Reported	
	Proair			C				Not Reported	
	Proair			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2015	11875391	NON-EXPEDITED			US-PFIZER INC-2015451259			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2015	11876440	NON-EXPEDITED			US-PFIZER INC-2015455172			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S	Unknown	Unk		Pfizer	
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Pfizer	
	Augmentin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2015	11876824	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015466554		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cough; Hypotension; Pharyngeal Oedema; Pyrexia; Rash; Wheezing	Zithromax			S	Oral	Unk, Single		Pfizer	
	Zinnat			S	Oral	Unk, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2015	11832456	NON-EXPEDITED			US-PFIZER INC-2015431323		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Medrol			S		Unk		Pfizer	
	Azithromycin			S		Unk		Not Reported	
	Metformin			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
	Theo			S		Unk		Not Reported	
	Metoprolol			S				Not Reported	
	Zetia			S				Not Reported	
	Lopresor			S				Not Reported	
	Lovastatin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2015	11879227	NON-EXPEDITED			US-PFIZER INC-2015433627			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2015	11879246	NON-EXPEDITED			US-PFIZER INC-2015474068			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2015	11879383	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2015469406		80 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased	Azithromycin			S	Oral	Unk		Pfizer	
	Atorvastatin			C		Unk		Not Reported	
	Digoxin			C		Unk		Not Reported	
	Hyoscine Butylbromide			C		Unk		Not Reported	
	Lansoprazole			C		Unk		Not Reported	
	Losartan			C		Unk		Not Reported	
	Mesalazine			C		Unk		Not Reported	
	Metformin			C		Unk		Not Reported	
	Metoclopramide			C		Unk		Not Reported	
	Propylthiouracil			C		Unk		Not Reported	
	Seretide			C		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2015	11880277	EXPEDITED (15-DAY)		HO	US-NOVAST LABORATORIES, LTD- US-2015NOV000082		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatocellular Injury	Drospirenone\Ethinyl Estradiol			S	Oral	Unkown		Novast	
	Azithromycin			S		Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2015	11442714	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2015285798		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Musculoskeletal Discomfort; Pruritus; Rash Erythematous	Azithromycin			S		Unk		Pfizer	
	Centrum Silver			S		Unk		Pfizer	
	Ipratropium Bromide			C		Unk		Not Reported	
	Fluticasone Propionate			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2015	11881698	NON-EXPEDITED			US-PFIZER INC- 2015474882			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Crestor			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Cosopt			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2016	11886548	NON-EXPEDITED			US-PFIZER INC- 2015433538			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Feldene			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Lincomycin			S		Unk		Not Reported
	Clindamycin			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Indocin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2016	11887120	EXPEDITED (15-DAY)		HO	GB-TEVA-622182ACC		80 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
International Normalised Ratio Increased	Azithromycin			S	Oral			Not Reported
	Atorvastatin			C				Not Reported
	Digoxin			C				Not Reported
	Hyoscine Butylbromide			C				Not Reported
	Lansoprazole			C				Not Reported
	Losartan			C				Not Reported
	Mesalazine			C				Not Reported
	Metformin			C				Not Reported
	Metoclopramide			C				Not Reported
	Propylthiouracil			C				Not Reported
	Seretide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2016	11888369	DIRECT		HO			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Fatigue; Heart Rate Increased; Hypertension; Sensory Disturbance; Somnolence	Azithromycin			S	Oral			Sandoz
	D2			C				Not Reported
	Hydrocortisone			C				Not Reported
	Multi Vitamin			C				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2016	11225710	EXPEDITED (15-DAY)		HO, OT	ZW-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-024150		37 YR	Male	ZWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastroenteritis; Tuberculosis	Efavirenz			S	Unknown	Unk		Bristol Myers Squibb	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Raltegravir			S	Unknown	Unk		Unknown	
	Isoniazid			S	Unknown	Unk		Not Reported	
	Albendazole			S	Unknown	Unk		Not Reported	
	Fluconazole			S	Unknown	Unk		Not Reported	
	Emtricitabine			C	Unknown	Unk		Not Reported	
	Tenofovir			C	Unknown	Unk		Not Reported	
	Co Trimoxazole			C	Unknown	Unk		Not Reported	
	Pyridoxine			C	Unknown	Unk		Not Reported	
	Pyrazinamide			C	Unknown	Unk		Not Reported	
	Rifampin			C	Unknown	Unk		Not Reported	
	Ethambutol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2016	11888549	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015R1-109034		16 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic; Hepatocellular Injury; Hepatomegaly; Pancreatitis; Pyrexia	Azithromycin			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Deferasirox			S	Unknown	Unk		Not Reported	
	Hydroxycarbamide			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2016	11891545	DIRECT		DS, HO			28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Azithromycin Z-Pac			S	Oral	1 Tablets At First		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2016	11892395	EXPEDITED (15-DAY)		HO	PHHY2015GB169631		80 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased	Azithromycin			S	Oral			Novartis	
	Atorvastatin			C	Unknown			Not Reported	
	Digoxin			C	Unknown			Not Reported	
	Hyoscine Butylbromide			C	Unknown			Not Reported	
	Lansoprazole			C	Unknown			Not Reported	
	Losartan			C	Unknown			Not Reported	
	Mesalazine			C	Unknown			Not Reported	
	Metformin			C	Unknown			Not Reported	
	Metoclopramide			C	Unknown			Not Reported	
	Propylthiouracil			C	Unknown			Not Reported	
	Seretide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2016	11895330	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Distribution Issue	Azithromycin			S				Not Reported	
	Prednisone			S	Oral			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2016	11895489	DIRECT					1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Urticaria	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2016	11687681	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2015367209		85 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Exfoliative Generalised	Zitromax			S		Unk		Pfizer	
	Medrol /00049601/			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2016	11874340	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2015-11703		47 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Amlodipine			S	Oral	Unk		Aurobindo	
	Oracilline /00001805/			S	Unknown	Unk		Not Reported	
	Ciloxan			S	Ophthalmic	Unk		Not Reported	
	Azyter			S	Ophthalmic	Unk		Not Reported	
	Noxafil			S	Oral	Unk		Not Reported	
	Ramipril Mylan			S	Oral	Unk		Not Reported	
	Eupressyl /00631801/			S	Unknown	Unk		Not Reported	
	Cancidas			S	Unknown	Unk		Not Reported	
	Furosemide Renaudin			S	Unknown	Unk		Not Reported	
	Aciclovir			C	Unknown	Unk		Not Reported	
	Vancomycine			C	Unknown	Unk		Not Reported	
	Ganciclovir			C	Unknown	Unk		Not Reported	

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

Nefopam	C	Unknown	Unk	Not Reported
Morphine	C	Unknown	Unk	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Insulin	C	Unknown	Unk	Not Reported
Valaciclovir /01269702/	C		Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Clairyg	C	Unknown	Unk	Not Reported
Entecavir	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2016	11894311	EXPEDITED (15-DAY)	DE		FR-ROCHE-1689506		81 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Agranulocytosis; Rash Maculo-Papular; Thrombocytopenia	Rocephine			S	Unknown			Not Reported	
	Rocephine			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycine			S	Oral			Not Reported	
	Previscan (France)			S	Oral	Alternating 0.5 Df/Day Day 1; 0.75 Df Day 2		Not Reported	
	Citalopram			S	Oral			Not Reported	
	Citalopram			S	Oral			Not Reported	
	Tamsulosine			S	Oral	0.4 Mg		Not Reported	
	Latanoprost			S	Ophthalmic			Not Reported	
	Pantoprazole			S	Oral	20 Mg		Not Reported	
	Prednisone			S	Oral	20 Mg		Not Reported	
	Prednisone			S	Oral	60 Mg		Not Reported	
	Desloratadine			C				Not Reported	
	Tazocilline			C	Unknown			Not Reported	
	Solumedrol			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2016	11895961	EXPEDITED (15-DAY)		LT	PHHY2015TW170436		17 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hypoxia; Lung Consolidation; Pulmonary Pneumatocele	Piperacillin+Tazobactam			S	Unknown			Novartis	
	Vancomycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Imipenem And Cilastatin			S	Unknown	Unk		Not Reported	
	Oseltamivir			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2016	11896390	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2016M1000244			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased	Azithromycin			S	Oral	Unk		Not Reported	
	Atorvastatin			C				Mylan	
	Digoxin			C				Mylan	
	Hyoscine Butylbromide			C				Mylan	
	Lansoprazole			C				Mylan	
	Losartan			C				Mylan	
	Mesalazine			C				Mylan	
	Metformin			C				Mylan	
	Metoclopramide			C				Mylan	
	Propylthiouracil			C				Mylan	
	Seretide			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2016	11811426	NON-EXPEDITED			US-PFIZER INC-2015422786			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2016	11828835	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2015427747		56 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Hyperthermia	Zithromac			S	Intravenous drip	500 Mg, 1x/Day		Pfizer	
	Meropen /01250501/			C	Intravenous drip	1000 Mg, 3x/Day		Not Reported	
	Teicoplanin			C	Intravenous drip	300 - 600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2016	11899240	NON-EXPEDITED			US-PFIZER INC-2016004297			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2016	11901105	NON-EXPEDITED			US-ABBVIE-15P-163-1503332-00		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Sinusitis	Viekira Pak			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2016	11902198	NON-EXPEDITED			US-TEVA-623654USA		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Decreased Appetite; Depression; Frustration Tolerance Decreased	Proair Hfa			S	Respiratory (inhalation)			Ivax	
	Zithromax			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2016	11908139	EXPEDITED (15-DAY)		HO	IT-TEVA-623854ACC		59 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Drug-Induced Liver Injury; Pain In Extremity; Pyrexia	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
	Veclam - 500 Mg Comprese Rivestite			S	Oral	500 Milligram Daily; Coated Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2016	11910982	DIRECT					30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Fatigue; Pruritus; Tongue Discomfort	Azithromycin 250mg			S	Oral	2 Tabs/1tsb		Not Reported	
	Zpak			C				Not Reported	
	Omega 3			C				Not Reported	
	B Vitamin			C				Not Reported	
	Multivitamin			C				Not Reported	
	Biotin Chews			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	10547968	NON-EXPEDITED			US-PFIZER INC-2014291827			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Neosporin			S		Unk		Pfizer	
	Trinalin			S		Unk		Not Reported	
	Roxicet			S		Unk		Not Reported	
	Motrin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11909620	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2016-00079		2 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Neutropenia	Rifabutin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2016	11911435	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2016006188		49 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Hypersensitivity; Pruritus; Throat Tightness	Azithromycin			S	Oral	1 Df, Total		Pfizer	
	Urbason			C	Oral	Unk		Not Reported	
	Atarax			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2016	10813534	NON-EXPEDITED			US-PFIZER INC- 2015061312			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Enbrel			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Humira			S				Not Reported	
	Ceftin			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Actemra			S		Unk		Not Reported	
	Cefuroxime			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2016	11914196	NON-EXPEDITED			GXBR2015US002255		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chills; Diarrhoea; Injection Site Pain; Myalgia; Pyrexia; Urinary Tract Disorder	Ceftriaxone			S	Intramuscular	1 G, Once/Single		Novartis	
	Azithromycin			S	Oral	Unk Df, Unk		Not Reported	
	Zofran			S	Oral	Unk Df, Unk		Not Reported	
	Duexis			C	Oral	800 Mg, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2016	11914370	EXPEDITED (15-DAY)		DE, HO	FR-MYLANLABS- 2016M1000430			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Agranulocytosis; Febrile Neutropenia; Rash Maculo-Papular; Rash Morbilliform; Thrombocytopenia	Azitromycine Mylan 250 Mg, Filmomhulde Tabletten			S	Oral	1 Df, Tid		Mylan	
	Latanoprost Mylan Pharma 0.005%, Collyre En Solution			S	Ophthalmic	Unk		Mylan	
	Rocephine			S	Intravenous (not otherwise specified)	2 G, Qd		Mylan	
	Previscan /00261401/			S	Oral	Unk		Mylan	
	Citalopram Zentiva			S	Oral	20 Mg, Qd		Mylan	
	Citalopram Zentiva			S		Unk		Mylan	
	Tamsulosine Biogaran			S	Oral	1 Df, Qd		Mylan	
	Pantoprazole			S	Oral	1 Df, Qd		Mylan	
	Prednisone			S	Oral	1 Df, Qd		Mylan	
	Doxycycline			C		100 Mg, Unk		Mylan	
	Plaquenil /00072602/			C		200 Mg, Unk		Mylan	
	Solumedrol			C		Unk		Mylan	
	Cortancyl			C		Unk		Mylan	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2016	11915829	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2016US00021			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock;	Levofloxacin			S	Unknown	Unk		Cipla
Bradycardia; Confusional	Ciprofloxacin			S	Unknown	Unk		Cipla
State; Cough; Dizziness;	Aciclovir			S	Unknown	Unk		Cipla
Headache; Nausea;	Propofol			S	Unknown	Unk		Not Reported
Neuropathy Peripheral;	Neosynephrine			S	Unknown	Unk		Not Reported
Psychomotor	Nystatin			S	Unknown	Unk		Not Reported
Hyperactivity; Pulmonary	Penicillin			S	Unknown	Unk		Not Reported
Oedema; Pylorospasm;	Plerixafor			S	Unknown	Unk		Not Reported
Rash; Retching;	Pyridium			S	Unknown	Unk		Not Reported
Tendonitis; Urticaria	Clinoril			S	Unknown	Unk		Not Reported
	Azasite Eye Drops			S	Ophthalmic	Unk		Not Reported
	Dextromethorphan			S	Unknown	Unk		Not Reported
	Duravent/Da			S	Unknown	Unk		Not Reported
	Mitrex			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Septra			S	Unknown	Unk		Not Reported
	Sulphadiazine			S	Unknown	Unk		Not Reported
	Cleocin-Us			S	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2016	11916007	EXPEDITED (15-DAY)		DE, OT	IT-TEVA-624635ACC			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Ventricular	Azithromycin			S				Not Reported

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

Tachyarrhythmia	Clarithromycin		S						Teva
	Erythromycin		S						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2016	11916814	NON-EXPEDITED			US-PFIZER INC-2015463239			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort	Azithromycin				S		500 Mg, Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2016	11916897	NON-EXPEDITED			US-PFIZER INC-2015460069			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer
	Doxycycline Hyclate				S		Unk		Pfizer
	Amoxicillin				S		Unk		Pfizer
	Cephalexin				S		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2016	11917468	NON-EXPEDITED			US-PFIZER INC-2016012495			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Clindamycin Hcl				S		Unk		Pfizer
	Erythromycin				S		Unk		Pfizer
	Azithromycin				S		Unk		Pfizer
	Biaxin				S		Unk		Not Reported
	Tramadol				S		Unk		Not Reported
	Tussinex				S		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2016	11919572	DIRECT		HO, LT			63 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dehydration; Dyspnoea; Fatigue; Hallucination; Insomnia; Myocardial Infarction	Azithromycin			S	Oral	2 Pills Then 1 For 5 Days, 2 Pills First Days		Teva	
	Humalin N Insulin			C				Not Reported	
	Humalin R Insulin			C				Not Reported	
	Aspirin			C				Not Reported	
	Lovastatin			C				Not Reported	
	Furosomide			C				Not Reported	
	Calcitriole			C				Not Reported	
	Hydralazine			C				Not Reported	
	Isosorbide Mn Er			C				Not Reported	
	Doxazosin			C				Not Reported	
	Omega Fish Oil			C				Not Reported	
	Probiotics			C				Not Reported	
	Coq10			C				Not Reported	
	Calcium With Vitamin D			C				Not Reported	
	Vitamin B-12			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2016	11919964	DIRECT	Y	OT			82 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Infusion Site Reaction; Pruritus; Urticaria	Azithromycin 500mg/250 MI Ns			S	Intravenous (not otherwise specified)			Not Reported	
	Guaifenesin Er			C			Not Reported		
	Atorvastatin			C			Not Reported		
	Levothyroxine			C			Not Reported		
	Duoneb			C			Not Reported		
	Flovent			C			Not Reported		
	Temazepam			C			Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Jan-2016	11919670	NON-EXPEDITED			US-PFIZER INC-2015462470			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

Augmentin		S		Unk		Not Reported			
Phenergan		S		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2016	10176139	NON-EXPEDITED			US-PFIZER INC-2014130714		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2016	11924165	NON-EXPEDITED			US-PFIZER INC-2015465634			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2016	11925198	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1001251			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Drug-Induced Liver Injury; Pain In Extremity; Pyrexia	Azithromycin			S	Oral	500 Mg Daily		Not Reported	
	Veclam			S	Oral	500 Mg Daily		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2016	11927466	EXPEDITED (15-DAY)		DE, LT	CA-TEVA-626455ACC		30 DAY	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest; Incorrect Dose Administered; Overdose;	Azithromycin			S	Intravenous (not otherwise specified)	216 Milligram Daily;		Not Reported	
	Morphine			C				Not Reported	

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

Premature Baby; Tachycardia; Ventricular Fibrillation Vitamin D Nos C Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2016	11929360	DIRECT		DE, HO			84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dyspnoea	Kenalog			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S			Not Reported	
	Nebulizer-Albuterol			C			Not Reported	
	Tikosyn			C			Not Reported	
	Synthroid			C			Not Reported	
	Htn Meds			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2016	11929994	DIRECT					65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Feeling Hot; Muscle Spasms	Azithromycin Tablets 250mg			S	Oral			Greenstone
	Distran Tec Greenstone Llc							
	Peapock, Nj 07977-Made In India							
	Synthroid			C			Not Reported	
	Calcium			C			Not Reported	
	Multi-Vitamin			C			Not Reported	
	Red Yeast Rice			C			Not Reported	
	Glucosamine Chondroitin			C			Not Reported	
	Aspirin			C			Not Reported	
	Fish Oil			C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2016	11929699	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1001481			Unknown	ITA

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Erythema;	Azithromycin Mylan	S	Oral	1 Df Total	Mylan
Hypersensitivity; Pruritus;	Urbason /00049601/	C	Oral		Mylan
Throat Tightness	Atarax /00058402/	C	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2016	11930033	DIRECT	Y				6 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oral Discomfort; Retching;	Azithromycin			S	Oral			Teva
Taste Disorder;	Generic (Walgreens Brand)			C				Not Reported
Unevaluable Event	Dimetapp Cough And Cold							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2016	11932052	NON-EXPEDITED			US-PFIZER INC-2015471354		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Circumstance Or Information Capable Of Leading To Medication Error; Dyspnoea; Fatigue; Muscular Weakness; Palpitations; Ventricular Extrasystoles	Zithromax			S	Oral	Four 250mg Tablets The First Day And One 250mg Tablet For 2 Days		Pfizer
	Zithromax			S	Oral	Four 250mg Tablets The First Day And One 250mg Tablet For 2 Days		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2016	11933536	NON-EXPEDITED			US-ELI_LILLY_AND_COMP ANY-US201601007083			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Cymbalta			S	Unknown	1 Df, Unknown		Eli Lilly And Co
Irritable Bowel Syndrome;	Zithromax			S	Unknown	1 Df, Unknown		Not Reported
Urticaria	Effexor			S	Unknown	225 Mg, Each Morning (75mgx3 Capsules Am		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Clonazepam	C	Unknown	With Food)	Not Reported
Centrum /02217401/	C	Unknown	5 Mg, Other: Every 8 Hours	Not Reported
Vitamin D3	C	Unknown	Unk, Qd:1/2	Not Reported
Ester C /00008001/	C	Unknown	100 Iu, Qd	Not Reported
Additiva Vitamin E	C	Unknown	500 Mg, Qod	Not Reported
Miralax /00754501/	C	Unknown	400 Iu, Other: 3-5 Days A Week	Not Reported
Citrucel	C	Unknown	Unk, Qod	Not Reported
Quetiapine	C	Unknown	Unk, Qod	Not Reported
Quetiapine	C	Unknown	50 Mg, Each Evening (25mgx2 At Night)	Not Reported
Quetiapine	C	Unknown	50 Mg, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2016	11935276	NON-EXPEDITED			US-PFIZER INC-2015465570			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Dilaudid			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2016	11935853	NON-EXPEDITED			US-PFIZER INC-2015474358			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11935876	NON-EXPEDITED			US-PFIZER INC-2015474411			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Reglan			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11935877	NON-EXPEDITED			US-PFIZER INC-2015474308			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Gastrointestinal Disorder	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2016	11935880	NON-EXPEDITED			US-PFIZER INC-2015474428			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardiac Disorder; Chest Discomfort	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	10669647	NON-EXPEDITED			US-PFIZER INC-2014352549			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ambien			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2016	11790610	NON-EXPEDITED		OT	US-PFIZER INC-2015407164		59 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Drug Hypersensitivity	Neurontin	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer
	Naproxen Sodium	S	Unk	Pfizer
	Doxycycline Calcium	S		Pfizer
	Zithromax	S		Pfizer
	Simvastatin	S	Unk	Not Reported
	Demerol	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2016	11857251	NON-EXPEDITED			US-PFIZER INC-2015419669		13 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Dyspnoea; Nausea; Off Label Use; Vomiting	Azithromycin			S	Oral	875mg One Tablet Every 12 Hours		Pfizer	
	Amoxicillin			S	Oral	1 Df, Every 12 Hours		Not Reported	
	Loratadine D			C		1 Df, 1x/Day, (Morning)		Not Reported	
	Prednisone			C	Oral	3 Df, Unk, (On Day 1)		Not Reported	
	Prednisone			C	Oral	3 Df, Unk, (On Days 2-3)		Not Reported	
	Prednisone			C	Oral	3 Df, Unk, (On Days 4-5)		Not Reported	
	Zofran			C		1 Df, 3x/Day, (Prn)		Not Reported	
	Zofran			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2016	11860489	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2015428454		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Transient Ischaemic Attack	Depo-Medrol			S	Intramuscular	80 Mg Once		Pfizer	
	Depo-Medrol			S				Pfizer	
	Azithromycin			S	Oral	250 Mg, Cyclic (2 Tabs Day One, Then One Tablet Po Days)		Pfizer	

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

Azithromycin
Methotrexate

S
C

Unk

Pfizer
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2016	11863499	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-108207			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hepatic Function Abnormal; Pathogen Resistance	Clarithromycin			S	Unknown	800 Mg, Daily		Sun
	Moxifloxacin			S	Unknown	400 Mg, Daily		Not Reported
	Azithromycin			S	Unknown	250 Mg, Daily		Not Reported
	Imipenem/Cilastin			C	Unknown	0.5 G, Qid		Not Reported
	Tobramycin			C	Unknown	90 Mg, Bid		Not Reported
	Cyclosporine A			C	Unknown	100 Mg, Daily		Not Reported
	Methylprednisolone			C	Unknown	12 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2016	11938433	NON-EXPEDITED			US-PFIZER INC- 2015477701			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2016	10824085	NON-EXPEDITED			US-ABBVIE-14K-163- 1314501-00		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Clostridium Difficile Infection; Clostridium Difficile Infection; Diarrhoea;	Humira			S	Subcutaneous			Not Reported
	Humira			S	Subcutaneous			Not Reported
	Z-Pack			S	Unknown			Not Reported

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

Diarrhoea; Fatigue;	Diovan	C	Not Reported
Oropharyngeal Pain; Rash	Coreg	C	Not Reported
Macular; Sinusitis;	Spiroglactone	C	Not Reported
Urticaria	Pravastatin	C	Not Reported
	Nexium	C	Not Reported
	Flonase	C	Not Reported
	Amitriptyline	C	Not Reported
	Amitriptyline	C	Not Reported
	Tylenol	C	Not Reported
	Tylenol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2016	11880801	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015471937		66 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Duodenal Ulcer; Nausea	Zithromac			S	Oral	500 Mg, 2x/Day		Pfizer	
	Olmetec			C	Oral	20 Mg, 1x/Day		Not Reported	
	PI			C	Oral	1 G, 3x/Day		Not Reported	
	Carbocisteine			C	Oral	500 Mg, 3x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2016	11935861	NON-EXPEDITED			US-PFIZER INC-2015475796			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2016	11951708	NON-EXPEDITED			US-ABBVIE-15K-163-1332161-00		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Dyspnoea;	Humira			S	Unknown			Not Reported	
Nasopharyngitis; Oxygen Saturation Decreased; Respiratory Tract	Azithromycin			S	Unknown			Not Reported	

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

Congestion

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2016	11952373	EXPEDITED (15-DAY)		DS, HO, OT	GB-PFIZER INC-2016029419		17 YR	Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ear Discomfort; Ototoxicity	Azithromycin			S	Oral	Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11852620	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015447846		22 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Drug Hypersensitivity; Nausea	Zithromac Sr			S	Oral	Unk		Pfizer	
	Lunabell			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11951636	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016031240			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nerve Injury; Road Traffic Accident	Neurontin			S		Unk		Pfizer	
	Norvasc			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jan-2016	11956029	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016034538		58 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Depression; Panic Disorder	Zithromax			S	Oral	1 G, Single		Pfizer	
	Ciflox /00697201/			S	Oral	250 Mg, 2x/Day		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2016	11968786	DIRECT	Y	DE, HO				Male	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zpak 250 Mg			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11742942	EXPEDITED (15-DAY)		OT	CA-TEVA-608478USA		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Vasculitis; Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11860242	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2015451842		77 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Unilateral; Drug Interaction	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Ciprofloxacin			S	Oral	500 Mg, 2x/Day		Not Reported	
	Losanox			C	Oral	50 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11919669	NON-EXPEDITED			US-PFIZER INC-2015465431			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Vicodin			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11964791	NON-EXPEDITED			US-PFIZER INC-2016009867			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11965540	NON-EXPEDITED			US-PFIZER INC-2016040175			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Diflucan			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Doxycycline			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11965556	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2016035032		60 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Joint Swelling; Pain In Extremity; Pyrexia; Skin Reaction; Urine Analysis Abnormal	Zithromax			S	Oral	0.25 Mg, 2x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11966124	NON-EXPEDITED			US-PFIZER INC-2016009574		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Diarrhoea	Zithromax		S	Oral	1 G, Single		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11967071	EXPEDITED (15-DAY)		OT	SE-APOTEX-2016AP005998			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	500 Mg, Single On Day 0		Apotex	
	Azithromycin			S	Unknown	250 Mg, On Days 1-4		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11967164	EXPEDITED (15-DAY)		OT	SE-APOTEX-2016AP005999			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	500 Mg On Day 0		Apotex	
	Azithromycin			S	Unknown	250 Mg, On Day 1-4		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2016	11967189	EXPEDITED (15-DAY)		OT	SE-APOTEX-2016AP006000			Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	500 Mg, On Day 0		Apotex	
	Azithromycin			S	Unknown	250 Mg, On Days 1-4		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2016	9695895	EXPEDITED (15-DAY)		HO, OT	BR-ROCHE-725088		43 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anaemia; Anaemia; Burning Sensation; Cough; Cyst; Decreased Appetite; Defaecation	Mabthera			S	Intravenous (not otherwise specified)	Form: Infusion		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	

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

Urgency; Diarrhoea;	Mabthera	S	Intravenous (not otherwise specified)	Not Reported
Dizziness; Dyspnoea;				
Dyspnoea; Erythema;	Mabthera	S	Intravenous (not otherwise specified)	Not Reported
Fatigue; Finger Deformity;				
Hand Deformity; Head	Mabthera	S	Intravenous (not otherwise specified)	Not Reported
Discomfort; Hot Flush;				
Hypersensitivity; Joint	Mabthera	S	Intravenous (not otherwise specified)	Not Reported
Range Of Motion				
Decreased; Lymphadenitis	Mabthera	S	Intravenous (not otherwise specified)	Not Reported
Bacterial; Malaise;				
Musculoskeletal	Azithromycin	S	Unknown	Not Reported
Discomfort; Nausea;	Azithromycin	S		Not Reported
Nausea; Off Label Use;	Actemra	S	Intravenous (not otherwise specified)	Not Reported
Oral Herpes;				
Oropharyngeal Pain;	Ranitidine	C	Unknown	Not Reported
Oropharyngeal Pain;				
Oropharyngeal Pain;	Euthyrox	C	Unknown	Not Reported
Osteoarthritis; Pain;	Euthyrox	C	Unknown	Not Reported
Palpitations; Peripheral				
Swelling; Pharyngeal	Deflazacort	C	Unknown	Not Reported
Inflammation; Pruritus;	Deflazacort	C	Unknown	Not Reported
Pyrexia; Renal Failure;	Deflazacort	C	Unknown	Not Reported
Renal Failure; Renal				
Impairment; Rheumatoid	Hydroxychloroquine	C	Unknown	Not Reported
Arthritis; Rotavirus				
Infection; Sensation Of				
Foreign Body; Sleep	Hydroxychloroquine	C	Unknown	Not Reported
Disorder; Swelling;				
Swollen Tongue;	Hydrochlorothiazide	C		Not Reported
Tachycardia; Tooth	Captopril	C	Unknown	Not Reported
Fracture; Urinary Tract				
Infection; Vomiting; Weight	Noripurum	C		Not Reported
Increased; White Blood	Celestone	C	Unknown	Not Reported
Cell Count Decreased;	Amlodipine	C		Not Reported
White Blood Cell Count	Chloroquine Phosphate	C	Unknown	Not Reported
Decreased				
	Tramal	C		Not Reported
	Methotrexate	C		Not Reported
	Prelone	C		Not Reported
	Rivotril	C		Not Reported
	Renagel	C		Not Reported
	Aas	C	Unknown	Not Reported

Drug Reported As:
Hydroxychloroquine
Formula

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Lyrica	C	Unknown	Not Reported
Eutirox	C	Unknown	Not Reported
Prednisone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2016	11972562	NON-EXPEDITED			US-PFIZER INC-2016047109		83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Verapamil Hcl			S		Unk		Pfizer
	Amoxil			S		Unk		Not Reported
	Cipro /00697201/			S		Unk		Not Reported
	Flecainide			S		Unk		Not Reported
	Multaq			S		Unk		Not Reported
	Zithromax Z-Pack			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2016	11972576	NON-EXPEDITED			US-PFIZER INC-2016036600			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Biaxin			S		Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2016	11972666	NON-EXPEDITED			US-PFIZER INC-2016008530		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Azithromycin			S		Unk		Pfizer

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

Arthralgia; Bone Pain;
Diarrhoea; Drug
Ineffective; Feeling
Abnormal; Myalgia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2016	11972691	EXPEDITED (15-DAY)		DS, HO, OT	PHHY2016GB006903		17 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Discomfort; Ototoxicity	Azithromycin			S	Oral			Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2016	11972716	NON-EXPEDITED			US-PFIZER INC-2016021902			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11644587	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2015-09328		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Tamponade;	Azithromycin			S	Unknown			Aurobindo	
Chest Pain; Cough; Drug	Azithromycin			S				Aurobindo	
Interaction; Dyspnoea;	Rivaroxaban			S	Unknown			Not Reported	
Pericardial Effusion;	Metoprolol			C	Unknown			Not Reported	
Pericardial Haemorrhage;	Levothyroxine			C	Unknown			Not Reported	
Pericarditis; Rales	Aspirin			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11846161	EXPEDITED (15-DAY)		HO, LT, OT	JP-PFIZER INC-2015442059		84 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Zithromac			S	Oral	500 Mg, 1x/Day		Pfizer
	Baktar			S	Oral	1 Df, 1x/Day		Not Reported
	Xarelto			S	Oral	10 Mg, 1x/Day		Not Reported
	Allelock			C		5 Mg, Unk		Not Reported
	Furosemide			C		10 Mg, Unk		Not Reported
	Nexium /01479302/			C		20 Mg, Unk		Not Reported
	Samsca			C		3.75 Mg, Unk		Not Reported
	Glactiv			C		50 Mg, Unk		Not Reported
	Atorvastatin			C		5 Mg, Unk		Not Reported
	Brotizolam			C		0.25 Mg, Unk		Not Reported
	Predonine /00016201/			C		5 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11975710	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-110463		46 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown	Unk		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11976245	EXPEDITED (15-DAY)		DS, HO, OT	GB-TEVA-627453ACC		17 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Discomfort; Ototoxicity	Azithromycin			S	Oral			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11980648	EXPEDITED (15-DAY)		OT	US-JNJFOC-20160116550			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Domperidone			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported
	Risperidone			S	Unknown			Not Reported
	Itraconazole			S	Unknown			Not Reported
	Ketoconazole			S	Unknown			Not Reported
	Miconazole		Y	S	Unknown			Not Reported
	Miconazole			S	Unknown			Not Reported
	Droperidol			S	Unknown			Not Reported
	Desipramine			S	Unknown			Not Reported
	Doxepin			S	Unknown			Not Reported
	Dronedarone			S	Unknown			Not Reported
	Clomipramine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Escitalopram			S	Unknown			Not Reported
	Flecainide			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Amitriptyline			S	Unknown			Not Reported
	Ibutilide			S	Unknown			Not Reported
	Imipramine			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Moxifloxacin			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Nortriptyline			S	Unknown			Not Reported

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

Octreotide	S	Unknown	Not Reported
Ondansetron	S	Unknown	Not Reported
Perflutren	S	Unknown	Not Reported
Propafenone	S	Unknown	Not Reported
Ranolazine	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Sotalol	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Voriconazole	S	Unknown	Not Reported
Aprepitant	S	Unknown	Not Reported
Cyclosporine	S	Unknown	Not Reported
Diltiazem	S	Unknown	Not Reported
Isoniazid	S	Unknown	Not Reported
Citalopram	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported
Nicardipine	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Tetracaine	S	Unknown	Not Reported
Tetracycline	S	Unknown	Not Reported
Verapamil	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported
Amidarone	S	Unknown	Not Reported
Clindamycin	S	Unknown	Not Reported
Fluconazole	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Lidocaine	S	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2016	11980979	EXPEDITED (15-DAY)		OT	IT-009507513-1601ITA008913		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hepatotoxicity	Raltegravir Potassium			S	Oral	Unk		Merck	
	Azithromycin			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Haloperidol			S	Oral	1 Mg, Tid		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	450 Mg, Bid		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	300 Mg, Bid		Not Reported	
	Voriconazole			S	Oral	250 Mg, Bid		Not Reported	
	Voriconazole			S	Oral	200 Mg, Bid		Not Reported	
	Voriconazole			S	Unknown	100 Mg, Bid		Not Reported	
	Delorazepam			S	Oral	1 Mg, Qd		Not Reported	
	Pregabalin			S	Unknown			Not Reported	
	Emtricitabine (+) Tenofovir			S	Unknown			Not Reported	
	Disoproxil Fumarate			S	Unknown			Not Reported	
	Atovaquone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2016	11941031	EXPEDITED (15-DAY)		HO	GXBR2016US000548		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastroenteritis	Ceftriaxone			S	Intravenous bolus	1.0 G, Qd		Novartis	
	Azithromycin Pfizer			S	Intravenous bolus	500 Mg, Qd		Not Reported	
	Tofacitinib Citrate			S	Oral	5 Mg, Bid		Not Reported	
	Folic Acid			C	Oral	1 Mg, Qd		Not Reported	

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

Lovastatin	C	Oral	20.0 Mg, Qd	Not Reported
Metoprolol Tartrate	C	Oral	25 Mg, Bid	Not Reported
Alprazolam	C	Oral	0.25 Mg, Prn	Not Reported
Citalopram Hydrobromide	C	Oral	10 Mg, Qd	Not Reported
Doxycycline Monohydrate	C	Oral	50 Mg, Qd	Not Reported
Methotrexate	C	Subcutaneous	20 Mg, Qw	Not Reported
Enalapril Hctz	C	Oral	1 Df, Qd	Not Reported
Hydroxychloroquine	C	Oral	200 Mg, Bid	Not Reported
Ibuprofen	C	Oral	400 Mg, Prn	Not Reported
Vitamin D Nos	C	Oral	5000 Iu, Qd	Not Reported
Claritin-D	C	Oral	1 Df, Qd	Not Reported
Fish Oil	C	Oral	2000 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2016	11983341	EXPEDITED (15-DAY)		DS, HO, OT	GB-MYLANLABS-2016M1003137			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Discomfort; Ototoxicity	Azithromycin			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2016	11984120	NON-EXPEDITED			US-APOTEX-2015AP015474			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oropharyngeal Pain; Stomatitis	Azithromycin			S	Unknown			Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2016	11984805	NON-EXPEDITED			US-PFIZER INC-2016050192			Male	USA

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

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Cordarone	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer
	Tiazac	S	Unk	Not Reported
	Plendil	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported
	Cozaar	S	Unk	Not Reported
	Diovan	S	Unk	Not Reported
	Albuterol Sulfate	S	Unk	Not Reported
	Norco	S	Unk	Not Reported
	Tramadol Hcl	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2016	11984894	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016046034			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Encephalopathy	Zithromac			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2016	11987467	DIRECT		OT			30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Fear; Feeling Abnormal; Postural Orthostatic Tachycardia Syndrome; Restlessness	Azithromycin			S	Oral	2 10ml By Mouth For 6 Days Once Daily Taken By Mouth		Not Reported
	Atenolol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2016	11113086	EXPEDITED (15-DAY)		HO, LT	IT-PFIZER INC-2015161030		48 YR	Male	ITA

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

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

Autoimmune Hepatitis; Hepatitis Acute	Amoxicillin Trihydrate	S	Oral	3 G, Daily	Pfizer
	Azithromycin	S	Oral	500 Mg, Daily	Pfizer
	Deflazacort	S	Oral	30 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2016	11857577	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2015M1043805			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance; Treatment Failure	Azithromycin			S		Unk		Not Reported	
	Clarithromycin			S				Not Reported	
	Amoxicillin/Clavulanic Acid			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2016	11888521	EXPEDITED (15-DAY)		DE, OT	FR-TEVA-622942ISR		4 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Diarrhoea; Drug Interaction; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents; Vomiting	Zithromax			S	Unknown			Not Reported	
	Colchicine			S	Unknown	.5 Mg/Kg Daily; 2 Consecutive Days 8 Mg Of Colchicine		Not Reported	
	Paracetamol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2016	11988276	NON-EXPEDITED			US-PFIZER INC-2016057049		81 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Advil			S		Unk		Pfizer	
	Septra			S		Unk		Pfizer	
	Amlodipine Besilate			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Protonix			S		Unk		Pfizer	

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

Azithromycin	S	Unk	Pfizer
Ciprofloxacin	S	Unk	Unknown
Amoxicillin	S	Unk	Pfizer
Enalapril	S	Unk	Not Reported
Benadryl	S	Unk	Not Reported
Iodine	S	Unk	Not Reported
Motrin	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2016	11112798	EXPEDITED (15-DAY)		HO	PHHY2015US035365		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain; Ascites; Breast Cancer Metastatic; Clostridium Difficile Colitis; Diarrhoea; Gastrointestinal Toxicity; Hepatic Enzyme Abnormal; Intestinal Dilatation; Malignant Neoplasm Progression; Metastases To Liver; Pyrexia; Urinary Tract Infection	Generic Letrozole			S	Oral	2.5 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Palbociclib			S	Oral	125 Mg, Cyclic (Once Daily, 3 Weeks On/1 Week Off, Every 28 Days Cycle)		Not Reported
	Kytril			C	Oral	1 Mg, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2016	11937845	EXPEDITED (15-DAY)		HO	US-HOSPIRA-3140818		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Obstructive Pulmonary Disease; Gastroenteritis	Citalopram			C	Oral			Not Reported
	Ceftriaxone Sodium			S	Intravenous bolus			Not Reported
	Ceftriaxone Sodium			S	Intravenous bolus			Not Reported

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

Azithromycin	S	Intravenous bolus		Not Reported
Azithromycin	S	Intravenous bolus		Not Reported
Famotidine	C	Oral		Not Reported
Loperamide	C	Oral	Once	Not Reported
Citalopram Hydrobromide	C	Oral		Not Reported
Enalapril W/Hydrochlorothiazide	C	Oral	Enalapril 10 Mg/Hydrochlorothiazide 25 Mg	Not Reported
Claritin-D	C	Oral		Not Reported
Fluarix Quadrivalent	C	Intramuscular	Once	Not Reported
Doxycycline Monohydrate	C	Oral		Not Reported
Fish Oil	C	Oral		Not Reported
Acetaminophen	C	Oral		Not Reported
Ranitidine	C	Oral		Not Reported
Lovastatin	C	Oral		Not Reported
Metoprolol Tartrate	C	Oral		Not Reported
Metoprolol Tartrate	C	Oral		Not Reported
Ergocalciferol	C	Oral		Not Reported
Atorvastatin	C	Oral	Qhs	Not Reported
Enoxaparin	C	Subcutaneous		Not Reported
Methylprednisolone	C	Intravenous bolus		Not Reported
Methylprednisolone	C	Intravenous bolus	Single	Not Reported
Ondansetron	C		Once, Iv Push	Not Reported
Potassium Chloride	C		X1 Dose	Not Reported
Potassium Chloride	C		X3 Doses	Not Reported
Folic Acid	C	Oral		Not Reported
Folic Acid	C	Oral		Not Reported
Methotrexate	C	Subcutaneous	Weekly	Not Reported
Ibuprofen	C	Oral		Not Reported
Hydrochlorothiazide	C	Oral		Not Reported

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

	Hydroxychloroquine Sulfate	C	Oral		Not Reported
	Hydroxychloroquine Sulfate	C	Oral		Not Reported
	Duoneb	C		3-9 MI Q3-Q4	Not Reported
	Lisinopril	C	Oral		Not Reported
	Tofacitinib Citrate	S	Oral		Not Reported
	Alprazolam	C	Oral		Not Reported
	Alprazolam	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2016	11978601	NON-EXPEDITED			US-ABBVIE-15K-163-1404164-00		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fibromyalgia;	Humira			S	Subcutaneous			Not Reported	
Haematemesis; Migraine;	Novatrex			S	Unknown			Not Reported	
Oral Herpes; Rhinorrhoea;	Multivitamin			C				Not Reported	
Weight Decreased	Vytorin			C				Not Reported	
	Zoloft			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2016	11998705	DIRECT					67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased	Azithromycin 250 Mg Tablet Pl. Knows Zpack Pliva			S		250 Mg, 2 Pill Today, 1 Pill For 4 Days, Mouth		Pliva	
	Carafate			C				Not Reported	
	Bystolic			C				Not Reported	
	Protonix			C				Not Reported	
	Amlodipine Besylate			C				Not Reported	
	Nexium			C				Not Reported	
	Prednisone			C				Not Reported	
	Aspirin			C				Not Reported	
	Citrucel-Fiber			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2016	11999540	DIRECT		DE, HO			84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Pneumonia	Kenalog Azithromycin			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2016	11999893	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error	Azithromycin			S	Oral	Suspension Oral 200 Mg Per 5 ML Bottle 15 ML In 1 Bottle		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2016	11983497	EXPEDITED (15-DAY)		OT	IT-JNJFOC- 20160123118		43 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hepatotoxicity	Tramadol Hydrochloride			S	Unknown			Not Reported	
	Atovaquone			S	Unknown			Not Reported	
	Pregabalin			S	Unknown			Not Reported	
	Raltegravir			S	Unknown			Not Reported	
	Delorazepam			S	Oral			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Emtricitabine W/Tenofovir			S	Unknown			Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)			Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)			Not Reported	

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

Haloperidol	S	Oral	Not Reported
Voriconazole	S	Oral	Not Reported
Voriconazole	S	Unknown	Not Reported
Voriconazole	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2016	11999818	EXPEDITED (15-DAY)		OT	SE-LUPIN PHARMACEUTICALS INC.-2016-00557			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Unknown	1 G		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2016	11999821	EXPEDITED (15-DAY)		OT	SE-LUPIN PHARMACEUTICALS INC.-2016-00560			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Unknown	500 Mg On Day 0		Not Reported	
	Azithromycin			S	Unknown	250 Mg On Days 1-4 (1.5 G)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2016	11999826	EXPEDITED (15-DAY)		OT	SE-LUPIN PHARMACEUTICALS INC.-2016-00561			Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Unknown	500 Mg On Day 0		Not Reported	
	Azithromycin			S	Unknown	250 Mg On Day 1-4 (1.5g)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2016	11999829	EXPEDITED (15-DAY)		OT	SE-LUPIN PHARMACEUTICALS INC.-2016-00562			Male	SWE

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Resistance	Azithromycin			S	Unknown	500 Mg On Day 0		Not Reported	
	Azithromycin			S	Unknown	250 Mg On Day 1-4 (1.5g)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12001179	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2016M1004312			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury; Toxicity To Various Agents	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12001202	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2016M1004500			Unknown	SWE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pathogen Resistance	Azithromycin			S	Unknown	1 G Single Dose		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Feb-2016	12010171	DIRECT		LT			22 DAY	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Urine Present; Chromaturia	Azithromycin 250mg			S	Oral	4 Pills At Once		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Feb-2016	11570208	NON-EXPEDITED			US-PFIZER INC-2015319400		80 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise; Micturition Urgency; Nausea; Oedema Peripheral; Vomiting	Norvasc			S	Oral	5 Mg, Daily		Pfizer	
	Norvasc			S	Oral	5 Mg, Daily		Pfizer	
	Metoprolol Tartrate			S	Oral	25 Mg, 2x/Day		Not Reported	

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

Azasite	S	Ophthalmic	1 Gtt, 2x/Day (Instill 1 Drop In The Affected Eye(S) Twice Daily 8 To 12 Hours Apart For The 1st 2 D	Not Reported
Aspirin	C	Oral	81 Mg, Daily	Not Reported
Aspirin	C	Oral	81 Mg, Unk	Not Reported
Albuterol Sulfate	C		Unk, 4x/Day ((2.5 Mg/3ml) 0.083% Inhalation Nebulization Solution)	Not Reported
Albuterol Sulfate	C		As Needed (Every 4 To 6 Hours)	Not Reported
Amlodipine Besylate	C		5 Mg, Daily	Not Reported
Zyrtec	C	Oral	10 Mg, 1x/Day (Take One Tab Po At Hs)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2016	12009275	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2016AP006194		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxicity To Various Agents	Azithromycin			S	Unknown			Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2016	12009810	EXPEDITED (15-DAY)		HO, OT	US-WATSON-2015-27508		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Haemodialysis; Tubulointerstitial Nephritis	Azithromycin (Unknown)			S	Unknown	500 Mg, Daily On Day 1		Not Reported	
	Azithromycin (Unknown)			S	Unknown	250 Mg, Daily On Day 2-5		Not Reported	
	Benazepril Hydrochloride (Actavis Laboratories FI)			S	Unknown	Unk		Actavis	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2016	12009966	EXPEDITED (15-DAY)		OT	RU-TEVA-628878ISR		3 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Neurosis; Vomiting	Sumamed Forte Sirup			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2016	12037519	DIRECT		DS			38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Zithromax			S	Oral	500mg X 1 Day 250mg Tab X 4 Da Once Daily Taken By Mouth		Pfizer	
	Vitamin B			C				Not Reported	
	Vitamin C			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Vitamin E			C				Not Reported	
	Multivitamin			C				Not Reported	
	Magnesium			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2016	11124170	EXPEDITED (15-DAY)		HO, LT	IT-AUROBINDO-AUR-APL-2015-04383		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Autoimmune Hepatitis; Blood Bilirubin Increased; Hepatic Cirrhosis; Hepatitis Acute	Amoxicillin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Oral	500 Mg, Daily		Aurobindo	
	Deflazacort			S	Oral	30 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2016	12022208	NON-EXPEDITED			US-ABBVIE-15K-163-1468628-00		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Humira			S	Unknown			Not Reported	
Constipation; Diarrhoea;	Z-Pack			S	Unknown	Took Only 1 Prescribed Dose		Not Reported	
Malaise; Nausea; Upper Respiratory Tract Infection									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2016	12027724	NON-EXPEDITED			US-ABBVIE-15K-163-1494056-00		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Triglycerides Increased;	Humira			S	Subcutaneous			Not Reported	
Blood Triglycerides Increased;	Azithromycin			S	Unknown			Not Reported	
Dizziness; Inner Ear Disorder; Nausea; Product Dose Omission;	Antivert			S	Unknown			Not Reported	
Somnolence; Vertigo	Sulfasalazine			C				Not Reported	
	Lomotil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	11837800	EXPEDITED (15-DAY)		HO, LT	FR-JNJFOC-20151210691		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diffuse Large B-Cell Lymphoma	Remicade			S	Intravenous (not otherwise specified)	In 250 MI Nacl 0.9%		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Every 8/9 Weeks		Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Methotrexate			S	Oral			Not Reported	

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

Methotrexate	S	Oral		Not Reported
Azithromycine	S	Oral	On Monday	Not Reported
Azithromycine	S	Oral	On Monday	Not Reported
Azithromycine	S	Oral	On Monday	Not Reported
Azithromycine	S	Oral		Not Reported
Azithromycine	S	Oral		Not Reported
Azithromycine	S	Oral	On Monday	Not Reported
Speciafoldine	C	Unknown	In The Morning	Not Reported
Crestor	C	Unknown		Not Reported
Uvedose	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	11891404	EXPEDITED (15-DAY)	HO		IT-ROCHE-1689518		64 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Leukopenia; Pyrexia	Rocefin			S	Intramuscular			Not Reported
	Augmentin			S	Oral	'875 Mg/125 Mg Film-Coated Tablets' 12 Tablets		Not Reported
	Zithromax			S	Oral	'500 Mg Film-Coated Tablets' 3 Tablets		Not Reported
	Deltacortene			C	Oral	'25 Mg Tablets' 10 Tablets		Not Reported
	Levoxacin			C	Oral	'500 Mg Film-Coated Tablets' 5 Tablets		Not Reported
	Asacol			C	Oral	'800 Mg Gastroresistant Tablets' 24 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	11903101	EXPEDITED (15-DAY)	HO, OT		IT-PFIZER INC-2016003032		59 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Drug-Induced Liver	Azithromycin			S	Oral	500 Mg, Daily		Pfizer

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

Injury; Pain In Extremity; Pyrexia Veclam S Oral 500 Mg, Daily Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	11928041	EXPEDITED (15-DAY)		OT	BE-GLAXOSMITHKLINE-BE2016GSK006391		59 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Macular Oedema; Vision Blurred	Epoprostenol Sodium			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Zolpidem			C		1/ Day		Not Reported
	Lormetazepam			C		2 Mg, Unk		Not Reported
	Zyloric			C		100 Mg, Bid		Not Reported
	Opsumit			C		Unk		Not Reported
	Adcirca			C		Unk		Not Reported
	Pantoprazole			C		20 Mg, Bid		Not Reported
	Burinex			C		1.5 Df, Qd		Not Reported
	Spironolactone			C		1 Df, Qd		Not Reported
	Spironolactone			C		2 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	11965584	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2016-00310		4 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Poisoning; Circulatory Collapse; Diarrhoea; Inappropriate Schedule Of Product Administration; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents; Vomiting	Azithromycin			S	Unknown			Aurobindo
	Colchicine			S	Unknown	2 Consecutive Days 8 Mg Of Colchicine		Not Reported
	Colchicine			S		2 Consecutive Days 8 Mg Of Colchicine At 0,5 Mg/Kg/Day		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	12037153	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-01121		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxicity To Various Agents	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	12037958	NON-EXPEDITED			US-ABBVIE-15K-163-1526984-00			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection; Pyrexia; Urticaria	Humira			S	Subcutaneous			Not Reported	
	Z-Pack			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	12046398	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016050247		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cough; Dyspnoea; Fatigue; Hepatic Enzyme Increased; Hyperhidrosis; Pharyngeal Swelling; Pneumonia; Pneumonia Haemophilus; Pneumonia Klebsiella; Retching	Ampicillin Sodium			S		Unk		Unknown	
	Ampicillin Sodium			S				Unknown	
	Ampicillin Sodium			S				Unknown	
	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Zithromax			S				Pfizer	
	Humira			S	Subcutaneous	40 Mg, Unk, (1 In 2 Wk)		Not Reported	
	Methotrexate			S	Oral	2.5 Mg, Unk, (7 Pills Every Sunday Night) (1 In 1 Wk)		Not Reported	
	Lisinopril			C		20 Mg, 2x/Day		Not Reported	
	Ibuprofen			C	Oral	800 Mg, 3x/Day		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	12047148	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2016065629		84 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased; Purpura	Zithromax			S		500 Mg, For 3 Days		Pfizer	
	Lipitor			C		Unk		Not Reported	
	Carloc			C		Unk		Not Reported	
	Warfarin			C		Unk		Not Reported	
	Lanolin			C		Unk		Not Reported	
	Puresis			C		Unk		Not Reported	
	Hypnor /00377801/			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2016	12050640	DIRECT					63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rotator Cuff Syndrome; Tendon Injury; Urticaria	Z Pak			S				Not Reported	
	Vitamins			C				Not Reported	
	Fish Oil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2016	8970175	NON-EXPEDITED			US-PFIZER INC-2012313961		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2016	12047666	EXPEDITED (15-DAY)		HO	US-HOSPIRA-3157464		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Condition Aggravated;	Methotrexate	S	Not Reported
Cough; Dyspnoea;	Humira	S	Not Reported
Fatigue; Hepatic Enzyme	Ampicillin Sodium	S	Not Reported
Increased; Hyperhidrosis;	Zithromax	S	Not Reported
Pharyngeal Swelling;			
Pneumonia Haemophilus;			
Pneumonia Klebsiella;			
Retching			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2016	12054221	NON-EXPEDITED			US-PFIZER INC- 2016022648			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2016	12056870	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2016067469			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Blood Urea Increased; Haemorrhage	Zithromac			S	Intravenous drip	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	11906217	EXPEDITED (15-DAY)		DE, OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-109408			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose;	Zithromax			S	Unknown	Unk		Not Reported
Diarrhoea; Drug	Colchicine			S	Unknown	2 Consecutive Days 8 Mg Of Colchicine		Not Reported
Interaction; Multiple Organ Dysfunction Syndrome;	Paracetamol			C	Unknown			Not Reported
Toxicity To Various Agents; Vomiting								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	12058551	EXPEDITED (15-DAY)		DE, HO, OT	US-GLENMARK PHARMACEUTICALS INC, USA.- 2016GMK02201		37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Infection; Citrobacter Infection; Multiple-Drug Resistance; Sepsis	Trimethoprim Sulfamethoxazole			S		Unk		Glenmark	
	Azithromycin			S		Unk		Not Reported	
	Ganciclovir			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	12061495	NON-EXPEDITED			US-PFIZER INC- 2016057137			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	12061515	NON-EXPEDITED			US-PFIZER INC- 2016060645			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	12061531	NON-EXPEDITED			US-PFIZER INC- 2016057675			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	

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

Levaquin	S	Unk	Not Reported
Augmentin	S	Unk	Not Reported
Ceftin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	12065781	DIRECT		OT			20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperglycaemic	Rocephin			S	Intramuscular			Not Reported	
Hyperosmolar Nonketotic Syndrome; Urticaria	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2016	12066798	DIRECT		HO			23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Abdominal Pain Upper; Diarrhoea; Dyspnoea; Headache	Azithromycin 250 Mg Teva Pharmaceutical Usa, Inc			S	Oral	6 2 First Day, 1daily Taken By Mouth		Teva	
	Ibuprofen			C				Not Reported	
	Proair Hfa			C				Not Reported	
	Trisprintec			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	11892710	NON-EXPEDITED			US-PFIZER INC-2015439324			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Disorder; Pallor; Reaction To Excipient; Vomiting	Azithromycin			S		250 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	11908151	EXPEDITED (15-DAY)		HO	IT-ABBVIE-16P-083-1535064-00		59 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Chills; Drug-Induced Liver Injury; Pain In Extremity; Pyrexia	Veclam		S	Oral					Not Reported
	Azithromycin		S	Oral					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	11990013	NON-EXPEDITED			US-PFIZER INC-2016020446		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Eye Disorder; Gingival Blister; Oral Mucosal Blistering; Rash Erythematous; Scar; Self Esteem Decreased; Skin Exfoliation; Skin Lesion	Zithromax			S	Oral	250 Mg, 2x/Day Orally		Pfizer	
	Tylenol			C		Weekly; 500mg, One To Two Tablets A Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	12070905	NON-EXPEDITED			US-AKORN-19667			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Pain; Wrong Technique In Product Usage Process	Azasite 1% Inspire			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2016	12073216	DIRECT		DS			56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis	Azithromycin Pfizer			S	Oral	1 Pill Mwf Taken By Mouth		Pfizer	
	Prograf			C				Not Reported	
	Azathioprine			C				Not Reported	
	Amlodipine			C				Not Reported	
	Bactrim/Sulfa			C				Not Reported	
	Trazadone			C				Not Reported	
	Wellbutrin			C				Not Reported	
	Valtrex			C				Not Reported	
	Pantoprazole			C				Not Reported	

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

Prednisone	C	Not Reported
Calcium	C	Not Reported
Vit D	C	Not Reported
Multi Vitamin	C	Not Reported
Baby Aspirin	C	Not Reported
Vit B	C	Not Reported
Fish Oil	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2016	11879574	NON-EXPEDITED			US-PFIZER INC-2015452092			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2016	12073040	NON-EXPEDITED			US-PFIZER INC-2016031397		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Decreased Appetite; Diarrhoea; Faeces Discoloured; Fatigue; Gastrointestinal Disorder; Paraesthesia; Rash; Vomiting	Zithromax			S		250 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2016	12075768	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-02239			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S	Unknown	Unk		Aurobindo
	Codeine Sulfate			S	Unknown	Unk		Not Reported
	Darvocet-N			S	Unknown	Unk		Not Reported
	Dexilant			S	Unknown	Unk		Not Reported

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

Endocet	S	Unknown	Unk	Not Reported
Fentanyl	S	Unknown	Unk	Not Reported
Acetaminophen\Hydrocodone Bitartrate	S	Unknown	Unk	Not Reported
Pencillin	S	Unknown	Unk	Not Reported
Percocet /00446701/	S	Unknown	Unk	Not Reported
Robaxin	S	Unknown	Unk	Not Reported
Ultram /00599202/	S	Unknown	Unk	Not Reported
Zithromax	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2016	12075873	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-02954			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash; Urticaria	Amoxicillin			S	Unknown			Aurobindo
	Clindamycin			S	Unknown			Aurobindo
	Septra			S	Unknown			Not Reported
	Penicillin /00000901/			S	Unknown			Not Reported
	Cefazolin			S	Unknown			Not Reported
	Flagyl /00012501/			S	Unknown			Not Reported
	Zithromax			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2016	12078405	EXPEDITED (15-DAY)		DE, HO, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-111599			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Drug Ineffective; Furuncle; Septic Shock; Staphylococcal Infection	Prednisolone			S	Oral	20 Mg, Daily		Taro
	Prednisolone			S	Unknown	40 Mg, Unk		Taro
	Piperacillin/Tazobactam			S	Unknown			Not Reported

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

		Azithromycin	S	Unknown				Sun	
		Vancomycin Hydrochloride	S	Intravenous (not otherwise specified)				Not Reported	
		Trimethoprim/Sulfamethoxazole	C	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2016	12079931	NON-EXPEDITED			US-PFIZER INC-2016080469		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Prednisone			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2016	12081060	EXPEDITED (15-DAY)		OT	FI-PFIZER INC-2016068289		12 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Chills; Dry Mouth; Feeling Abnormal; Hallucination; Malaise; Mydriasis; Skin Tightness	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2016	12081958	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-00303			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Amoxicillin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2016	12083923	DIRECT		OT			54 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abdominal Pain Upper; Agitation; Chills; Dizziness; Dysphagia; Dyspnoea; Fatigue; Hyperhidrosis; Muscular Weakness; Nausea; Nervousness; Restlessness; Speech Disorder; Vertigo; Vision Blurred; Vomiting	Azithromycin 250 Mg Teva Pharmaceuticals			S	Oral	6 Pills Once Daily Taken By Mouth		Teva
	Atorvastatin			C				Not Reported
	Robitussin Dm			C				Not Reported
	Ibuprofen			C				Not Reported
	Mulberry Leaf Extract Tablets			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2016	12088228	DIRECT		DS			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Unilateral	Azithromycin			S	Oral	2 Pills First Day 1 Pill Per Da Once Daily Taken By Mouth		Greenstone
	Atenolol			C				Not Reported
	Losarton			C				Not Reported
	Meteor In			C				Not Reported
	Glimepiride			C				Not Reported
	Furosemide			C				Not Reported
	Levothyroxin			C				Not Reported
	Allopurinol			C				Not Reported
	Montelukast			C				Not Reported
	Lovastatin			C				Not Reported
	Advair			C				Not Reported
	Zometa			C				Not Reported
	Tamoxifen			C				Not Reported
	B-12			C				Not Reported
	D-3			C				Not Reported
	Fish Oil			C				Not Reported
	81 Mg Baby Aspirin			C				Not Reported
	Calcium Plus D3			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	11950625	NON-EXPEDITED			US-PFIZER INC-2015476417		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Cardura			S		Unk		Pfizer	
	Arthrotec			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Norvasc			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Daypro			S		Unk		Pfizer	
	Pantoprazole			S		Unk		Pfizer	
	Omeprazole			S		Unk		Not Reported	
	Cefzil			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Cozaar			S		Unk		Not Reported	
	Pilocarpine			S		Unk		Not Reported	
	Vasotec			S		Unk		Not Reported	
	Tenex			S		Unk		Not Reported	
	Clarinx			S		Unk		Not Reported	
	Flonase			S		Unk		Not Reported	
	Zestoretic			S		Unk		Not Reported	
	Ceftin			S		Unk		Not Reported	
	Prevacid			S		Unk		Not Reported	
	Ferrous Sulfate			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	
	Methadone			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12083681	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016081529		92 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Oedema	Zithromax			S	Oral	250.0 Mg, Unk		Pfizer	
	Zithromax			S	Oral	500.0 Mg, Single		Pfizer	
	Seroquel			C				Not Reported	
	Tylenol			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Voltaren			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12084398	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2016019440		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Tanzeum Solution For Injection In Pre-Filled Pen			S	Intravenous (not otherwise specified)	30 Mg, We		Glaxosmithkline	
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12088087	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2014-12543			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S	Unknown			Aurobindo	
	Azathioprine			S	Unknown			Not Reported	
	Bentyl			S	Unknown			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Ditropan			S	Unknown			Not Reported	
	Omeprazole			S	Unknown			Not Reported	
	Sulfa /00076401/			S	Unknown			Not Reported	

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

Zithromax	S	Unknown	Not Reported
Zovirax /00587301/	C	Unknown	Not Reported
Tums /00193601/	C	Unknown	Not Reported
Cortef /00028601/	C	Unknown	Not Reported
Imodium	C	Unknown	Not Reported
Ativan	C	Unknown	Not Reported
Magnesium	C	Unknown	Not Reported
Zofran /00955301/	C	Unknown	Not Reported
Protonix	C	Unknown	Not Reported
Tacrolimus	C	Unknown	Not Reported
Actigall	C	Unknown	Not Reported
Toviaz	C	Unknown	Not Reported

1 Df, Daily

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2016	12088097	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2014-12529			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S	Unknown			Aurobindo
	Azithromycin			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported
	Macrobid /00024401/			S	Unknown			Not Reported
	Pencillin			S	Unknown			Not Reported
	Effexor Xr			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2016	11938453	NON-EXPEDITED			US-PFIZER INC- 2016012693		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer

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

	Erythromycin		S		Unk		Pfizer		
	Azithromycin		S		Unk		Pfizer		
	Bactrim		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2016	12089689	NON-EXPEDITED			US-PFIZER INC-2016047199			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Tegretol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2016	12091716	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-03621		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S	Unknown			Aurobindo	
	Zithromax			S	Unknown			Not Reported	
	Biaxin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2016	12092986	DIRECT					70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthralgia; Gait Disturbance	Azithromycin			S	Oral	6 Pills 2 First Day 1 A Day After Mouth		Sandoz	
	Anacin			C				Not Reported	
	A Complex			C				Not Reported	
	B Vitamins			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2016	12093393	DIRECT					77 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoacusis	Azithromycin			S	Oral			Teva
	Exemestane			C				Not Reported
	Thyroxine			C				Not Reported
	Medication For Cholesterol			C				Not Reported
	Vitamin C			C				Not Reported
	Calcium			C				Not Reported
	Geritol			C				Not Reported
	Fish Oil			C				Not Reported
	Low Dose Aspirin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	9924591	NON-EXPEDITED			US-PFIZER INC-2014048073		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12092169	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04387		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tubulointerstitial Nephritis	Azithromycin			S	Unknown	Day 1		Not Reported
	Azithromycin			S	Unknown	For 4 Days		Not Reported
	Aspirin			C	Oral	81 Mg		Not Reported
	Atorvastatin			C	Oral	20 Mg		Not Reported
	Ezetimibe			C	Oral	10 Mg		Not Reported
	Insulin Glargine			C	Subcutaneous	40 Units		Not Reported
	Insulin Aspart			C	Unknown	According To A Sliding Scale		Not Reported
	Irbesartan			C	Oral	75 Mg		Not Reported

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

	Metoprolol Succinate	C	Oral	50 Mg				Not Reported	
	Multivitamin	C	Oral					Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12092172	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2015-04391		59 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Kidney Injury; Hypersensitivity	Azithromycin			S	Oral	Day 1		Not Reported	
	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12092174	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2016-00043		81 YR	Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Glossitis	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Co-Trimoxazole			S	Unknown			Not Reported	
	Foscarnet			C	Unknown	2.4 Mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12092175	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04388		43 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tubulointerstitial Nephritis	Azithromycin			S	Unknown	250 Mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12092176	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04390		16 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Tubulointerstitial Nephritis		Azithromycin		S	Unknown	10 Mg/Kg/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12092550	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2015-04389		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tubulointerstitial Nephritis	Azithromycin			S	Unknown	6 Mg/Kg		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12092555	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2015-04227		18 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	500 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12092977	NON-EXPEDITED			US-PFIZER INC- 2016050225			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2016	12094040	EXPEDITED (15-DAY)		HO	US-ABBVIE-16K-163- 1560333-00		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Humira			S	Subcutaneous			Not Reported	
Crohn'S Disease; Crohn'S	Z-Pack			S	Unknown			Not Reported	
Disease; Crohn'S Disease;	Budesonide			C	Oral			Not Reported	
Drug Ineffective;	Budesonide			C	Oral			Not Reported	
Nasopharyngitis; Small									
Intestinal Obstruction									

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

Budesonide C Oral 10-Apr-2016 Predicted Stop Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12094958	EXPEDITED (15-DAY)			UA-PERNIX THERAPEUTICS-2015PT000167			Unknown	UKR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Cedax			S	Oral	400 Mg, Daily		Pernix
	Ceftriaxone Sodium			S	Intramuscular	1 G, Twice Daily		Not Reported
	Azithromycin			S	Oral	500 Mg, Daily		Not Reported
	Lasolvan			C				Not Reported
	Aerofillinum			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12095169	NON-EXPEDITED			US-PFIZER INC-2016046832			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pruritus; Rash	Azithromycin			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2016	12095171	NON-EXPEDITED			US-PFIZER INC-2016051540		69 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Pressure Increased;	Azithromycin			S		Unk		Pfizer
Gastric Disorder; Heart	Atenolol			C		Unk		Not Reported
Rate Increased	Quinapril			C		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2016	11865606	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2015462475		69 YR	Female	JPN

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

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

Abdominal Pain; Loss Of Consciousness; Road Traffic Accident	Zithromac	S	Oral	500 Mg, Daily	Pfizer
	Thyradin	C		Unk	Not Reported
	Depas (Etizolam)	C		Unk	Not Reported
	Loxonin	C	Oral	Unk	Not Reported
	Ebastel	C		5 Mg, 2x/Day	Not Reported
	Carbocisteine	C		250 Mg, 2x/Day	Not Reported
	Klaricid	C		50 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12055771	NON-EXPEDITED			US-PFIZER INC-2016075646		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12099193	NON-EXPEDITED			US-PFIZER INC-2016053459			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12099322	NON-EXPEDITED			US-TEVA-591725USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Amoxicillin			S	Oral	1500 Milligram Daily;		Teva	
	Azithromycin			S	Unknown	Stopped At Day Two Of Five		Not Reported	

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

Alka-Seltzer			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12099357	NON-EXPEDITED			US-TEVA-599827USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
	Amitriptyline			S	Unknown			Teva	
	Lisinopril And Hydrochlorothiazide			S	Unknown			Ivax	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12099403	NON-EXPEDITED			US-TEVA-576219USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S	Unknown			Teva	
	Penicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2016	12099744	EXPEDITED (15-DAY)		LT	GR-TEVA-637207ISR		60 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterium Avium Complex Infection; Pathogen Resistance	Azithromycin			S				Not Reported	
	Isoniazid			C				Not Reported	
	Rifampicin			C				Not Reported	
	Ethambutol			C				Not Reported	
	Pyrazinamide			C				Not Reported	
	Amikacin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2016	11323883	NON-EXPEDITED			US-MYLANLABS-2015M1008972			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Irritable Bowel Syndrome; Rash; Skin Exfoliation	Azithromycin			S		Unk		Not Reported	
	Simvastatin			S		40 Mg, Qd		Not Reported	
	Simvastatin			S		40 Mg, Qd		Not Reported	
	Multivitamin /00097801/			C		Unk		Mylan	
	Ginko Biloba			C		Unk		Mylan	
	Fibertab			C		Unk		Mylan	
	Probiotics /07325001/			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2016	11339808	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2015-06787		64 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria	Azithromycin			S	Unknown	1 Df, Daily		Aurobindo	
	Paracetamol			S	Oral	1 Df, Daily		Not Reported	
	Tantum Verde			S		1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2016	12106298	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016101720		40 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Zithromac			S	Oral			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2016	12106301	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2016100547			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Emotional Distress; Eye Irritation; Nervous System Disorder;	Azithromycin			S	Oral	Unk		Pfizer	
	Flucloxacillin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pain; Paraesthesia;
Seizure; Staphylococcal
Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2016	12107300	EXPEDITED (15-DAY)		OT	PHHY2016GB021779			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Emotional Distress; Eye Irritation; Nervous System Disorder; Pain; Paraesthesia; Seizure; Staphylococcal Infection	Azithromycin Flucloxacillin			S S	Oral Unknown			Novartis Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2016	12109261	NON-EXPEDITED			US-PFIZER INC- 2016061072		8 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash; Urticaria	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2016	12111096	NON-EXPEDITED			US-PFIZER INC- 2016103506			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Insomnia	Azithromycin Lisinopril Asmanex Asmanex			S S S S		Unk Unk 2 Df, 2x/Day (Two Puffs)		Pfizer Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2016	12111557	EXPEDITED (15-DAY)		HO, LT, OT	US-FRESENIUS KABI- FK201600899		47 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Long Qt Syndrome; Mitral Valve Disease; Ventricular Fibrillation	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2016	12111857	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2016M1007182			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Maternal Exposure During Pregnancy; Normal Newborn; Septic Shock	Azithromycin			S	Unknown			Not Reported
	Dobutamine			S	Unknown			Not Reported
	Dopamine			S	Unknown			Not Reported
	Furosemide			S	Intravenous (not otherwise specified)			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Hydralazine			S	Unknown			Not Reported
	Liothyronine			S	Intravenous bolus	10 Mcg		Not Reported
	Metoprolol			S	Unknown			Not Reported
	Milrinone			S	Unknown	0.375 Mcg/Kg/Min		Not Reported
	Heparin			S	Intravenous (not otherwise specified)	Unk		Mylan
	Nitric Oxide			S	Unknown	20 Ppm		Mylan
	Oseltamivir			S	Unknown			Mylan
	Piperacillin			S	Unknown			Mylan
	Tazobactam			S	Unknown			Mylan
	Vasopressin			S	Unknown	0.1 Units/Min		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2016	12111866	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2016M1007578			Unknown	USA

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

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

Cerebral Ventricle Dilatation; Foetal Exposure During Pregnancy	Azithromycin	S	Transplacental		Not Reported
	Azithromycin	S		Unk	Not Reported
	Dobutamine	S	Transplacental		Not Reported
	Dopamine	S	Transplacental		Not Reported
	Furosemide	S	Transplacental		Not Reported
	Vancomycin	S	Transplacental		Not Reported
	Hydralazine	S	Transplacental		Not Reported
	Liothyronine	S	Transplacental	10 Mcg	Not Reported
	Metoprolol	S	Transplacental		Not Reported
	Milrinone	S	Transplacental	0.375 Mcg/Kg/Min	Not Reported
	Heparin	S	Transplacental		Mylan
	Nitric Oxide	S	Transplacental	20 Ppm	Mylan
	Oseltamivir	S	Transplacental		Mylan
	Piperacillin	S	Transplacental		Mylan
	Tazobactam	S	Transplacental		Mylan
	Vasopressin	S	Transplacental	0.1 Units/Min	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12113218	EXPEDITED (15-DAY)		OT	PHHY2016GB023272		49 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Dizziness; Drug Interaction; Extrasystoles; Heart Rate Decreased	Azithromycin			S	Oral	500 Mg, Qd, For 3 Days		Novartis
	Salmeterol			S	Unknown	200 Ug, Qd		Not Reported
	Budesonide			C	Unknown			Not Reported
	Salbutamol Sulfate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12113585	EXPEDITED (15-DAY)		LT	GR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016R1-112083		60 YR	Female	GRC

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterium Avium Complex Infection; Pathogen Resistance	Azithromycin			S	Unknown	250 Mg, 3/Week		Sun	
	Isoniazid			C	Unknown	Unk		Not Reported	
	Rifampicin			C	Unknown	Unk		Not Reported	
	Ethambutol			C	Unknown	Unk		Not Reported	
	Pyrazinamide			C	Unknown	Unk		Not Reported	
	Amikacin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12113935	NON-EXPEDITED			US-PFIZER INC-2016050418		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Blood Pressure Increased; Heart Rate Increased	Azithromycin			S		250 Mg, Unk		Pfizer	
	Accupril			C		10 Mg, Unk		Not Reported	
	Atenolol			C		25 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12113957	NON-EXPEDITED			US-PFIZER INC-2016062608		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Palpitations	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12115492	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2016106512		49 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Extrasystoles; Heart Rate Decreased	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Salmeterol Xinafoate			S		200 Ug, 1x/Day		Not Reported	
	Budesonide			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Salbutamol Sulfate			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12116295	NON-EXPEDITED			US-MYLANLABS-US2013293169		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin			S		Unk		Not Reported	
	Doxycycline			S		Unk		Not Reported	
	Doxycycline			S				Not Reported	
	Vancomycin			S		Unk		Not Reported	
	Zithromax			S		Unk		Mylan	
	Lisinopril			S		Unk		Mylan	
	Ampicillin			S		Unk		Not Reported	
	Lincomycin Hcl			S		Unk		Mylan	
	Percodan			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12116314	NON-EXPEDITED			US-PFIZER INC-2016067978			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12116498	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2016M1007661			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Condition Aggravated; Cough; Drug Ineffective; Focal Segmental Glomerulosclerosis; Haematuria; Myalgia;	Azithromycin			S		Unk		Not Reported	
	Ciprofloxacin Mylan			S		Unk		Mylan	

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

Proteinuria; Pulmonary
Mass; Purulent Discharge;
Rhinorrhoea; Vasculitis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2016	12118548	DIRECT					49 YR	Male	

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Product Substitution Issue	Azithromycin Tablets Usp 250 Mg			S	Oral	2 Pills Day 1 Once Daily Taken By Mouth		Not Reported
	Lisinopril			C				Not Reported
	Singulair			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2016	10720929	NON-EXPEDITED			US-PFIZER INC- 2015016051			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Diarrhoea; Drug Hypersensitivity; Dyspnoea; Nausea; Rash; Urticaria; Vomiting	Procardia			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Clonidine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Proventil			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2016	11995329	NON-EXPEDITED			US-TAKEDA- 2016TEU000698		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Pantoprazole			S	Unknown	Unk		Not Reported
	Prevacid			S	Unknown	Unk		Takeda

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

Cardura	S	Unknown	Unk	Not Reported
Arthrotec	S	Unknown	Unk	Not Reported
Zithromax	S	Unknown	Unk	Not Reported
Gabapentin	S	Unknown	Unk	Not Reported
Erythromycin	S	Unknown	Unk	Not Reported
Daypro	S	Unknown	Unk	Not Reported
Omeprazole	S	Unknown	Unk	Not Reported
Cefzil	S	Unknown	Unk	Not Reported
Lisinopril	S	Unknown	Unk	Not Reported
Cozaar	S	Unknown	Unk	Not Reported
Pilocarpine	S	Unknown	Unk	Not Reported
Vasotec /00574902/	S	Unknown	Unk	Not Reported
Tenex	S	Unknown	Unk	Not Reported
Clarinox /01202601/	S	Unknown	Unk	Not Reported
Flonase /00908302/	S	Unknown	Unk	Not Reported
Zestoretic	S	Unknown	Unk	Not Reported
Ceftin /00454603/	S	Unknown	Unk	Not Reported
Ferrous Sulfate	S	Unknown	Unk	Not Reported
Wellbutrin	S	Unknown	Unk	Not Reported
Methadone	S	Unknown	Unk	Not Reported
Norvasc	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2016	12118237	EXPEDITED (15-DAY)		OT	GB-TEVA-636306ACC			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Azithromycin			S	Oral	Unk		Not Reported
Diarrhoea; Emotional	Flucloxacillin			S		Unk		Not Reported
Distress; Eye Irritation;								
Nervous System Disorder;								
Pain; Paraesthesia;								

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

Seizure; Staphylococcal
Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2016	12118531	NON-EXPEDITED			US-PFIZER INC- 2016064909			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cephalexin			S		Unk		Not Reported	
	Tizanidine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2016	12119883	EXPEDITED (15-DAY)		OT	IN-PFIZER INC- 2016106444		35 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous	Azithromycin			S	Oral	500 Mg, For Three Consecutive Days A Week For 4 Weeks		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	11893531	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC- 2015478353		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac	Azithromycin			S	Oral	250 Mg, 2x/Day		Pfizer	
Arrest; Cardiac Disorder;	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
Cardiac Hypertrophy;	Azithromycin			S				Pfizer	
Cardiomegaly; Chest Pain;	Invokana			C		300 Mg, 1x/Day		Not Reported	
Cough; Diabetic	Invokana			C		300 Mg, Unk		Not Reported	
Complication; Diarrhoea;	Invokana			C		Unk		Not Reported	
Drug Ineffective; Dry	Invokana			C				Not Reported	
Mouth; Fatigue;	Glucosine			C				Not Reported	
Gastrointestinal Disorder;	Metformin			C		100 Mg, 2x/Day		Not Reported	
Hepatic Fibrosis; Hepatic	Metformin			C		1000 Mg, 2x/Day		Not Reported	
Steatosis; Hyperhidrosis;									
Hypersensitivity;									

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

Intentional Product Misuse; Nausea; Pneumonia; Pulmonary Oedema; Pyrexia; Vomiting	Metformin	C	1000 Mg, Unk	Not Reported
	Topamax	C	Unk	Not Reported
	Fluoxetine	C	Unk	Not Reported
	Atorvastatin	C	20 Mg, Daily	Not Reported
	Atorvastatin	C	20 Mg, Unk	Not Reported
	Losartan	C	100 Mg, Daily	Not Reported
	Losartan	C	100 Mg, Unk	Not Reported
	Gabapentin	C	2 - 300 Mg, 2x/Day	Not Reported
	Gabapentin	C	300 Mg, Unk	Not Reported
	Vitamin D Nos	C		Not Reported
	Klonopin	C	1 Mg Sns	Not Reported
	Mirtazapine	C	(15 And 8 Day)	Not Reported
	Mirtazapine	C	30 Mg, Daily (Every Night At Bedtime)	Not Reported
	Mirtazapine	C	30 Mg, Unk	Not Reported
	Luvox	C	100 Mg, 1x/Day	Not Reported
	Levoxyl	C	100 Mg, 1x/Day	Not Reported
	Glipizide	C	10 Mg, 1x/Day	Not Reported
	Glipizide	C	10 Mg, Unk	Not Reported
	Topiramate	C	25 Mg, Unk	Not Reported
	Levothyroxine	C	100 Mg, Unk	Not Reported
	Fluvoxamine	C	100 Mg, Unk	Not Reported
	Clonazepam	C	1 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	12124002	NON-EXPEDITED			US-PFIZER INC-2016070710		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Nausea; Product Use In Unapproved Indication;	Azithromycin			S	Oral	8 MI Of The 200mg/5ml Concentration		Pfizer	
	Azithromycin			S				Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pyrexia; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	12124019	NON-EXPEDITED			US-PFIZER INC-2016061084			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Product Prescribing Error	Celebrex			S				Pfizer	
	Effexor Xr			S				Pfizer	
	Azithromycin			S				Pfizer	
	Lorabid			S				Pfizer	
	Cymbalta			S				Not Reported	
	Codeine			S				Not Reported	
	Potassium			S				Not Reported	
	Vioxx			S				Not Reported	
	Bactrim			S				Not Reported	
	Keflex			S				Not Reported	
	Augmentin			S				Not Reported	
	Levaquin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	12126131	EXPEDITED (15-DAY)		HO, LT, OT	US-APOTEX-2016AP006759		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Long Qt Syndrome; Mitral Valve Prolapse	Azithromycin			S	Unknown	Unk, Unknown		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	12126971	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1007435			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Emotional Distress; Eye Irritation; Nervous System Disorder; Pain; Paraesthesia; Seizure; Staphylococcal	Azithromycin			S	Oral	Unk		Not Reported	
	Flucloxacillin			S		Unk		Not Reported	

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

Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	12127937	NON-EXPEDITED			US-PFIZER INC-2016071318			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2016	12132384	DIRECT		DE			67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder	Azithromycin 250mh Vivimed Labes (Alathai Protimate Lt D			S	Oral			Wockhardt	
	Metoprolol			C				Not Reported	
	Meloxicam			C				Not Reported	
	Phospha			C				Not Reported	
	Omeprazole			C				Not Reported	
	Equate Multivitamin			C				Not Reported	
	Equate Aspirin			C				Not Reported	
	Sring Valleyy Vitamin E			C				Not Reported	
	Spring Valley Vitamin D			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2016	11989923	NON-EXPEDITED			US-PFIZER INC-2016018763		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Ear Swelling; Erythema; Pruritus; Swelling; Swelling Face; Urticaria	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Azithromycin			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2016	12131952	NON-EXPEDITED			US-PFIZER INC-2016119319			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Restoril			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2016	12133604	NON-EXPEDITED			US-PFIZER INC-2016079054			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2016	12134311	EXPEDITED (15-DAY)		OT	GB-GLAXOSMITHKLINE-GB2016024546		49 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dizziness; Drug Interaction; Extrasystoles; Heart Rate Decreased	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline	
	Salmeterol Xinafoate			S				Glaxosmithkline	
	Budesonide			C				Not Reported	
	Salbutamol Sulfate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2016	12135197	EXPEDITED (15-DAY)		OT	GB-TEVA-637538ACC		49 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dizziness; Drug Interaction; Extrasystoles; Heart Rate Decreased	Azithromycin			S	Oral	For 3 Days		Not Reported	
	Salmeterol Xinafoate			S				Not Reported	
	Budesonide			C				Not Reported	
	Salbutamol Sulfate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2016	12136365	NON-EXPEDITED			US-PFIZER INC-2016088308			Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2016	12137538	NON-EXPEDITED			US-PFIZER INC-2016079112		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Flushing; Pruritus; Sinusitis	Azithromycin			S		Unk		Pfizer	
	Tecfidera			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2016	12138069	EXPEDITED (15-DAY)		LT, OT	IT-PFIZER INC-2016124118		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Brain Hypoxia; Cardiac Arrest	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Single		Pfizer	
	Nitroglicerina			C	Transdermal	Unk		Not Reported	
	Cardioaspirin			C	Oral	100 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2016	12138886	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1007996			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dizziness; Drug Interaction; Extrasystoles; Heart Rate Decreased	Azithromycin			S	Oral	500 Mg, Qd (For 3 Days)		Not Reported	
	Salmeterol Xinafoate			S		200 Mg, Qd		Mylan	
	Budesonide			C		Unk		Mylan	
	Salbutamol Sulfate			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12139542	EXPEDITED (15-DAY)		HO, LT, OT	US-TEVA-609976USA		47 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Long Qt Syndrome	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12140270	NON-EXPEDITED			US-PFIZER INC-2016084605			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12140967	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2016-0200466		29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Neutropenia; Pneumonia	Viread			S	Unknown			Gilead	
	Vfend			S	Oral	200 Mg, Bid		Not Reported	
	Neurontin			S	Oral	100 Mg, Tid		Not Reported	
	Nitrostat			S	Unknown	1 Df, Prn		Not Reported	
	Protonix /00661201/			S	Oral	40 Mg, Qd		Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Norvir			C	Oral	100 Mg, Qd		Not Reported	
	Prezista			C	Oral	800 Mg, Qd		Not Reported	
	Darunavir			C				Not Reported	
	Combivir			C	Oral	1 Df, Bid		Not Reported	
	Emtriva			C				Not Reported	
	Colace			C	Oral	1 Df, Bid		Not Reported	
	Duoneb			C				Not Reported	
	Duoneb			C				Not Reported	
	Miralax /00754501/			C	Oral	17 G, Qd		Not Reported	

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

Mucinex	C	Oral	1 Df, Unk	Not Reported
Normal Saline	C	Intravenous (not otherwise specified)	250 MI, Unk	Not Reported
Sodium Chloride	C			Not Reported
Tylenol /00020001/	C	Oral	650 Mg, Q4hr	Not Reported
Ultram /00599202/	C	Oral	50 Mg, Q4hr	Not Reported
Zofran /00955301/	C	Intravenous (not otherwise specified)	4 Mg, Q4hr	Not Reported
Zofran /00955301/	C			Not Reported
Albuterol /00139501/	C		1.25 Mg, Tid	Not Reported
Azithromycin	C	Oral	1200 Mg, Unk	Not Reported
Docusate Sodium	C	Oral	100 Mg, Bid	Not Reported
Hydralazine	C	Intravenous (not otherwise specified)	10 Mg, Q4hr	Not Reported
Nystatin	C	Oral	5 MI, Qid	Not Reported
Prednisone	C	Oral	40 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12142100	NON-EXPEDITED			US-PFIZER INC-2016083465			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Zithromax			S		Unk		Pfizer
Drug Hypersensitivity;	Doxycycline Hyclate			S		Unk		Pfizer
Nausea	Carafate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12142311	NON-EXPEDITED			US-PFIZER INC-2016078764		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12142445	EXPEDITED (15-DAY)		OT	PHHY2016AT027012		5 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Creatine Phosphokinase Increased; Gait Disturbance	Azithromycin Sandoz			S	Oral	200 Mg/5 MI		Novartis	
	Otanol//Ciprofloxacin Hydrochloride			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2016	12142606	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016127385		52 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2016	12144284	EXPEDITED (15-DAY)		OT	GR-LUPIN PHARMACEUTICALS INC.-2016-00866		60 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Unknown			Not Reported	
	Isoniazid			C	Unknown			Not Reported	
	Rifampicin			C	Unknown			Not Reported	
	Ethambutol			C	Unknown			Not Reported	
	Pyrazinamide			C	Unknown			Not Reported	
	Amikacin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2016	12146865	NON-EXPEDITED			GXBR2016US000531		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Eructation; Flatulence; Vomiting	Azithromycin 250 Mg	S	Oral	500 Mg Day 1, Then 250 Mg Qd2-5	Novartis
	Hctz	C		Unk Df, Unk	Not Reported
	Probiotics Nos	C		Unk Df, Unk	Not Reported
	Multi-Vit	C		Unk Df, Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12146968	NON-EXPEDITED			GXBR2016US000818			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nasal Congestion	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12147465	EXPEDITED (15-DAY)		HO	US-TEVA-640147USA		6 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Erythema; Fatigue; Headache; Myalgia; Pain; Pain In Extremity; Pruritus; Pyrexia; Scab; Scar; Strabismus; Swelling; Urticaria	Azithromycin			S		200mg-5ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2016	12147773	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2016068179		6 YR	Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Haematochezia; Hypersensitivity	Zithromax			S	Oral	1.5 Sachets, Daily		Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2016	12154749	DIRECT	Y				81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain	Azithromycin			S	Oral			Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	10522085	NON-EXPEDITED			US-PFIZER INC-2014281749			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk, Stopped After 2 Doses		Pfizer
	Omnicef			S		Unk, Stopped After 3 Days		Pfizer
	Omnicef			S				Pfizer
	Amoxicillin			S		Unk Unk, 1x/Day		Pfizer
	Amoxicillin			S				Pfizer
	Ciprofloxacin			S		Unk, Stopped After 4 Doses		Unknown
	Clindamycin Hcl			S		Unk, Stopped After 3 Days		Pfizer
	Tetracycline Hcl			S		Unk, Stopped After 3 Days		Pfizer
	Levaquin			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	11924576	EXPEDITED (15-DAY)		DE	FR-JNJFOC-20160110115		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Prezista			S	Oral			Not Reported
	Eupantol			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycine Arrow			S	Oral			Not Reported

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

Triflucan	C	Intravenous (not otherwise specified)	Not Reported
Ogastoro	C	Unknown	Not Reported
Ziagen	C	Unknown	Not Reported
Epivir	C	Unknown	Not Reported
Calcitonine	C	Unknown	Not Reported
Mianserine	C	Unknown	Not Reported
Isentress	C	Unknown	Not Reported
Kivexa	C	Unknown	Not Reported
Calciparine	C	Unknown	Not Reported
Clarithromycine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12154311	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR-APL-2016-02690		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Death; Respiratory Arrest	Cyclobenzaprine			S	Unknown			Aurobindo	
	Escitalopram			S	Unknown			Aurobindo	
	Lisinopril			S	Unknown			Aurobindo	
	Metoprolol			S	Unknown			Aurobindo	
	Oxycodone			S	Unknown			Aurobindo	
	Cephalexin /00145501/			S	Unknown			Not Reported	
	Clonidine			S	Unknown			Not Reported	
	Nitroglycerin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Diclofenac			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Doxycycline			S	Unknown			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12154426	NON-EXPEDITED			US-PFIZER INC-2016112804			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Cephalexin /00145501/			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12154439	NON-EXPEDITED			US-PFIZER INC-2016116668			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12156426	NON-EXPEDITED			US-PFIZER INC-2016117242			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer	
	Atorvastatin Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Ezetimibe			S		Unk		Not Reported	
	Naprosyn			S		Unk		Not Reported	
	Potassium Clavulanate			S		Unk		Not Reported	
	Codem			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12157852	DIRECT		CA, LT			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Arrhythmia; Ventricular Extrasystoles	Zithromax	S	Oral	500mg Day 1, 250mg Days 2-5 Once Daily Taken By Mouth	Pfizer
	Rescue Albuterol Inhaler	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12158918	DIRECT		DS			72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Decreased Appetite; Listless; Vomiting	Azithromycin			S	Oral	250 Mg 11 2 On 2/1/2016 1 Daily Mouth		Not Reported	
	Altenanol			C				Not Reported	
	Nephredipine			C				Not Reported	
	Simvastatin			C				Not Reported	
	Triamterene			C				Not Reported	
	Multivitamin			C				Not Reported	
	Black Cohosh			C				Not Reported	
	Flax Seed Oil			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2016	12159105	DIRECT					61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Vertigo	Azithromycin 250mg			S	Oral	7 2 First Day One Till Gone Mouth		Sandoz	
	Multiple Vitamine			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamine			C				Not Reported	
	Vitamine C			C				Not Reported	
	Metamusal			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2016	9916866	NON-EXPEDITED			US-PFIZER INC- 2014046307		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax		S			Unk		Pfizer	
	Prednisone		S			Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2016	12159322	NON-EXPEDITED			US-PFIZER INC-2016116432			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Atropine Sulfate			S		Unk		Unknown	
	Azithromycin			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
	Percodan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2016	12160632	NON-EXPEDITED		HO, OT	US-APOTEX-2016AP006898		1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme	Amoxicillin And Clavulanate			S	Unknown			Apotex	
	Potassium Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2016	12160725	EXPEDITED (15-DAY)		OT	JP-BAYER-2016-042503		12 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Claritin			S	Oral	10 Mg, Qd		Bayer	
	Zithromac			S	Oral	400 Mg, Qd		Not Reported	
	Medicon			C	Oral	15 Mg, Tid		Not Reported	
	C Cysten Tsuruhara			C	Oral	250 Mg, Tid		Not Reported	
	Singulair			C	Oral	5 Mg, Qd		Not Reported	

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

	Lamictal	C	Oral	100 Mg		Not Reported			
	Lamictal	C	Oral	5 Mg, Bid		Not Reported			
	Mystan	C	Oral	0.3 Mg, Qd		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2016	9443543	NON-EXPEDITED			US-PFIZER INC-2013224919		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Hydrochlorothiazide			S		Unk		Unknown	
	Ibuprofen			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2016	11812084	NON-EXPEDITED			US-PFIZER INC-2015393467			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Remicade			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2016	12164574	NON-EXPEDITED			US-PFIZER INC-2016099544		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Azithromycin			S		Unk		Pfizer	
	Lorazepam			C		Unk		Not Reported	
	Mirtazapine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2016	12165509	NON-EXPEDITED			US-PFIZER INC-2016098371			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	10525523	EXPEDITED (15-DAY)		HO, LT, OT	UG-GILEAD-2014-0118171		20 YR	Male	UGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Outlet Obstruction; Glomerulonephritis	Tenofovir Disoproxil Fumarate			S	Unknown	Unk		Gilead	
	Emtricitabine			S	Unknown	Unk		Gilead	
	Efavirenz			S	Unknown	Unk		Not Reported	
	Co-Trimoxazole			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Raltegravir			S	Unknown	Unk		Not Reported	
	Isoniazid			S	Unknown	Unk		Not Reported	
	Abacavir			S	Unknown	Unk		Not Reported	
	Vitamin B6			S	Unknown	Unk		Not Reported	
	Ciprofloxacin			C	Unknown	Unk		Not Reported	
	Doxycycline			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	11983478	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2016047399		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Eupantol			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Azithromycine Arrow			S	Oral	Unk		Not Reported	
	Prezista			S	Oral	Unk		Not Reported	
	Triflucan			C		Unk		Not Reported	
	Ogastoro			C		Unk		Not Reported	
	Ziagen			C		Unk		Not Reported	

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

Norvir	C	Unk	Not Reported
Calcitonin	C	Unk	Not Reported
Mianserin	C	Unk	Not Reported
Isentress	C	Unk	Not Reported
Kivexa	C	Unk	Not Reported
Calciparine	C	Unk	Not Reported
Clarithromycin	C	Unk	Not Reported
Epivir	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12010695	EXPEDITED (15-DAY)			JP-PFIZER INC-2016042812		42 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hallucination	Zithromac			S	Oral	500 Mg, 1x/Day		Pfizer
	Mucodyne			C	Oral	1 Df, 3x/Day		Not Reported
	Allegra			C	Oral	1 Df, 2x/Day		Not Reported
	Calonal			C		Unk, As Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12167529	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2016033874			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Ineffective For Unapproved Indication; Rhinorrhoea	Flonase Allergy Relief Otc Nasal Spray			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12168061	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2016M1009805			Unknown	USA

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

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

Brain Oedema; Hyperammonaemia; Neurological Symptom; Pathogen Resistance; Systemic Infection; Ureaplasma Infection	Tacrolimus	S	Unknown	Trough Level Was Maintained At 8-12 Ng/ML	Not Reported
	Mycophenolate Mofetil	S	Unknown		Not Reported
	Azithromycin	S	Unknown	500mg Daily For 5 Days	Not Reported
	Methylprednisolone	S	Unknown	500 Mg	Mylan
	Basiliximab	S	Unknown	20 Mg	Mylan
	Prednisone	S	Unknown	0.5 Mg/Kg	Mylan
	Co Trimoxazole	C	Unknown		Mylan
	Valganciclovir	C	Unknown		Mylan
	Voriconazole	C	Unknown		Mylan
	Vancomycin	C	Unknown		Mylan
	Cefepime	C	Unknown		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12168062	EXPEDITED (15-DAY)		OT	US-MYLANLABS- 2016M1009812			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperammonaemia	Tacrolimus			S	Unknown	To Achieve Trough Level Of 10-14 Ng/ML		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Azithromycin			S		Unk		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 Gm		Mylan
	Methylprednisolone			S	Unknown	Total 8 Doses		Mylan
	Basiliximab			S	Intravenous (not otherwise specified)	20 Mg		Mylan
	Rituximab			S	Unknown			Mylan
	Immune Globulin Nos			C	Intravenous (not otherwise specified)			Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12168247	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2016M1010079			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Premature Delivery	Furosemide			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Linezolid			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Oseltamivir			S	Unknown			Mylan
	Oseltamivir			S				Mylan
	Oseltamivir			S				Mylan
	Heparin			S	Unknown			Mylan
	Meropenem			S	Unknown			Mylan
	Phenylephrine			S	Unknown			Mylan
	Betamethasone			S	Unknown			Mylan
	Norepinephrine			S	Unknown			Mylan
	Vasopressin			S	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12168272	EXPEDITED (15-DAY)		HO, OT	US-INVAGEN PHARMACEUTICALS, INC.-1048878		84 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Asthenia; Blood Pressure Abnormal; Diarrhoea; Drug Interaction; Gastric Haemorrhage; Insomnia; Nausea; Rash Pruritic; Sinusitis; Vomiting	Warfarin Sodium			S	Oral			Invagen
	Omeprazole			C				Not Reported
	Xanax			C				Not Reported
	Sotalol			C				Not Reported
	Pravastatin			C				Not Reported
	Aspirin			C				Not Reported
	Levothyroxine			C				Not Reported
	Methylprednisolone			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Azithromycin		S		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12168550	NON-EXPEDITED			US-PFIZER INC-2016136883			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Tetracycline Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Exemestane			S		Unk		Pfizer	
	Acetaminophen			S		Unk		Not Reported	
	Aspirin			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Histamic			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Oxacillin			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12168558	NON-EXPEDITED			US-PFIZER INC-2016146698			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Phenergan			S		Unk		Not Reported	
	Asa			S		Unk		Not Reported	

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

	Phentermine		S		Unk		Not Reported		
	Tizanidine		S		Unk		Not Reported		
	Lamotrigine		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2016	12171354	DIRECT	Y	HO			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2016	11889767	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015478555			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Drug Hypersensitivity; Pruritus; Rash; Respiratory Distress	Azithromycin			S		Unk		Pfizer	
	Rocephin			S		Unk		Not Reported	
	Synthroid			C		Unk		Not Reported	
	Calcium			C		600 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2016	11984889	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016043443		6 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Zithromac			S	Oral	Unk		Pfizer	
	Topina			S	Oral			Not Reported	
	E Keppra			S	Oral			Not Reported	
	Selenica R			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2016	12170521	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2016AP007000		44 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Hyperammonaemia; Ureaplasma Infection	Mycophenolate Mofetil			S	Unknown	1000 Mg, Twice Daily		Apotex	
	Azithromycin			S	Unknown	500 Mg,Daily		Apotex	
	Azithromycin			S	Parenteral	Unk		Apotex	
	Methylprednisolone			S	Unknown	500 Mg, Unk		Not Reported	
	Basiliximab			S	Unknown	20 Mg, Unk		Not Reported	
	Tacrolimus			S	Unknown	Target Trough Level 8-12 Ng/ML		Not Reported	
	Prednisone			S	Unknown	0.5 Mg/Kg, Unk		Not Reported	
	Trimethoprim Sulfamethoxazole			C	Unknown			Not Reported	
	Valganciclovir			C	Unknown	Unk		Not Reported	
	Voriconazole			C	Unknown	Unk		Not Reported	
	Vancomycin			C	Unknown	Unk		Not Reported	
	Cefepime			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2016	12171266	EXPEDITED (15-DAY)		OT	IN-LUPIN PHARMACEUTICALS INC.-2016-00944		35 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fixed Eruption	Azithromycin			S	Unknown	Three Consecutive Days A Week		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2016	12171308	NON-EXPEDITED			US-PFIZER INC- 2016102360		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pruritus; Rash	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2016	12172845	NON-EXPEDITED			US-PFIZER INC-2016061471			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Vancomycin Hcl			S		Unk		Pfizer	
	Metoprolol Tartrate			S		Unk		Unknown	
	Lisinopril			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
	Darvocet			S		Unk		Not Reported	
	Lortab			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Z-Pack			S		Unk		Not Reported	
	Amoxicillin			S		Unk		Not Reported	
	Diovan			S		Unk		Not Reported	
	Hctz			S		Unk		Not Reported	
	Azmacort			S		Unk		Not Reported	
	Flovent			S		Unk		Not Reported	
	Asa			S		Unk		Not Reported	
	Benadryl			S		Unk		Not Reported	
	Naproxen			S		Unk		Not Reported	
	Iron			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	
	Singulair			S		Unk		Not Reported	
	Osa			S		Unk		Not Reported	
	Hydralazine			S		Unk		Not Reported	
	W/Hydrochlorothiazide/Reserpin								

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

e									
Nabumetone		S			Unk				Not Reported
Guanfacine		S			Unk				Not Reported
Dolobid		S			Unk				Not Reported
Compazine		S			Unk				Not Reported
Percolone		S			Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2016	12175808	NON-EXPEDITED			US-PFIZER INC-2016103212			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Haldol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2016	12175823	NON-EXPEDITED			US-PFIZER INC-2016108476			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2016	12176839	NON-EXPEDITED			US-PFIZER INC-2016106995			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extravasation	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2016	12176993	EXPEDITED (15-DAY)		DE, HO	US-TEVA-642247USA		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Resistance; Hyperammonaemia	Methylprednisolone	S	Unknown	500 Mg	Duramed
	Mycophenolate Mofetil	S	Unknown		Teva
	Azithromycin	S	Unknown		Not Reported
	Basiliximab	S	Unknown	20 Mg	Not Reported
	Tacrolimus	S	Unknown	Trough Level Was Maintained At 8-12 Ng/ML	Not Reported
	Prednisone	S	Unknown	0.5 Mg/Kg	Not Reported
	Co Trimoxazole	C	Unknown		Not Reported
	Valganciclovir	C	Unknown		Not Reported
	Voriconazole	C	Unknown		Not Reported
	Vancomycin	C	Unknown		Not Reported
	Cefepime	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2016	12178366	DIRECT		HO			40 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Cough; Decreased Appetite; Heart Rate Increased; Heart Rate Irregular; Initial Insomnia; Pruritus; Pyrexia; Speech Disorder; Urticaria; Wheezing; Yellow Skin	Zithromax/Azithromycin 250mg & 500mg Pfizer/Teva			S	Oral	2 Pills First Day/ 1 Pill After Once Daily Taken By Mouth		Pfizer
	Centrum Daily Vitamins			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2016	11891257	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR- APL-2015-12117		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cardiac Death; Long Qt Syndrome; Ventricular Fibrillation	Azithromycin			S	Unknown			Aurobindo

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2016	11913683	NON-EXPEDITED			US-PFIZER INC-2016002223		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Ligament Sprain	Lyrica			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2016	12133701	NON-EXPEDITED			US-PFIZER INC-2016129403		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Dysuria; Urinary Tract Infection; Vulvovaginal Dryness	Ibrance			S	Oral	125 Mg, 1x/Day		Pfizer	
	Ibrance			S	Oral	125 Mg, 1x/Day		Pfizer	
	Ibrance			S	Oral	75 Mg, Cyclic (1 Tab Daily Days 1-21, Then 7 Days Off)		Pfizer	
	Aromasin			S				Pfizer	
	Zithromax			S				Pfizer	
	Faslodex			C	Intramuscular	125 Mg, Cyclic (250 Mg/5 MI Syrg, Every Other Month)		Not Reported	
	Ondansetron			C	Oral	8 Mg, As Needed(Every 12 Hours)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2016	12181793	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016151455			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Zithromac			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2016	12182914	DIRECT		LT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Chest Pain; Deafness; Tinnitus; Vertigo	Z-Pack			S	Oral			Not Reported	
	Coreg			C				Not Reported	
	Maxide			C				Not Reported	
	Losartan			C				Not Reported	
	Magnesium			C				Not Reported	
	Daily Mvi			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12183598	NON-EXPEDITED			US-PFIZER INC- 2016112996			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Product Label Issue; Suspected Counterfeit Product	Azithromycin			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12183699	NON-EXPEDITED			US-PFIZER INC- 2016158238			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Cephalexin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12184076	NON-EXPEDITED			US-PFIZER INC- 2016112376			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Diarrhoea	Azithromycin		S		Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2016	12185672	EXPEDITED (15-DAY)		HO	CA-HOSPIRA-3204572		83 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease;	Solu-Cortef			C				Not Reported	
Diarrhoea; Somnolence;	Azithromycin			S	Unknown			Not Reported	
Urinary Tract Infection	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2016	12186800	NON-EXPEDITED			US-PFIZER INC-2016139193		77 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Metoclopramide Hcl			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Cisapride			S		Unk		Not Reported	
	Clarithromycin			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2016	12187169	EXPEDITED (15-DAY)		HO, LT, OT	UG-VIIV HEALTHCARE LIMITED-UG2014008741			Unknown	UGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Outlet Obstruction;	Tenofovir Disoproxil Fumarate			S	Unknown	Unk		Glaxosmithkline	
Glomerulonephritis	Abacavir			S	Unknown	Unk		Viiv	

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

Vitamin B6	S	Unknown	Unk	Glaxosmithkline
Emtricitabine	S	Unknown	Unk	Not Reported
Efavirenz	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S	Unknown	Unk	Glaxosmithkline
Azithromycin	S	Unknown	Unk	Glaxosmithkline
Raltegravir	S	Unknown	Unk	Not Reported
Ciprofloxacin	C	Unknown	Unk	Glaxosmithkline
Doxycycline	C			Glaxosmithkline
Isoniazid	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2016	12190150	DIRECT					18 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Feeling Abnormal; Nausea; Vaginal Haemorrhage	Azithromycin 250 Mg			S	Oral	6 Pills Once Daily Taken By Mouth		Not Reported
	Loryna			C				Not Reported
	Daily Vitamin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12190960	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2016-01018		44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Azithromycin			S	Unknown	500 Mg		Not Reported
	Azithromycin			S	Parenteral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12191815	NON-EXPEDITED			US-PFIZER INC-2016160327		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Ibuprofen			S				Pfizer

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

	Morphine Sulfate			S					Pfizer
	Azithromycin			S					Pfizer
	Levaquin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12191819	NON-EXPEDITED			US-PFIZER INC-2016156629			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12192672	NON-EXPEDITED			US-PFIZER INC-2016116046		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Amox-Clav			S		875 Mg, 2x/Day		Not Reported	
	Amox-Clav			S				Not Reported	
	Fluticasone			S	Nasal	Unk		Not Reported	
	Fluticasone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2016	12192903	NON-EXPEDITED			US-PFIZER INC-2016118423		80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Foreign Body	Zithromax			S		250 Mg		Pfizer	
In Mouth; Therapeutic	Zithromax			S		250 Mg		Pfizer	
Product Effect Incomplete;	Multivitamins			C				Not Reported	
Throat Lesion	Tamsulosin Hydrochloride			C		1 Df, 2x/Day		Not Reported	
	Trazodone			C		50,1 At Bedtime		Not Reported	
	Iron			C		Unk Unk, 2x/Day		Not Reported	
	Xarelto			C		20 Mg, Daily		Not Reported	

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

Lasix	C	20, 1 Tablet Daily	Not Reported
Ranitidine	C	150, 1 Tablet Daily	Not Reported
Losartan Potassium	C	20 Mg, Daily	Not Reported
Aspirin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	11921866	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2016019529		83 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Skin Exfoliation	Zitromax			S	Oral	500 Mg, Daily		Pfizer	
	Allopurinol			C	Oral	150 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12178001	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016145058		4 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Second Degree	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Catapressan /00171101/			S	Intravenous (not otherwise specified)	1 Ug/Kg/Hour		Not Reported	
	Atrovent			S	Respiratory (inhalation)	One Puff Each 8 Hours (3 Daily)		Not Reported	
	Amoxicillin			C		Unk		Not Reported	
	Aerius /01009701/			C	Oral	One Measure Spoon Daily		Not Reported	
	Morphine			C	Intravenous (not otherwise specified)	33 Ug/Kg, Once Per Hour		Not Reported	
	Morphine			C	Intravenous bolus	40 Ug/Kg, Unk		Not Reported	
	Claforan /00497602/			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Midazolam Hydrochloride			C	Intravenous (not otherwise specified)	Up To 80 Ug/Kg/Hour		Not Reported	
	Ventoline /00139501/			C	Respiratory	2 Df, 2x/Day		Not Reported	

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

		(inhalation)		
Acupan	C	Intravenous (not otherwise specified)	2 Mg/Kg, Once Per Hour	Not Reported
Paracetamol	C		Unk	Not Reported
Budesonide	C	Respiratory (inhalation)	1 Mg Each 12 Hours	Not Reported
Gentamicin	C		3 Injections	Not Reported
Lasilix /00032601/	C		2 Injections	Not Reported
Lasilix /00032601/	C		Unk	Not Reported
Speciafoldine	C		5 Mg, Daily	Not Reported
Oracilline /00001801/	C		500000 Iu, 2x/Day	Not Reported
Siklos	C		300 Mg, Daily	Not Reported
Flixotide	C		50 Ug One Puff In The Morning And In The Evening	Not Reported
Tracrium	C	Intravenous (not otherwise specified)	0.6 Mg/Kg, Once Per Hour	Not Reported
Oramorph	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12195474	EXPEDITED (15-DAY)		DS, HO, OT	PHHY2015CA174534			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Forced Expiratory Volume Decreased; Product Use In Unapproved Indication	Seebri Breezhaler			S	Respiratory (inhalation)	Unk, Qd		Not Reported
	Azithromycin Sandoz			S	Oral	250 Mg, Qod		Novartis
	Ventolin /00942701/			C	Unknown	Unk Unk, Bid		Not Reported
	Advair			C	Unknown	Unk Unk, Bid		Not Reported
	Adalat			C	Unknown	20 Mg, Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12197932	DIRECT		DS			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Formulation Issue; Rhinorrhoea	Azithromycin 250 Mg Greenstone Llc			S		2 Pills First Day, 1 Afterward Once Daily		Greenstone	
	Cardizem			C				Not Reported	
	Losartan			C				Not Reported	
	Losartan/Hctz			C				Not Reported	
	Crestor			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12198415	DIRECT		HO, LT			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Fall; Generalised Tonic-Clonic Seizure; Malaise; Rib Fracture; Syncope; Tongue Injury	Azithromycin			S	Oral	1 Pill Once Daily Taken By Mouth		Greenstone	
	Allegra			C				Not Reported	
	Singulair			C				Not Reported	
	Dulera			C				Not Reported	
	Restasis			C				Not Reported	
	Nasonex			C				Not Reported	
	Xopenex			C				Not Reported	
	Pulmicort			C				Not Reported	
	Sudafed			C				Not Reported	
	Mucinex			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12203217	DIRECT	Y	OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Electrocardiogram Qt Prolonged	Amiodarone 200 Mg			S				Not Reported	
	Levofloxacin 250 Mg			S				Not Reported	
	Azithromycin 500 Mg			S				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2016	12203305	DIRECT	Y	OT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Electrocardiogram Qt Prolonged	Amiodarone 200 Mg			S				Not Reported	
	Levofloxacin 250 Mg			S				Not Reported	
	Azithromycin 500 Mg			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2016	10653215	EXPEDITED (15-DAY)		OT	IN-PFIZER INC- 2014336632		27 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Areflexia; Cyanosis; Hypotonia; Myasthenia Gravis Crisis	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Unk		Not Reported	
	Pantoprazole			C	Intravenous (not otherwise specified)	40 Mg, Unk		Not Reported	
	Paracetamol			C	Oral	500 Mg, Unk		Not Reported	
	Pyridostigmine			C		60 Mg, 4x/Day		Not Reported	
	Pyridostigmine			C				Not Reported	
	Prednisolone			C		55 Mg, 1x/Day		Not Reported	
	Prednisolone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2016	12199252	NON-EXPEDITED			US-PFIZER INC- 2016123002		52 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S				Pfizer	
	Pravachol			S		Unk		Not Reported	
	Crestor			S		Unk		Not Reported	
	Fish Oil			S		Unk		Not Reported	

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

	Niacin		S		Unk			Not Reported	
	Toprol XL		S		Unk			Not Reported	
	Combivent		S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2016	12199260	NON-EXPEDITED			US-PFIZER INC-2016127783		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2016	12202467	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2016160323		6 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2016	11264688	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2015229707		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Frequent Bowel Movements; Gastric Ulcer; Product Complaint	Zithromax			S		Unk		Pfizer	
	Zithromax			S		2 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2016	11928254	NON-EXPEDITED			US-PFIZER INC-2015465562			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

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

Rocephin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2016	12084637	EXPEDITED (15-DAY)		HO, OT	US-TAKEDA-2016TUS002332		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Diarrhoea; Hypoglycaemia	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Q8weeks		Takeda	
	Imuran /00001501/			S	Unknown	150 Mg, Qd		Not Reported	
	Estrogens			S	Unknown	Unk		Not Reported	
	Zithromax			S	Unknown	Unk		Not Reported	
	Valtrex			C		400 G, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2016	12205738	EXPEDITED (15-DAY)		DE	AE-MYLANLABS-2016M1012388			Unknown	ARE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronavirus Infection; Maternal Exposure During Pregnancy; Middle East Respiratory Syndrome; Normal Newborn	Ceftriaxone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	6992872	EXPEDITED (15-DAY)		HO, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-14619191		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Disorder; Oral Fungal Infection; Pneumonia; Sinusitis; Vulvovaginal Mycotic Infection	Abatacept			S	Intravenous (not otherwise specified)	500 Mg, Q4wk		Bristol Myers Squibb	
	Hydrocortisone			S	Oral	20 Mg, Qd		Not Reported	
	Novatrex			S	Unknown	Novatrex 2.5mg 1 D.F=8		Not Reported	

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

Cortancyl	S	Oral	Tablets/Week	
Speciafoldine	C	Unknown	Cortancyl 1 Mg	Not Reported
Fosamax	C	Unknown	5 Mg, Unk	Not Reported
Smecta	C	Unknown	70 Mg, Unk	Not Reported
Actonel	C	Unknown	35 Mg, Qwk	Not Reported
Doliprane	C	Unknown	Unk Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	10621751	NON-EXPEDITED			US-PFIZER INC-2014328455			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Lexapro			S		Unk		Not Reported
	Vitamin D Nos			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	10665233	NON-EXPEDITED			US-PFIZER INC-2014347116			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	10971461	EXPEDITED (15-DAY)			US-GLAXOSMITHKLINE-US2015GSK020580			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Diarrhoea; Drug Hypersensitivity; Influenza Like Illness; Nausea; Rash; Vomiting	Ceftin			S		Unk, U		Glaxosmithkline
	Fluocinonide			S		Unk, U		Glaxosmithkline

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

Fluocinolone Acetonide	S	Unk, U	Glaxosmithkline
Zithromax	S	Unk, U	Glaxosmithkline
Doxycycline	S	Unk, U	Glaxosmithkline
Erythromycin	S	Unk, U	Glaxosmithkline
Cataflam	S	Unk, U	Glaxosmithkline
Cipro	S	Unk, U	Not Reported
Ciprocin	S		Not Reported
Procin [Ciprofloxacin]	S		Not Reported
Cefuroxime	S		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12119670	EXPEDITED (15-DAY)		HO, OT	AU-SA-2016SA032896		37 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Clexane			S	Intravenous (not otherwise specified)	2 Doses Inclusive.		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	3 Doses Total		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	Dose: 2 Doses		Not Reported
	Tazobactam/Piperacillin			S	Intravenous (not otherwise specified)	Total 8 Doses		Not Reported
	Vancomycin Hydrochloride			S	Intravenous (not otherwise specified)	3 Doses Total		Not Reported
	Lamivudine			C	Unknown			Not Reported
	Lamivudine			C	Unknown	25 Mg Nocte		Not Reported
	Pulmicort			C	Unknown	2 Puffs Mane Dose Dose:2 Puff(S)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12206495	NON-EXPEDITED			US-PFIZER INC-2016130952			Female	USA

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

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

Abdominal Pain; Diarrhoea		Azithromycin		S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12206546	NON-EXPEDITED			US-PFIZER INC- 2016173096		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Benzylpenicillin Potassium			S		Unk		Pfizer	
	Sulfadiazine Silver			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Tylenol /00020001/			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
	Phenoxymethylpenicillin Potassium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12207224	EXPEDITED (15-DAY)		HO	CN-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2016- BI-17		43 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jaundice; Off Label Use	Harnal			S	Oral	0.2 Mg		Boehringer Ingelheim	
	Zithromax			S	Intravenous (not otherwise specified)	2 G		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12208913	NON-EXPEDITED			US-PFIZER INC- 2016146606			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12210472	DIRECT		HO, LT, RI, OT			32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Chills; Haematemesis; Hepatic Failure; Nausea; Pyrexia; Splenomegaly	Azithromycin			S	Oral	1 Pills 250mg For 5 Days Twice Daily Taken By Mouth	2 DAY	Not Reported	
	Dandelion Root			C				Not Reported	
	Milk Thistle			C				Not Reported	
	Tumeric			C				Not Reported	
	Aloe Vera			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2016	12210691	DIRECT					61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Product Quality Issue; Vertigo	Azithromycin 250mg Common Brandname Zithromax			S	Oral	7 2 First Day One Till Gone Mouth		Sandoz	
	Multiple Vitamine			C				Not Reported	
	Calcium Vitamine D3			C				Not Reported	
	Vitamine C			C				Not Reported	
	Metamusal			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2016	9791035	NON-EXPEDITED			US-PFIZER INC- 2013370782			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	

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

Ciprofloxacin			S		Unk			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	11920080	EXPEDITED (15-DAY)		HO	US-TEVA-625475USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dehydration; Dyspnoea; Hallucination; Somnolence	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12130868	NON-EXPEDITED			US-PFIZER INC- 2016071477			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
	Percocet			S		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12210133	NON-EXPEDITED			US-PFIZER INC- 2016139946			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Vomiting	Zithromax			S		Unk			Pfizer
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12210134	NON-EXPEDITED			US-PFIZER INC- 2016130867		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Mar-2016	12210148	NON-EXPEDITED			US-PFIZER INC- 2016143680			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2016	12210160	NON-EXPEDITED			US-PFIZER INC-2016137083			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use Issue	Zithromax			S		500 Mg, Daily (500mg Qd X 3 Days)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2016	12211308	NON-EXPEDITED			US-PFIZER INC-2016137342			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Vioxx			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2016	12211553	NON-EXPEDITED			US-AKORN-8916			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite 1%			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2016	12080970	NON-EXPEDITED		OT	US-PFIZER INC-2016085176		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Azithromycin			S	Oral	250 Mg, (Three Times A Week)		Pfizer	

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

Azithromycin	S				Pfizer
Wellbutrin	C	Oral	300 Slow Release, 1x/Day		Not Reported
Sulfamethoxazole	C		One Tablet Three Times A Week		Not Reported
Azathioprine	C	Oral	Unk, 1x/Day		Not Reported
Amlodipine	C	Oral	2.5 Mg, 1x/Day		Not Reported
Prograf	C		2 Mg, 2x/Day		Not Reported
Valaciclovir	C		1 Df, Daily (One A Day)		Not Reported
Vitamin D Nos	C		Unk Unk, 1x/Day		Not Reported
Calcium	C		2 Df, 2x/Day (Two Twice A Day)		Not Reported
Aspirin	C		1 Df, Daily (One A Day)		Not Reported
Fish Oil	C		1 Df, Daily (One A Day)		Not Reported
Prednisone	C		2.5 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2016	12213574	NON-EXPEDITED			US-PFIZER INC-2016146837			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2016	12214839	NON-EXPEDITED			US-PFIZER INC-2016139837			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Cefaclor			S		Unk		Not Reported
	Naproxen			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2016	12115762	NON-EXPEDITED			US-PFIZER INC-2016064042			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Rash	Zithromax			S		Unk		Pfizer	
	Lincocin			S		Unk		Pfizer	
	Avelox			S		Unk		Not Reported	
	Ceftin			S		Unk		Not Reported	
	Hycodan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2016	12189765	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-03540			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Erythema Multiforme; Pruritus; Rash Erythematous	Amoxicillin+Clavulanic Acid			S	Unknown			Aurobindo	
	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2016	12196276	EXPEDITED (15-DAY)		HO	PHHY2016IT035082		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Ceftriaxone			S	Intramuscular			Novartis	
	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2016	12216753	NON-EXPEDITED			US-PFIZER INC-2016142297		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Vomiting	Zithromax	S	Oral	4 Df, Single	Pfizer
	Prenatal Vitamins	C		1 Mg; 1mg Folic Acid Multivitamin And Multimineral Dose According To Product	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12219046	EXPEDITED (15-DAY)		HO	GXJP2016JP000614		6 YR	Male	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Generalised Exanthematous Pustulosis	Azithromycin Tablets			S	Oral			Novartis	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Mar-2016	12219349	NON-EXPEDITED			US-PFIZER INC- 2016143500		40 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Epistaxis; Headache; Nasal Congestion	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12094210	NON-EXPEDITED			US-PFIZER INC- 2016049446			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cough; Inappropriate Schedule Of Product Administration; Product Prescribing Error	Zithromax			S		Unk		Pfizer	
	Lipitor			C		10 Mg, Unk		Not Reported	
	Amlodipine			C		5 Mg, Unk		Not Reported	
	Valsartan			C		160 Mg, Unk		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2016	12221947	NON-EXPEDITED			US-PFIZER INC- 2016146539			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Ceclor	S	Unk	Not Reported
	Levaquin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2016	12223134	NON-EXPEDITED			US-PFIZER INC-2016154798		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Medrol			S		Unk		Pfizer	
	Z-Pak			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2016	12223795	NON-EXPEDITED			US-PFIZER INC-2016134339			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pharyngeal Erythema; Streptococcal Infection; Tonsillitis	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2016	12223864	EXPEDITED (15-DAY)		OT	PHHY2016GB038896		65 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Anxiety; Depression; Negative Thoughts; Tearfulness	Azithromycin Sandoz			S	Oral	250 Mg, Qd		Novartis	
	Amlodipine			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Budesonide			C	Unknown			Not Reported	
	Carbocysteine			C	Unknown			Not Reported	
	Macrogol 3350			C	Unknown			Not Reported	

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

	Mebeverine	C	Unknown					Not Reported	
	Pantoprazole	C	Unknown					Not Reported	
	Quinine Sulphate	C	Unknown					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2016	12185945	EXPEDITED (15-DAY)		HO, LT	IT-ROCHE-1726381		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dyspnoea; Hypersensitivity; Rash	Ceftriaxone			S	Intramuscular				Not Reported
	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2016	12225478	NON-EXPEDITED			US-AKORN-10539			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite 1%			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2016	12225495	NON-EXPEDITED			US-AKORN-9536		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Pain; Eye Pruritus	Azasite 1%			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2016	12226885	NON-EXPEDITED			US- ELI_LILLY_AND_COMP ANY-US201603010762		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Agitation; Chest Pain; Diarrhoea; Dizziness; Dyspepsia; Euphoric	Zyprexa			S	Unknown	Unk, Unknown			Unknown
	Baclofen			S	Unknown	Unk, Unknown			Not Reported
	Carbatrol			S	Unknown	Unk, Unknown			Not Reported

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

Mood; Fatigue; Headache; Hypersensitivity; Pain; Sedation; Therapeutic Reaction Time Decreased	Daypro	S	Unknown	Unk, Unknown	Not Reported
	Escitalopram	S	Unknown	Unk, Unknown	Not Reported
	Eszopiclone	S	Unknown	Unk, Unknown	Not Reported
	Levoxyl	S	Unknown	Unk, Unknown	Not Reported
	Oxycodone	S	Unknown	Unk, Unknown	Not Reported
	Seroquel	S	Unknown	Unk, Unknown	Not Reported
	Ultram /00599202/	S	Unknown	Unk, Unknown	Not Reported
	Vicodin	S	Unknown	Unk, Unknown	Not Reported
	Wellbutrin	S	Unknown	Unk, Unknown	Not Reported
	Zantac	S	Unknown	Unk, Unknown	Not Reported
	Zithromax	S	Unknown	Unk, Unknown	Not Reported
	Zolpidem	S	Unknown	Unk, Unknown	Not Reported
	Sertraline	C	Unknown	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2016	12227072	NON-EXPEDITED			US-PFIZER INC- 2016169480		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Zantac			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2016	12210455	EXPEDITED (15-DAY)		DE, OT	US-AUROBINDO-AUR- APL-2016-03801		44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Oedema; Drug Resistance;	Azithromycin 500 Mg			S	Unknown	500 Mg, Daily		Aurobindo
Hyperammonaemia; Lung Consolidation; Mental Status Changes;	Methylprednisolone			S	Unknown	500 Mg, Unk		Aurobindo
Ureaplasma Infection	Basiliximab			S	Unknown	20 Mg, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Mg, Two Times A Day		Not Reported

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

		Tacrolimus		S	Unknown				Not Reported
		Prednisone		S	Unknown	0.5 Unk, Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2016	12223814	NON-EXPEDITED		OT	US-PFIZER INC-2016178712			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea Haemorrhagic; Faeces Discoloured	Azithromycin			S		Two Tablets		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2016	12228468	NON-EXPEDITED			US-PFIZER INC-2016151131		76 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Clonidine			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Pravachol			S		Unk		Not Reported	
	Zocor			S		Unk		Not Reported	
	Lescol			S		Unk		Not Reported	
	Baycol			S		Unk		Not Reported	
	Mevacor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2016	12228851	NON-EXPEDITED			US-PFIZER INC-2016158324		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2016	12232494	NON-EXPEDITED			US-PFIZER INC-2016158661			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Gemfibrozil			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2016	12234119	DIRECT		DS, OT			46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Blood Potassium Decreased; Bradyphrenia; Burning Sensation; Cholecystitis; Erythema; Fatigue; Feeling Abnormal; Feeling Abnormal; Fungal Infection; Gastric Disorder; Impaired Work Ability; Multiple Allergies; Oropharyngeal Pain; Pericardial Effusion; Prescribed Overdose; Skin Disorder; Weight Decreased	Azithromycin			S				Not Reported	
	Generic Claritin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2016	12232776	NON-EXPEDITED			FR-LUPIN PHARMACEUTICALS INC.-2016-01077		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Disorder;	Clarithromycin			S	Unknown			Not Reported	

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

Vestibular Disorder	Clarithromycin	S	Unknown	Not Reported
	Linezolid	S	Unknown	Not Reported
	Imipenem	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Tobramycin	S	Unknown	Not Reported
	Tobramycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12221639	NON-EXPEDITED			US-PFIZER INC-2016146733			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Indocin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Vioxib			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12233174	EXPEDITED (15-DAY)		DE, OT	ET-ROCHE-1735421			Unknown	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Haemorrhage; International Normalised Ratio Increased	Ceftriaxone			S	Unknown			Not Reported	
	Metronidazole			S	Unknown			Not Reported	
	Tramadol			S	Unknown			Not Reported	
	Azithromycine			S	Unknown			Not Reported	
	Cimetidine			S	Unknown			Not Reported	
	Heparin			S	Unknown			Not Reported	
	Furosemide			S	Unknown			Not Reported	
	Spironolactone			S	Unknown			Not Reported	

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

Vancomycine			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12234049	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2016-057010		71 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Fatigue; Haemoptysis; Malaise; Pneumonia; Pulmonary Mass; Pyrexia	Avelox			S	Oral	1 Df, Unk		Bayer	
	Avelox			S	Oral	400.0 Mg, Qd		Bayer	
	Azithromycin			S	Oral	250 Mg, Unk		Not Reported	
	Azithromycin			S	Oral	250 Mg, Bid		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q2wk		Not Reported	
	Cortisone			C		Unk		Not Reported	
	Coumadin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12234129	NON-EXPEDITED			US-PFIZER INC-2016153064		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Prescription Drug Used Without A Prescription	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12237243	DIRECT					59 YR	Female	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Azithromycin 250			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12237255	DIRECT	Y	HO			86 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Lactic Acid Increased; Diarrhoea; Liver Function Test Increased; Nausea; Thrombocytopenia; Vomiting	Linezolid			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12237956	DIRECT					51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Feeling Abnormal; Skin Burning Sensation	Zpak			S	Oral			Not Reported	
	Levothyroxine			C				Not Reported	
	Multivitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2016	12237977	DIRECT		DS, HO, OT			62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Ear Disorder; Rash; Transient Ischaemic Attack	Azithromycin. 250 Mg			S	Oral	5 Tablet(S) Ibce A Day		Not Reported	
	Lipator			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2016	11965341	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2016-00395		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Blood Urea Increased	Azithromycin Arrow			S	Oral	Unk		Aurobindo	
	Eupantol			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prezista			S	Oral	Unk		Not Reported	
	Triflucan			C	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

		otherwise specified)		
Ogastoro	C	Oral	Unk	Not Reported
Ziagen	C	Unknown		Not Reported
Epivir	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2016	12240391	EXPEDITED (15-DAY)		HO	FR-BAUSCH-SP08410		8 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Pancreatitis Acute; Product Use In Unapproved Indication; Product Use Issue	Normix			S	Oral	Compresse Rivestite Con Film		Not Reported
	Metronidazole			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Ceftazidime			S	Unknown			Not Reported
	Amikacin			S	Unknown			Not Reported
	Prograf			S	Oral			Not Reported
	Cellcept			S	Unknown			Not Reported
	Certican			C				Not Reported
	Alinia			C				Not Reported
	Ursolvan			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2016	12241606	DIRECT					13 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria; Vomiting	Azithromycin 250 Mg, 250 Mg Teva			S	Oral	6 Tablet(S) Once A Day Taken By Mouth		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2016	12241901	DIRECT		RI			65 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chromaturia; Dizziness; Dyspnoea; Haematochezia; Muscle Spasms; Pyrexia	Azithromycin			S	Oral	2 Pills One Thereafter By Mouth		Not Reported	
	Sinus Rx			C				Not Reported	
	Vitamins			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	11023864	NON-EXPEDITED			US-PFIZER INC- 2015124906			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Macrodantin			S		Unk		Not Reported	
	Amitriptyline			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12057703	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2015-04076			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S	Unknown			Aurobindo	
	Clindamycin			S	Unknown			Aurobindo	
	Naproxen			S	Unknown			Aurobindo	
	Koflex			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Mandol			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12213384	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-113797		56 YR	Female	ITA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Ceftriaxone			S	Intramuscular	Daily		Not Reported	
	Azithromycin			S	Oral	Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12216155	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2016-03761		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S	Oral			Aurobindo	
	Ceftriaxone			S	Intramuscular			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12218772	NON-EXPEDITED		OT	US-MDT-ADR-2016-00580		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Implant Site Swelling; Infection; Swelling	Bacitracin			S	Topical	As Needed To Stoma Site		Not Reported	
	Budesonide			S	Respiratory (inhalation)	0.5mg Suspension Inhalation Twice Daily		Not Reported	
	Calcium Carbonate			S	Other	600mg Daily		Not Reported	
	Cetirizine			S	Other	10mg Daily		Not Reported	
	Clotrimazole			S	Topical	4 Times Daily As Needed For Itching And Rash		Not Reported	
	Diastat			S	Rectal	50mg Gel As Needed For Seizures Longer Than 3 Minutes		Not Reported	
	Diazepam			S	Other	5mg Daily		Not Reported	
	Diazepam			S	Other	5mg Every 4 Hours As Needed Spasms		Not Reported	
	Compounded Baclofen			S	Intrathecal			Not Reported	
	Acetaminophen			S	Other	5mg Every 6 Hours As Needed For Pain		Not Reported	

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

Albuterol Sulfate	S	Respiratory (inhalation)	2.5 Mg Nebs Twice Daily	Not Reported
Albuterol Sulfate	S	Respiratory (inhalation)	2.5mg Inhalation Every 2 Hours As Needed For Respiratory Distress	Not Reported
Azithromycin	S	Other	300mg Every Monday, Wednesday, Friday	Not Reported
Diazepam	S	Other	5-10mg As Needed For Seizure Protocol	Not Reported
Diphenhydramine	S	Other	25mg Every 6 Hours As Needed For Difficulty Sleeping, Itching Or Allergy Sx	Not Reported
Duo Neb	S	Respiratory (inhalation)	3ml Every 4 Hours As Needed For Wheezing During Respiratory Illness	Not Reported
Lamotrigine	S	Other	200mg 3 Times Daily	Not Reported
Lidocaine	S	Topical	2% As Needed For Catheterization Every 4 Hours; During Catheterization Only	Not Reported
Mupirocin	S	Topical	As Needed To The Stoma Site	Not Reported
Nystain	S	Topical	4 Times Daily As Needed For Skin Irritation	Not Reported
Omeprazole	S	Other	60mg Twice Daily	Not Reported
Probiotic	S	Other	1 Tablet Daily	Not Reported
Simethicone	S	Other	40mg 4 Times Daily	Not Reported
Baclofen	S	Oral	10mg Every 6 Hours In Case Of Withdrawal	Not Reported
Glycopyrrrolate	S	Other	2mg In 1mg/5ml Solution 4 Times Daily	Not Reported
Lidocaine	S	Topical	As Need To G-Tube Stoma Site For Irritation	Not Reported
Lorazepam	S	Other	0.25-1mg As Needed For	Not Reported

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

Melatonin	S	Other	Seizure Control	Not Reported
Mononessa	S	Oral	3mg Daily At Bedtime	Not Reported
Sucralfate	S	Other	1 Table Daily	Not Reported
Gabitril	S	Other	500mg 4 Times Daily	Not Reported
Tizanidine	S	Other	6mg 4 Times Daily	Not Reported
Zinc Oxide	S	Other	1mg 4 Times Daily	Not Reported
	S	Topical	As Needed To G-Tube, J-Tube Sites And Perianal Area For Itching And Irritation	Not Reported
Gabapentin	S	Other	800mg 3 Times Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12241377	NON-EXPEDITED			US-PFIZER INC-2016160830		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12241422	NON-EXPEDITED			US-PFIZER INC-2016158600			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2016	12244061	NON-EXPEDITED			GXBR2016US001158			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pruritus	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12203827	EXPEDITED (15-DAY)		HO	IT-TEVA-644742ACC			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Urticaria	Ceftriaxone			S	Intramuscular	Daily		Not Reported	
	Azithromycin			S	Oral	Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12245293	NON-EXPEDITED			US-PFIZER INC-2016154694			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accident	Celebrex			S		200 Mg, Unk		Pfizer	
	Chantix			S		1.4 Mg, Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12246429	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2016189991			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epiglottitis	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12246476	NON-EXPEDITED			US-PFIZER INC-2016160300			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12247339	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2016189021		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Asthenia; Blood Bilirubin Increased; Blood Glucose Fluctuation; Blood Urine Present; Cholestasis; Chromaturia; Diarrhoea; Dizziness; Faeces Discoloured; Hypoglycaemia; Insomnia; Jaundice; Pruritus; Pyrexia	Zithromax			S		Unk		Pfizer	
	Estrogens Conjugated			S		Unk		Pfizer	
	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk, Q8weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2016	12248257	DIRECT					29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Pain Upper	Azithromycin Tablets 250 Mg, 250 Mg Greenstone Brand			S	Oral	2 Tablet(S) Once A Day Taken By Mouth	5 DAY	Greenstone	
	Marlissa			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12249237	EXPEDITED (15-DAY)		HO	ES-PERRIGO-16ES014770		5 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Acetaminophen			S	Unknown	750 Mg, Qd		Perrigo	
	Acetaminophen			S	Unknown	Unk Q 6-8 Hr		Perrigo	
	Ibuprofen			S	Unknown	1 Dose		Perrigo	
	Azithromycin			S	Unknown	3 Doses		Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2016	12249674	NON-EXPEDITED			US-PFIZER INC-2016197702		73 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Ultram			S		Unk		Not Reported	
	Lortab			S		Unk		Not Reported	
	Advair Diskus			S		Unk		Not Reported	
	Spiriva			S		Unk		Not Reported	
	Xopenex			S		Unk		Not Reported	
	Fosamax			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	11508297	EXPEDITED (15-DAY)		HO, LT, OT	JP-PFIZER INC-2015302011		74 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease	Zithromac			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zyvox			S	Intravenous drip	600 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	11971973	NON-EXPEDITED			US-PFIZER INC-2016043013			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Tessalon			S		Unk		Pfizer	
	Wellbutrin			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	

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

Toprol XL	S	Unk	Not Reported
Avelox	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Zofran	S	Unk	Not Reported
Pyridium	S	Unk	Not Reported
Actonel	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	11987949	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA012758			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use In Unapproved Indication	Seebri Breezhaler			S	Respiratory (inhalation)	50 Ug, Qd		Not Reported
	Ultibro Breezhaler			S	Respiratory (inhalation)	1 Df, Qod (50/110 Mcg)		Not Reported
	Azithromycin Sandoz			S	Oral	250 Mg, Tid (For 3 Weeks)		Novartis
	Atorvastatin Sandoz			S	Oral	20 Mg, Unk		Not Reported
	Montelukast			C	Unknown			Not Reported
	Qvar			C	Unknown			Not Reported
	Ventolin//Salbutamol			C	Unknown			Not Reported
	Alendronat Teva			C	Unknown			Not Reported
	Dexilant			C	Unknown			Not Reported
	Calcite			C	Unknown			Not Reported
	Pulmicort			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12224022	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016178268		34 YR	Male	ITA

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

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

Petechiae	Zitromax	S	Oral	1 Df, Daily	Pfizer				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12240604	EXPEDITED (15-DAY)		DS, HO, OT	PHHY2016FR041741		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Unilateral; Endophthalmitis; Eye Pain; Ocular Hyperaemia; Retinal Detachment; Retinal Ischaemia	Lucentis			S	Intraocular	Unk		Not Reported	
	Lucentis			S	Intraocular	Unk (In Left Eye)		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12252211	EXPEDITED (15-DAY)		OT	US-HOSPIRA-3240776		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Decreased Appetite; Dizziness; Dyspepsia; Nausea	Ondansetron			S	Intravenous (not otherwise specified)	Daily		Not Reported	
	Lorazepam			S	Intravenous (not otherwise specified)	Q6h		Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Bisacodyl			C	Oral	Daily		Not Reported	
	Budesonide			C		Svn		Not Reported	
	Tylenol /00020001/			C	Oral	Q4h		Not Reported	
	Amikacin			S	Respiratory (inhalation)			Not Reported	
	Sodium Chloride			C	Intravenous bolus	10-20 MI		Not Reported	
	Sodium Chloride			C	Intravenous bolus	10-20 MI		Not Reported	
	Montelukast			C	Oral	Bedtime		Not Reported	
	Pepcid /00305201/			C	Oral			Not Reported	
	Alprazolam			C	Oral	Daily		Not Reported	
	Enoxaparin			C	Subcutaneous			Not Reported	

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

Simvastatin	C	Oral	Bedtime	Not Reported
Albuterol Sulfate	C		Svn	Not Reported
Theophylline	C	Oral	Daily	Not Reported
Spiriva	C	Respiratory (inhalation)	Daily	Not Reported
Tygacil	S	Intravenous (not otherwise specified)		Not Reported
Codeine W/Guaifenesin /08428801/	C	Oral	Q6h	Not Reported
Fluticasone	C		1 Spray, Both Nostrils, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12252910	EXPEDITED (15-DAY)		OT	NZ-APOTEX-2016AP007558		20 YR	Female	NZL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Menstrual Disorder; Rectal Haemorrhage	Azithromycin			S	Oral	Unk, Unknown		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12256258	DIRECT					50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Zithromax			S	Oral			Not Reported
	Bioidentical Estrogen-Progestosterone			C				Not Reported
	Aleve			C				Not Reported
	Multivitamin			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Probiotic			C				Not Reported
	Flaxseed Oil			C				Not Reported
	Ibuprofen			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2016	12257104	DIRECT	Y	HO			36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Drug Hypersensitivity; Dry Throat; Dyspnoea; Feeling Hot; Pneumonia; Pruritus; Urticaria	Azithromycin			S	Oral	500 Mg Po On Day 1, Then 250mg Daily X4 250 Mg Daily X 4		Not Reported	
	Acyclovir			C				Not Reported	
	Dapsone			C				Not Reported	
	Penicillin			C				Not Reported	
	Nystatin			C				Not Reported	
	Metoprolol			C				Not Reported	
	Folic Acid			C				Not Reported	
	Magnesium Oxide			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Calcium Carbonate			C				Not Reported	
	Choline Magnesium Trisalicylate			C				Not Reported	
	Ursodiol			C				Not Reported	
	Omega-3 Ethyl Ester			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2016	11902901	EXPEDITED (15-DAY)		DE, OT	FR-TAKEDA-2016TUS000354		4 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Off Label Use; Toxicity To Various Agents	Colchicine			S	Unknown	Unk		Takeda	
	Zithromax			S	Unknown	Unk		Not Reported	
	Acetaminophen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2016	12237111	EXPEDITED (15-DAY)		DS, HO, OT	FR-ROCHE-1735871		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Unilateral; Endophthalmitis; Retinal	Lucentis			S	Other			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Detachment; Retinal Ischaemia	Lucentis	S	Other	In The Left Eye	Not Reported
	Azithromycin	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2016	12255678	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2014-11856		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vertigo	Metformin			S	Unknown	Unk		Aurobindo	
	Aldactone /00006201/			S	Unknown	Unk		Not Reported	
	Norvasc			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Morphine Sulfate			S	Unknown	Unk		Not Reported	
	Levaquin			S	Unknown	Unk		Not Reported	
	Phenergan /00033001/			S	Unknown	Unk		Not Reported	
	Demerol			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2016	12256080	NON-EXPEDITED			US-PFIZER INC-2016162915			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2016	12256094	NON-EXPEDITED			US-PFIZER INC-2016169650		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Amoxil			S		Unk		Not Reported	
	Ceclor			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2016	12257704	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016201365		64 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Intestinal Obstruction	Zithromax			S	Oral	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12261688	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-07950			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Metformin			S	Unknown			Aurobindo	
	Zithromax			S	Unknown			Not Reported	
	Augmentin /00756801/			S	Unknown			Not Reported	
	Levaquin			S	Unknown			Not Reported	
	Cymbalta			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12261955	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2015-11365			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown			Aurobindo	
	Metformin			S	Unknown			Aurobindo	
	Metoprolol			S	Unknown			Aurobindo	
	Augmentin /00756801/			S	Unknown			Not Reported	
	Lipitor			S	Unknown			Not Reported	
	Lopresor			S	Unknown			Not Reported	
	Lovastatin			S	Unknown			Not Reported	
	Medrol /00049601/			S	Unknown			Not Reported	
	Theo			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Zetia			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12262335	EXPEDITED (15-DAY)		HO	SA-MYLANLABS-2016M1015114			Unknown	SAU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Coronavirus Infection; Drug Ineffective; Maternal Exposure During Pregnancy; Middle East Respiratory Syndrome; Premature Delivery	Dexamethasone			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Vancomycin			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Imipenem			S	Unknown			Mylan	
	Imipenem			S				Mylan	
	Oseltamivir			S	Unknown			Mylan	
	Oseltamivir			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12262337	EXPEDITED (15-DAY)		HO	SA-MYLANLABS-2016M1015271			Unknown	SAU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Dexamethasone			S	Transplacental			Not Reported	
	Vancomycin			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental			Not Reported	
	Imipenem			S	Transplacental			Mylan	
	Oseltamivir			S	Transplacental			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12262379	NON-EXPEDITED			US-PFIZER INC-2016209341			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer	

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

	Azithromycin		S		Unk		Pfizer		
	Phenergan		S		Unk		Not Reported		
	Hydrocodone		S		Unk		Not Reported		
	Demerol		S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12265637	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-070721			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Interaction; Maternal Exposure During Pregnancy	Mirena			S	Intra-uterine	20 Mcg/24hr, Cont		Bayer	
	Azithromycin			S				Not Reported	
	Isotretinoin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2016	12265764	EXPEDITED (15-DAY)		DE	FR-FRESENIUS KABI-FK201601804		4 YR	Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dose Calculation Error; Drug Interaction; Multiple Organ Dysfunction Syndrome; Toxicity To Various Agents	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Colchicine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2016	11858755	EXPEDITED (15-DAY)		HO, LT	US-AUROBINDO-AUR-APL-2015-11372		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Drug Interaction; Hypoxia; Respiratory Distress; Respiratory Failure; Transaminases Increased	Azithromycin			S	Oral			Aurobindo	
	Suboxone			S	Sublingual	Unk		Not Reported	
	Lorazepam			S	Sublingual			Not Reported	
	Cocaine			C				Not Reported	
	Tramadol			C	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2016	12261987	EXPEDITED (15-DAY)		HO	CH-CIPLA LTD.- 2016CH03651			Unknown	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy; Drug Interaction;	Citalopram			S	Oral	10 Mg, Qd		Invagen	
Electrocardiogram Qt Prolonged; Medication Error	Azithromycin			S	Oral	250 Mg/3×Per Week, Unk		Cipla	
	Ciprofloxacin			S	Oral	500 Mg, Qd		Cipla	
	Domperidone			S	Oral	30 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2016	12266619	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2015-08759		5 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activated Partial Thromboplastin Time Ratio Decreased; Blood Creatine Phosphokinase Increased; Campylobacter Infection; Condition Aggravated; Conjunctivitis; Cutaneous Symptom; Epidermal Necrosis; Gastroenteritis; Genital Erosion; Haematochezia; Haematocrit Decreased; Haemoglobin Decreased; Oral Mucosa Erosion; Pyrexia; Rash; Rash Maculo-Papular; Red Cell Distribution Width Increased; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Paracetamol			S	Unknown	750 Mg, Once A Day		Aurobindo	
	Paracetamol			S	Unknown	Readministered Every 6-8 Hours		Aurobindo	
	Paracetamol			S	Intravenous (not otherwise specified)	750 Mg, Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk, Three Doses		Aurobindo	
	Ibuprofen			C	Unknown			Not Reported	
	Hydroxyzine			C	Unknown	Three Doses		Not Reported	
	Hydroxyzine			C		Three Doses		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12267766	NON-EXPEDITED			US-AKORN-12877			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Lacrimation Increased	Azasite			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12267854	NON-EXPEDITED			US-DRREDDYS-USA/USA/16/0055325			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dry Skin; Rash	Zenatane			S	Oral				Not Reported
	Ibuprofen			S	Unknown				Not Reported
	Azithromycin			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12267936	NON-EXPEDITED			US-AKORN-14181		62 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysgeusia; Eye Pain; Oral Discomfort	Azasite 1%			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12267972	NON-EXPEDITED			US-AKORN-15198			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Disorder; Pruritus	Azasite 1% Ophthalmic Solution			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12269214	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-070696			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Bronchitis; Drug Interaction; Pregnancy With Contraceptive Device	Mirena	S	Intra-uterine	20 Mcg/24hr, Cont	Bayer
	Azithromycin	S			Not Reported
	Accutane	S			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Apr-2016	12270263	DIRECT		DE			55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Brain Death; Cardiac Arrest	Azithromycin Tablets Usp 250 Mg			S	Oral	6 Tablet (S) Day1-2; Then 1/Day Taken By Mouth		Teva
	Evamist			C				Not Reported
	Steroid Shot			C				Not Reported
	Benzonatate			C				Not Reported
	Z-Pack			C				Not Reported
	Zyrtec			C				Not Reported
	Women'S Multivitamin			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12270634	NON-EXPEDITED			US-PFIZER INC-2016171804		72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective	Zithromax			S		250 Mg		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12273294	NON-EXPEDITED			US-AKORN-28355		73 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Irritation	Azasite 1% Ophthalmic Solution			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Apr-2016	12273295	NON-EXPEDITED			US-AKORN-21441			Female	USA

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

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

Eye Discharge; Eye Swelling		Azasite 1% Ophthalmic Solution		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12273337	NON-EXPEDITED			US-AKORN-19841			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Liquid Product Physical Issue		Azasite 1% Ophthalmic Solution		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12273338	NON-EXPEDITED			US-AKORN-16368			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Eye Irritation; Eye Irritation; Eye Pain; Eye Swelling		Azasite 1% Ophthalmic Solution		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12273339	NON-EXPEDITED			US-AKORN-17815		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Product Physical Issue; Product Quality Issue		Azasite 1% Ophthalmic Solution		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12273340	NON-EXPEDITED			US-AKORN-21743		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Irritation; Eye Pruritus; Ocular Hyperaemia; Swelling Of Eyelid; Wrong Technique In Product		Azasite 1% Ophthalmic Solution		S		Not Reported			

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

Usage Process

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2016	12273366	NON-EXPEDITED			US-AKORN-21746			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Visual Impairment	Azasite1% Ophthalmic Solution			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12009612	NON-EXPEDITED			US-PFIZER INC-2016057838			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort	Zithromax			S		500 Mg, Single		Pfizer
	Regn668			C	Subcutaneous	600 Mg, Single		Not Reported
	Regn668			C	Subcutaneous	300 Mg, Weekly		Not Reported
	Fluticasone			C	Nasal	Unk		Not Reported
	Nuvaring			C		Unk		Not Reported
	Vitamin B12			C		Unk		Not Reported
	Xyzal			C		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Pulmicort			C	Respiratory (inhalation)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12207749	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2016165378		67 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia	Zithromac			S	Oral	500 Mg, 1x/Day		Pfizer
	Rocephin			S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen			C		Unk		Not Reported

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

	Flomox [Cefcapene Pivoxil Hydrochloride]	C	Unk	Not Reported
	Astomin	C	Unk	Not Reported
	Cravit	C	Unk	Not Reported
	Mucodyne	C	Unk	Not Reported
	Mucodyne	C	Unk	Not Reported
	Loxonin	C	Unk	Not Reported
	Huscode	C	Unk	Not Reported
	Brocin	C	Unk	Not Reported
	Apricot Kernel Water	C	Unk	Not Reported
	Senega Syrup	C	Unk	Not Reported
	Norvasc	C		Pfizer
	Exforge	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12278212	EXPEDITED (15-DAY)		HO	JP-MYLANLABS-2016M1014971			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Ileus Paralytic; Pleural Effusion; Vomiting	Clarithromycin			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12279540	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASL2016045917		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atypical Pneumonia; Blood Creatinine Increased; Brain Injury; Cerebrovascular Accident; Coagulopathy; Dialysis Related Complication; Endotracheal Intubation; Immune System Disorder; Malaise; Oxygen	Nplate			S	Unknown	Unk		Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	

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

Consumption Decreased;
Platelet Count Decreased;
Pulmonary Mass; Red
Blood Cell Abnormality;
Sinusitis; Vomiting; White
Blood Cell Count
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12279753	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2016212413		2 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia; Flatulence; Gastrointestinal Disorder; Vomiting	Zithromax			S	Oral	1.3 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2016	12281212	DIRECT	Y	LT			59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Inhibitory Drug Interaction; Product Prescribing Error; Toxicity To Various Agents; Unresponsive To Stimuli	Azithromycin, 500 Mg	Y		S	Intravenous drip			Not Reported	
	Diltiazem, 125 Mg/125ml	Y		S	Intravenous drip	15 Mg 15mg/Hr Intravenous Drip		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12265348	EXPEDITED (15-DAY)		OT	US-ABBVIE-16K-163- 1601841-00		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chest Discomfort; Constipation; Cough; Flatulence; Haemorrhoidal	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous	Two Weeks Later		Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous	Two Weeks Later		Not Reported	
Haemorrhage; Increased Upper Airway Secretion; Influenza; Pain In	Z-Pak			S	Unknown			Not Reported	
	Tramadol			C				Not Reported	

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

Extremity; Pain In Jaw; Pyrexia	Prevacid	C	Topical	Not Reported
	Losartan Hctz	C		Not Reported
	Nitro Bid	C		Not Reported
	Carvedilol	C		Not Reported
	Gliperide	C		Not Reported
	Potassium	C		Not Reported
	Furosemide	C		Not Reported
	Dicyclomine	C		Not Reported
	Proctozone	C		Not Reported
	Hydrocortisone	C		Not Reported
	Lipitor	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12281146	NON-EXPEDITED			US-PFIZER INC- 2016177628		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Trazodone			S		Unk		Not Reported	
	Amitriptyline			S		Unk		Not Reported	
	Cephalexin /00145501/			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12282283	EXPEDITED (15-DAY)		HO, OT	US-SEBELA IRELAND LIMITED- 2016SEB00265		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Diarrhoea; Hypoglycaemia; Insomnia	Imuran			S		150 Mg, 1x/Day		Sebela	
	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Every 8 Weeks		Not Reported	
	Estradiol			S		Unk		Not Reported	
	Zithromax			S		Unk		Not Reported	
	Valtrex			C		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12285627	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Swelling; Product Substitution Issue; Urticaria	Azithromycin Tab			S	Oral	250mg 6 Mouth		Teva	
	250mg/Azithromycin Tablets								
	250mg Greenstone								
	Centreum Daily Vitamins			C				Not Reported	
	Daily Spring Valley Glucosamine			C				Not Reported	
	Condroitin								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2016	12285781	DIRECT	Y	LT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Hyperkalaemia; Hypertensive Urgency; Pulmonary Oedema; Torsade De Pointes	Amiodarone			S				Not Reported	
	Azithromycine			S				Not Reported	
	Amitriptyline			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12176788	EXPEDITED (15-DAY)		HO	ZA-ROCHE-1724895		2 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Decreased; Seizure; Status Epilepticus	Rocephin			S	Unknown			Not Reported	
	Epilim			S	Oral			Not Reported	
	Epilim			S	Intravenous (not otherwise specified)			Not Reported	
	Amikacin			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Duolin (Ipratropium Bromide\Salbutamol Sulphate)			C				Not Reported	

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

Perfalgan

C

Intravenous (not
otherwise specified)

Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12284446	EXPEDITED (15-DAY)		HO	CA-APOTEX-2016AP007704		57 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardiac Failure; Myocarditis; Pulse Absent	Apo-Azithromycin Tablets 250 Mg			S	Oral	250 Mg, 1 Every 5 Days		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12285348	EXPEDITED (15-DAY)		OT	UA-TEVA-650855ISR		7 YR	Female	UKR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Ear Infection; Tympanic Membrane Disorder	Sumamed			S	Oral	1 Dosage Form= 100 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12285357	EXPEDITED (15-DAY)		OT	UA-TEVA-650857ISR			Male	UKR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Disease Progression; Drug Ineffective; Pneumonia	Sumamed			S	Oral	1 Dosage Form=100 Mg/ 5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2016	12288202	NON-EXPEDITED			US-AKORN-27113			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eyelid Margin Crusting	Azasite			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2016	12289148	DIRECT		DE			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Pulmonary Oedema	Azithromycin			S	Oral			Greenstone
	Fluvoxamine Maleate			C				Not Reported
	Gabapentin			C				Not Reported
	Invokana			C				Not Reported
	Klonopin			C				Not Reported
	Mirtazapine			C				Not Reported
	Glipizideer			C				Not Reported
	Metformin Hcl			C				Not Reported
	Losartin Potassium			C				Not Reported
	Atrovastatin			C				Not Reported
	Cough Syruo With Codeine			C				Not Reported
	Aspirin			C				Not Reported
	Topiramate			C				Not Reported
	Levothyroxine			C				Not Reported
	Vitamin D Nos			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	10017440	NON-EXPEDITED			US-PFIZER INC-2014073819		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Clindamycin Phosphate			S		Unk		Pfizer
	Ceftin			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported
	Vioxx			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	11240175	EXPEDITED (15-DAY)		OT	PHHY2015CA076192		25 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	150 Mg, Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Novartis
	Rifadin			S	Unknown	Unk		Not Reported
	Avelox//Levofloxacin			S	Unknown	Unk		Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown	10 Mg, Unk		Not Reported
	Reactine//Cetirizine Hydrochloride			S	Unknown	20 Mg, Bid (For 2 Weeks)		Not Reported
	Benadryl//Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported
	Benadryl//Diphenhydramine Hydrochloride			S				Not Reported
	Benadryl//Diphenhydramine Hydrochloride			S				Not Reported
	Benadryl//Diphenhydramine Hydrochloride			S				Not Reported
	Benadryl//Diphenhydramine Hydrochloride			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12272363	EXPEDITED (15-DAY)		HO	DE-TEVA-649521GER		76 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Angioedema; Arthritis; Blister; Circulatory Collapse; Decreased Appetite; Diarrhoea; Dizziness; Erythema; Faeces Hard; Fall; Fatigue; Osteitis;	Azithromycin Abz 500mg Filmtabletten			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rash; Rash Macular;
Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12290193	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2016217184		83 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysbiosis; Fungal Infection; Leukoplakia Oral	Sulperazon			S	Intravenous drip	1.5 G, 3x/Day		Pfizer	
	Azithromycin			S	Oral	0.5 G, 1x/Day		Pfizer	
	Tazocin			S	Intravenous drip	4.5 G, 2x/Day		Pfizer	
	Zuo Ke			S	Intravenous drip	0.4 G, 1x/Day		Not Reported	
	Ambroxol Hydrochloride			C	Intravenous drip	30 Mg, 1x/Day		Not Reported	
	Ambroxol Hydrochloride			C				Not Reported	
	Singulair			C	Oral	10 Mg, 1x/Day		Not Reported	
	Singulair			C				Not Reported	
	Theophylline			C	Oral	1 Tablet, 2x/Day		Not Reported	
	Theophylline			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12290678	NON-EXPEDITED			US-PFIZER INC- 2016182209		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amiodarone Hcl			S		Unk		Pfizer	
	Pravachol			C		Unk		Not Reported	
	Lasix			C		Unk		Not Reported	
	Hydralazine			C		Unk		Not Reported	
	Potassium			C		Unk		Not Reported	
	Norvasc			C		Unk		Not Reported	
	Zestril			C		Unk		Not Reported	
	Toprol			C		Unk		Not Reported	

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

		Allopurinol		C					Not Reported
		Fenofibrate		C					Not Reported
		Warfarin		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12290682	NON-EXPEDITED			US-PFIZER INC-2016180118		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Cyclosporine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12290740	NON-EXPEDITED			US-PFIZER INC-2016195016		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12291140	EXPEDITED (15-DAY)		LT	ES-PFIZER INC-2016225440		27 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Auditory; Psychotic Behaviour; Suicidal Ideation	Pristiq			S	Oral	100 Mg Every 24 Hours		Pfizer	
	Azitromicina Pharmacia			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2016	12293537	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2016217755			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Cough; Drug	Azithromycin			S				Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ineffective; Meningitis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2016	12293608	NON-EXPEDITED			US-PFIZER INC-2016192645			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Intolerance; Malaise	Azithromycin			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2016	12293719	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016225403		2 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Epilepsy	Zithromax			S	Oral	0.15 G, 1x/Day		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12156425	NON-EXPEDITED			US-PFIZER INC-2016091934		69 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eyelid Ptosis	Zithromax			S	Oral	500 Mg, Single Dose (First Day Dose)		Pfizer	
	Zithromax			S	Oral	250 Mg, Daily (The Next Day, You Take One)		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2016	12294458	EXPEDITED (15-DAY)		DE, HO	FR-LUPIN PHARMACEUTICALS INC.-2016-01601		4 YR	Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; Toxicity To Various Agents	Colchicine			S	Unknown	8 Mg		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Paracetamol			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12297678	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1016402			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Pertussis	Digoxin			S	Unknown			Not Reported	
	Sotalol			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Dtap Vaccine			S	Unknown			Mylan	
	Misoprostol			S	Unknown	25microg Q6		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12297682	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2016M1016585			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Tachycardia Foetal	Digoxin			S	Transplacental			Not Reported	
	Sotalol			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental			Not Reported	
	Dtap Vaccine			S	Transplacental			Mylan	
	Misoprostol			S	Transplacental	25microg Q6		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12297874	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2016222699			Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Hemiparesis; Hypoaesthesia; Paraesthesia; Sensation Of Foreign Body	Zmax			S		Single Dose		Pfizer	
	Urizone			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12297906	NON-EXPEDITED			US-PFIZER INC-2016199391		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Fall; Hand Fracture; Head Injury	Azithromycin			S		250 Mg, 5 Day Pack 2 First Day Then It Is 1, 1, 1		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2016	12297926	NON-EXPEDITED			US-PFIZER INC-2016198007		71 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Guaifenesin		Y	S		Unk		Unknown	
	Ambien			S		Unk		Not Reported	
	Minocin			S		Unk		Not Reported	
	Zephrex-D			S		Unk		Not Reported	
	Pravastatin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2016	12298805	EXPEDITED (15-DAY)		OT	BR-UCBSA-2016014475		63 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Nervous System Infection; Hypersensitivity; Pharyngitis	Certolizumab Pegol			S		400 Mg, Ev 15 Days		Ucb	
	Azithromycin			S	Oral	Unk		Not Reported	
	Prednisone			S	Oral	20 Mg, 2x/Day (Bid)		Not Reported	
	Meloxicam			C	Oral	15 Mg, Once Daily (Qd)		Not Reported	
	Nimesulide			C	Oral	100 Mg, 2x/Day (Bid)		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2016	12299621	NON-EXPEDITED			US-PFIZER INC-2016228240			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dimetapp			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2016	12300844	EXPEDITED (15-DAY)		OT	US-DRREDDYS-DRL/USA/16/0078824		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection; Upper Respiratory Tract Infection	Augmentin			S	Unknown			Not Reported	
	Humira			S	Subcutaneous	Loading Dose 160mg Once		Not Reported	
	Humira			S	Subcutaneous	Loading Dose 80mg Once		Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2016	12294773	NON-EXPEDITED			US-PFIZER INC-2016192961			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2016	12304910	NON-EXPEDITED			US-PFIZER INC-2016189879		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	

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

Azithromycin			S		Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2016	12306968	NON-EXPEDITED			US-ALKERMES INC.- ALK-2015-004583			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthma	Vivitol			S	Intramuscular	380 Mg, Qmo		Alkermes	
Exercise Induced; Lower	Z-Pak			S		Unk		Not Reported	
Respiratory Tract	Z-Pak			S		Unk		Not Reported	
Infection; Melaena;	Lamictal			C		Unk		Not Reported	
Wheezing	Topamax			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2016	12310304	DIRECT		OT			73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Azithromycin			S	Oral			Greenstone	
	Simvastatin			C				Not Reported	
	Aspirin			C				Not Reported	
	Vitamin B6			C				Not Reported	
	Calcium Magnesium Citrate			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Loratadine			C				Not Reported	
	Multivitamin			C				Not Reported	
	Omega-Fish Oil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	10931278	EXPEDITED (15-DAY)		OT	US-003170		12 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Impavido (Miltefosine) Capsules			S	Unknown			Knight Therapeutics	
Nausea; Off Label Use;	Fluconazole			S				Not Reported	
Pancreatitis; Therapeutic	Rifampin			S	Unknown			Not Reported	

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

Response Unexpected; Vomiting	Azithromycin	S	Unknown	Not Reported
	Dexamethasone	C	Unknown	Not Reported
	Amphotericin B	C	Intravenous (not otherwise specified)	Not Reported
	Amphotericin B	C	Intravenous (not otherwise specified)	Not Reported
	Amphotericin B	C	Intrathecal	Not Reported
	Amphotericin B	C	Intrathecal	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	12166111	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016134177		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Ventricular Extrasystoles; Ventricular Tachycardia	Zithromax			S	Oral	1 G, Single		Pfizer	
	Zithromax			S	Oral	250 Mg, Daily		Pfizer	
	Lantus			C		Unk, 1x/Day		Not Reported	
	Lovastatin			C		50 Mg, 2x/Day		Not Reported	
	Omeprazole			C		40 Mg, 1x/Day		Not Reported	
	Lorazepam			C		1 Mg, As Needed		Not Reported	
	Tylenol			C		Unk, As Needed		Not Reported	
	Cardinol			C		Unk, As Needed		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	12309483	NON-EXPEDITED			US-PFIZER INC-2016208780		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Wellbutrin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	

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

	Ambien		S		Unk		Not Reported		
	Dynabac		S		Unk		Not Reported		
	Iodine		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	12309505	NON-EXPEDITED			US-PFIZER INC-2016230230			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Ciprofloxacin Hcl			S		Unk		Not Reported	
	Voltaren			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	12310901	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2016224897		27 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Zithromac			S	Oral	500 Mg, Daily		Pfizer	
	Loxoprofen Sodium			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	12311261	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016228234		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer	Lyrica			S	Oral	100 Mg, 3x/Day		Pfizer	
	Lyrica			S	Oral	100 Mg, 3x/Day		Pfizer	
	Lyrica			S	Oral	75 Mg, 2x/Day		Pfizer	
	Lyrica			S	Oral	100 Mg, 3x/Day		Pfizer	
	Lyrica			S	Oral	100 Mg, 3x/Day		Pfizer	
	Lyrica			S	Oral	100 Mg, 3x/Day		Pfizer	

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

Lyrica	S	Oral	100 Mg, 3x/Day	Pfizer
Lipitor	S	Oral	20 Mg, 1x/Day	Pfizer
Zoloft	S	Oral	50 Mg, 1x/Day	Pfizer
Neurontin	S	Oral	400 Mg, 1x/Day	Pfizer
Zithromax	S		250 Mg, Unk	Pfizer
Omeprazole	C	Oral	40 Mg, Daily	Not Reported
Percocet	C	Oral	1 Df, As Needed, 325mg, Twice A Day)	Not Reported
Percocet	C	Oral	1 Df, As Needed, (Oxycodone: 7.5mg,Acetaminophen: 325mg, Twice A Day)	Not Reported
Percocet	C	Oral	1 Df, As Needed, (Oxycodone: 7.5mg,Acetaminophen: 325mg, Twice A Day)	Not Reported
Percocet	C	Oral	1 Df, As Needed, (Oxycodone: 7.5mg,Acetaminophen: 325mg, Twice A Day)	Not Reported
Compazine	C	Oral	10 Mg, As Needed, (Every 6 Hrs)	Not Reported
Compazine	C	Oral	10 Mg, As Needed, (Every 6 Hrs)	Not Reported
Compazine	C	Oral	10 Mg, As Needed, (Every 6 Hrs)	Not Reported
Compazine	C	Oral	10 Mg, As Needed, (Every 6 Hrs)	Not Reported
Emla	C	Topical	Unk, (2.5-2.5%;On Days Of Chemotherapy)	Not Reported
Levaquin	C	Oral	500 Mg, Daily	Not Reported
Levaquin	C	Oral	500 Mg, Daily, (If Temperature Is More One Hundred)	Not Reported

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

Levaquin	C	Oral	500 Mg, Daily	Not Reported
Zofran	C	Oral	8 Mg, As Needed, (Every 6 Hours)	Not Reported
Decadron	C	Oral	8 Mg, 1x/Day	Not Reported
Decadron	C	Oral	8 Mg, 1x/Day	Not Reported
Decadron	C	Oral	8 Mg, 2x/Day, (Start Day Before Chemo)	Not Reported
Decadron	C	Oral	8 Mg, 1x/Day	Not Reported
Decadron	C	Oral	8 Mg, 1x/Day	Not Reported
Decadron	C	Oral	8 Mg, 1x/Day	Not Reported
Decadron	C	Oral	8 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day	Not Reported
Zantac	C	Oral	150 Mg, 1x/Day, (Daily And Half An Hour Before Chemo)	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported
Benadryl	C	Oral	50 Mg, 1x/Day	Not Reported

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

Benadryl	C	Oral	50 Mg, 1x/Day, (Half An Hour Before Chemo)	Not Reported
Aristocort A	C	Topical	Unk, 3x/Day, (0.5%, 1 Application, Apply To Affected Skin)	Not Reported
Femara	C	Oral	2.5 Mg, 1x/Day	Not Reported
Femara	C	Oral	2.5 Mg, 1x/Day	Not Reported
Valtrax	C		1 G, 3x/Day	Not Reported
Bentyl	C	Oral	20 Mg, 4x/Day	Not Reported
Zithromax Z-Pak	C	Oral	250 Mg, Daily, (Take 2 Tabs On First Day)	Not Reported
Xeloda	C	Oral	1500 Mg, Cyclic, (Twice A Day For 2 Weeks And 1 Week Off)	Not Reported
Bactrim Ds	C	Oral	1 Df, 2x/Day, (Sulfamethoxazole-800;Trimethoprim-160mg)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2016	12311265	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2016225226		39 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Memory Impairment; Monoplegia; Transaminases Increased	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
	Vitamin B			C		Unk		Not Reported	
	Vitamin C			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	10342050	NON-EXPEDITED			US-PFIZER INC-2014202998			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

Levaquin	S	Unk	Not Reported
Zebeta	S	Unk	Not Reported
Compazine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	10880209	NON-EXPEDITED			US-PFIZER INC-2015072844			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Macrobid			S		Unk		Not Reported	
	Tequin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Motrin			S		Unk		Not Reported	
	Naproxen			S		Unk		Not Reported	
	Reglan			S		Unk		Not Reported	
	Aleve			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12061502	NON-EXPEDITED			US-PFIZER INC-2016025098		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Burning Sensation; Loss Of Personal Independence In Daily Activities; Pruritus; Rash; Scar; Swelling	Zithromax			S	Oral	500 Mg, Daily 2df First Day		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day (1df For 4 Day)		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12185470	EXPEDITED (15-DAY)		HO, OT	US-TEVA-644122USA		9 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Eosinophilic Pneumonia; Pneumomediastinum; Pneumopericardium; Pneumothorax	Bactrim			S	Unknown			Teva	
	Azithromycin			S				Not Reported	
	Amoxicillin			C				Not Reported	
	Hydrocortisone			C	Topical			Not Reported	
	Diphenhydramine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12281123	NON-EXPEDITED			US-PFIZER INC- 2016216477		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Distension; Discomfort; Dizziness; Flatulence; Gastric Disorder; Nausea	Azithromycin			S	Oral	2 Capsules, Daily		Pfizer	
	Azithromycin			S	Oral	1 Capsule, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12313271	NON-EXPEDITED			US-PFIZER INC- 2016228421		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circumstance Or Information Capable Of Leading To Medication Error; Diarrhoea	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12313280	NON-EXPEDITED			US-PFIZER INC- 2016226534		58 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12313304	NON-EXPEDITED			US-PFIZER INC-2016232379		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12313339	NON-EXPEDITED			US-PFIZER INC-2016230988		8 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Trimethoprim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12313341	NON-EXPEDITED			US-PFIZER INC-2016221858		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Excedrin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12315055	NON-EXPEDITED			US-PFIZER INC-2016200740			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12315394	EXPEDITED (15-DAY)		OT	PHHY2016CA057107		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Anxiety; Crying; Diarrhoea; Dyspnoea; Hot Flush; Insomnia; Mental Disorder; Nausea; Panic Attack; Paranoia	Azithromycin Monohydrate	S	Oral	500 Mg, Once/Single (2 Tablets On Day One, Then One Tablet On Day 2 Through 5)	Novartis
	Azithromycin Monohydrate	S	Oral	250 Mg, Qd (2 Tablets On Day One, Then One Tablet On Day 2 Through 5)	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2016	12315428	EXPEDITED (15-DAY)		OT	GB-VIIV HEALTHCARE LIMITED- GB2016059047		27 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chills; Cough; Dermatitis Allergic; Headache; Influenza Like Illness; Myalgia	Azithromycin			S	Oral	1 G, Unk, Stat Dose.		Glaxosmithkline	
	Triumeq			S	Oral	1 Df, Qd, Triumeq = Abacavir 600mg, Lamivudine 300mg, Dolutegravir 50mg.		Viiv	
	Colecalciferol			C	Unknown	800 Iu, Qd		Not Reported	
	Sanatogen			C		1 Df, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12190738	EXPEDITED (15-DAY)		HO, OT	US-ACTAVIS-2016- 05910		9 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Eosinophilic Pneumonia; Pneumomediastinum; Pneumopericardium; Pneumothorax	Sulfamethoxazole-Trimethoprim (Watson Laboratories)			S	Unknown	Unk		Watson	
	Azithromycin (Unknown)			S	Unknown	Unk		Not Reported	
	Amoxicillin (Unknown)			S	Unknown	Unk		Not Reported	
	Hydrocortisone			C	Topical	Unk		Not Reported	
	Diphenhydramine			C	Oral	Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12212038	NON-EXPEDITED			US-PFIZER INC-2016164925			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Sulfacetamide			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12310731	EXPEDITED (15-DAY)		DE	PHHY2016IT052829		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Lactic Acidosis; Shock Haemorrhagic	Azithromycin			S	Unknown	500 Mg		Novartis	
	Amiodarone			S	Oral	400 Mg, Qd		Not Reported	
	Levoxacin			S	Oral	250 Mg, Qd		Not Reported	
	Tazocin			S	Intravenous (not otherwise specified)	2 Df, Qd		Not Reported	
	Tazocin			S	Unknown	4.5 G, Bid		Not Reported	
	Calciparin			C	Subcutaneous	2 Df		Not Reported	
	Calciparin			C	Unknown	0.5 Unk, Bid		Not Reported	
	Citalopram			C	Unknown	20 Mg		Not Reported	
	Lanoxin			C	Unknown			Not Reported	
	Cardarone			C	Intravenous drip			Not Reported	
	Cardarone			C	Unknown	1 Tablet Bid		Not Reported	
	Glucose			C	Unknown	5 %		Not Reported	
	Dilzene			C	Unknown			Not Reported	
	Medrol			C	Unknown	4 Mg		Not Reported	
	Pantorc			C	Unknown	40 Mg		Not Reported	
	Mirapexin			C	Unknown			Not Reported	
	Torvast			C	Unknown	10 Mg		Not Reported	

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

Insulin	C	Unknown	Not Reported
Lantus	C	Unknown	Not Reported
Carnitine	C	Unknown	Not Reported
Eporatio	C	Unknown	Not Reported
Halcion	C	Unknown	Not Reported
Renvela	C	Unknown	Not Reported
Dibase	C	Unknown	Not Reported
Asa	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12317406	NON-EXPEDITED			US-PFIZER INC-2016192200		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12317437	NON-EXPEDITED			US-PFIZER INC-2016206668			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12317469	NON-EXPEDITED			US-PFIZER INC-2016228374		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Zithromax			S	Oral	Unk, 1x/Day		Pfizer
Abdominal Pain;	Flagyl			S	Oral	Unk, 1x/Day		Pfizer
Arthralgia; Diarrhoea;	Probiotics			C	Oral	Unk, Daily		Not Reported
Dizziness; Fatigue;								
Incorrect Dose Administered; Lactose								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Intolerance; Night Sweats;
Product Use In
Unapproved Indication;
Tinnitus; Urine Output
Decreased; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12317488	NON-EXPEDITED			US-PFIZER INC- 2016192400			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Ceclor			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Ketoprofen			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12318425	NON-EXPEDITED			US-PFIZER INC- 2016233055		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lortab			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12318431	NON-EXPEDITED			US-PFIZER INC- 2016212078			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling Of Eyelid	Azithromycin			S		250 Mg, Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12318440	NON-EXPEDITED			US-PFIZER INC-2016213043			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex /00145501/			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12318443	NON-EXPEDITED			US-PFIZER INC-2016211920		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Oral Fungal Infection; Upper Respiratory Tract Infection	Zithromax			S		Unk		Pfizer	
	Humira			S	Subcutaneous	160 Mg, 1x/Day		Not Reported	
	Humira			S	Subcutaneous	80 Mg, 1x/Day		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Unk (1 In 2 Wk)		Not Reported	
	Augmentin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12318913	EXPEDITED (15-DAY)		OT	PHHY2016GB058105		27 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chills; Cough; Dermatitis Allergic; Headache; Influenza Like Illness; Myalgia	Azithromycin			S	Oral	1 G, Unk		Novartis	
	Triumeq			S	Oral	1 Df, Qd (Abacavir 600mg, Lamivudine 300mg, Dolutegravir 50mg)		Not Reported	
	Colecalciferol			C	Unknown	800 Iu, Qd		Not Reported	
	Sanatogen Multivitamins			C	Unknown	1 Df, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2016	12320059	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1017523			Unknown	GBR

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chills; Cough; Dermatitis Allergic; Headache; Influenza Like Illness; Myalgia	Azithromycin			S	Oral	1 G, Unk (Stat Dose.)		Not Reported	
	Triumeq			S	Oral	1 Df, Qd (Triumeq = Abacavir 600mg, Lamivudine 300mg, Dolutegravir 50mg.)		Mylan	
	Colecalciferol			C		800 Iu, Qd		Mylan	
	Sanatogen /00481701/			C		1 Df, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12322721	NON-EXPEDITED			US-PFIZER INC-2016229605			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12322736	NON-EXPEDITED			US-PFIZER INC-2016232622		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12322762	NON-EXPEDITED			US-PFIZER INC-2016238606		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Telmisartan			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12323441	NON-EXPEDITED			US-PFIZER INC-2016222836		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12323845	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2016235713		27 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chills; Cough; Dermatitis Allergic; Headache; Influenza Like Illness; Myalgia	Azithromycin			S	Oral	1 G, Single (Stat Dose)		Pfizer	
	Triumeq			S	Oral	[Abacavir 600mg]/[Dolutegravir Sodium 50mg]/[Lamivudine 300mg], 1x/Day		Not Reported	
	Colecalciferol			C		800 Iu, 1x/Day		Not Reported	
	Sanatogen			C		1 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12323905	EXPEDITED (15-DAY)		OT	US-TEVA-655656USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Diarrhoea; Dysphagia; Intentional Product Misuse; Vomiting; Wrong Technique In Product Usage Process	Azithromycin			S		500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2016	12325024	EXPEDITED (15-DAY)		OT	PH-PFIZER INC-2016235168		55 YR	Male	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Bradycardia		Zithromax		S		Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2016	12325974	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR- APL-2016-05222		4 YR	Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Multiple Organ Dysfunction Syndrome; Syncope; Toxicity To Various Agents; Vomiting	Azithromycin			S	Unknown			Aurobindo	
	Colchicine			S	Unknown	8 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2016	12325983	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR- APL-2016-05582		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Necrotising Myositis; Pure White Cell Aplasia	Azithromycin			S	Unknown			Aurobindo	
	Atorvastatin			S	Unknown	40 Mg, Daily		Not Reported	
	Atorvastatin			S				Not Reported	
	Amlodipine			C	Unknown	10 Mg, Daily		Not Reported	
	Losartan			C	Unknown	100 Mg, Daily		Not Reported	
	Carvedilol			C	Unknown	25 Mg, Daily		Not Reported	
	Triamterene/Hctz			C	Unknown	Unk Unk, Daily		Not Reported	
	Aspirin /00002701/			C	Unknown	325 Mg, Daily		Not Reported	
	Sertraline			C	Unknown	50 Mg, Daily		Not Reported	
	Calcia + Vitamin D			C	Unknown	(1500mg/2000 Iu),, Daily		Not Reported	
	Lansoprazole			C	Unknown	30 Mg, Daily		Not Reported	
	Levothyroxine			C	Unknown	125 Mcg, Daily		Not Reported	
	Alprazolam			C	Unknown	0.25 Mg, Two Times A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2016	12329102	NON-EXPEDITED			US-PFIZER INC- 2016240859			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2016	12329175	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2016M1018016			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Linezolid			S	Intravenous (not otherwise specified)	Twice In 2008		Not Reported	
	Linezolid			S	Oral	600 Mg/Kg, Bid		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Clarithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2016	12329419	EXPEDITED (15-DAY)		OT	GB-TEVA-656033ACC		27 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chills; Cough; Dermatitis Allergic; Headache; Influenza Like Illness; Myalgia	Azithromycin			S	Oral	Stat Dose.		Not Reported	
	Triumeq			S	Oral	1 Dosage Forms Daily; Triumeq = Abacavir 600mg, Lamivudine 300mg, Dolutegravir 50mg		Not Reported	
	Colecalciferol			C		800 lu (International Unit) Daily;		Not Reported	
	Sanatogen			C		1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12192260	NON-EXPEDITED			US-PFIZER INC-2016160568			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Drug	Azithromycin			S		Unk		Pfizer	

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

Hypersensitivity; Vomiting	Metformin Hcl	S	Unk	Pfizer
	Augmentin	S	Unk	Not Reported
	Elavil	S	Unk	Not Reported
	Lisinopril	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12331766	EXPEDITED (15-DAY)		HO	US-RANBAXY-2013US-66181		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cytomegalovirus Test Positive; Focal Segmental Glomerulosclerosis; Renal Tubular Necrosis	Azithromycin			S	Unknown	Unk		Sun	
	Mesalamine			S	Unknown	4.8 Mg, Daily		Not Reported	
	6-Mercaptopurine			S	Unknown	50 Mg, Daily		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Clonidine			C	Unknown	Unk		Not Reported	
	Labetalol			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12331976	NON-EXPEDITED			US-PFIZER INC-2016237950			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12332638	NON-EXPEDITED			US-PFIZER INC-2016235387			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12335047	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2015312871		1 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12335051	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2016237421		10 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Cough; Eyelid Oedema; Lip Oedema; Nasal Obstruction; Urticaria	Zitromax			S	Oral	200 Mg / 5 MI; Unk		Pfizer	
	Metalgalial			S	Oral	500 Mg/MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2016	12335141	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016240564		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage; Thirst	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2016	11837672	EXPEDITED (15-DAY)		LT, OT	PT-GILEAD-2015-0185818		59 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Harvoni			S	Oral	1 Df, Qd		Gilead	
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported	
	Alopurinol			S	Oral	300 Mg, Qd		Not Reported	
	Exforge			C	Oral	1 Df, Unk		Not Reported	
	Exforge			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2016	12336096	NON-EXPEDITED			US-PFIZER INC-2016244603		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Neomycin Sulfate			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Imitrex			S		Unk		Not Reported	
	Phenergan			S				Not Reported	
	Toradol			S		Unk		Not Reported	
	Cipro			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12340054	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2016US04480			Unknown	MWI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuropathy Peripheral	Stavudine			S	Unknown	Unk		Cipla	
	Lamivudine			S	Unknown	Unk		Cipla	
	Nevirapine			S	Unknown	Unk		Cipla	
	Zidovudine			S	Unknown	Unk		Cipla	
	Ritonavir			S	Unknown	Unk		Cipla	
	Abacavir			S	Unknown	Unk		Cipla	
	Tenofovir			S	Unknown	Unk		Cipla	
	Efavirenz			S	Unknown	Unk		Cipla	
	Bleomycin			S	Unknown	15 Units/M2		Cipla	
	Bleomycin			S	Intramuscular	10 Units/M2 Every 3 Weeks As Salvage Regimen		Cipla	

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

Vincristine	S	Intravenous (not otherwise specified)	1.4 Mg/M2	Cipla
Vincristine	S	Intravenous (not otherwise specified)	1.4 Mg/M2, Every 3 Weeks As Salvage Regimen	Cipla
Doxorubicin	S	Intravenous (not otherwise specified)	35 Mg/M2, Every 3 Weeks As Salvage Regimen	Cipla
Paclitaxel	S	Intravenous (not otherwise specified)	75 Mg/M2, Infusion Every 3 Weeks	Cipla
Ciprofloxacin	S	Oral	Unk	Cipla
Amoxicillin	S	Oral	Unk	Not Reported
Azithromycin	S	Oral	Unk	Cipla
Fluconazole	S	Oral	Unk	Cipla
Quinine	S	Parenteral	Unk	Not Reported
Albendazole	S	Unknown	Unk	Not Reported
Mebendazole	S	Unknown	Unk	Not Reported
Lopinavir	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S	Oral	Unk	Not Reported
Co-Trimoxazole	S			Not Reported
Ceftriaxone	S	Parenteral	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Metronidazole	S			Not Reported
Rifampicin	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Ethambutol	S	Unknown	Unk	Not Reported
Streptomycin	S	Unknown	Unk	Not Reported
Praziquantel	S	Unknown	Unk	Not Reported
Artesunate	S	Oral	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12340110	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2016US04483			Unknown	MWI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Meningitis Bacterial	Stavudine			S	Unknown	Unk		Cipla	
	Nevirapine			S	Unknown	Unk		Cipla	
	Zidovudine			S	Unknown	Unk		Cipla	
	Lamivudine			S	Unknown	Unk		Cipla	
	Ritonavir			S	Unknown	Unk		Cipla	
	Abacavir			S	Unknown	Unk		Cipla	
	Tenofovir			S	Unknown	Unk		Cipla	
	Efavirenz			S	Unknown	Unk		Cipla	
	Bleomycin			S	Unknown	15 Units/M2 Via Intramuscular Or Intravenous Injection		Cipla	
	Bleomycin			S	Intramuscular	10 Units/M2, Every 3 Weeks As Salvage Regimen		Cipla	
	Vincristine			S	Intravenous (not otherwise specified)	1.4 Mg/M2, Unk		Cipla	
	Vincristine			S	Intravenous (not otherwise specified)	1.4 Mg/M2, Every 3 Weeks As Salvage Regimen		Cipla	
	Doxorubicin			S	Unknown	35 Mg/M2, Every 3 Weeks As Salvage Regimen Iv		Cipla	
	Paclitaxel			S	Intravenous (not otherwise specified)	75 Mg/M2, Infusion Every 3 Weeks		Cipla	
	Ciprofloxacin			S	Oral	Unk		Cipla	
	Amoxicillin			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Cipla	
	Fluconazole			S	Oral	Unk		Cipla	

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

Quinine	S	Parenteral	Unk	Not Reported
Albendazole	S	Unknown	Unk	Not Reported
Mebendazole	S	Unknown	Unk	Not Reported
Lopinavir	S	Unknown	Unk	Not Reported
Ceftriaxone	S	Parenteral	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Metronidazole	S			Not Reported
Rifampicin	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Ethambutol	S	Unknown	Unk	Not Reported
Streptomycin	S	Unknown	Unk	Not Reported
Praziquantel	S	Unknown	Unk	Not Reported
Artesunate	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12340116	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2016US04481			Unknown	MWI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Stavudine			S	Unknown	Unk		Cipla
	Nevirapine			S	Unknown	Unk		Cipla
	Zidovudine			S	Unknown	Unk		Cipla
	Lamivudine			S	Unknown	Unk		Cipla
	Ritonavir			S	Unknown	Unk		Cipla
	Abacavir			S	Unknown	Unk		Cipla
	Tenofovir			S	Unknown	Unk		Cipla
	Efavirenz			S	Unknown	Unk		Cipla
	Bleomycin			S	Unknown	15 Units/M2 Via		Cipla

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

			Intramuscular Or Intravenous Injection	
Bleomycin	S	Intramuscular	10 Units/M2, Every 3 Weeks	Cipla
Vincristine	S	Intravenous (not otherwise specified)	1.4 Mg/M2, Unk	Cipla
Vincristine	S	Intravenous (not otherwise specified)	1.4 Mg/M2, Every 3 Weeks	Cipla
Doxorubicin	S	Intravenous (not otherwise specified)	35 Mg/M2, Unk	Cipla
Paclitaxel	S	Intravenous (not otherwise specified)	75 Mg/M2, Unk	Cipla
Ciprofloxacin	S	Oral	Unk	Cipla
Amoxicillin	S	Oral	Unk	Not Reported
Azithromycin	S	Oral	Unk	Cipla
Fluconazole	S	Oral	Unk	Cipla
Quinine	S	Parenteral	Unk	Not Reported
Albendazole	S	Unknown	Unk	Not Reported
Mebendazole	S	Unknown	Unk	Not Reported
Lopinavir	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S	Oral	Unk	Not Reported
Co-Trimoxazole	S			Not Reported
Ceftriaxone	S	Parenteral	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Metronidazole	S			Not Reported
Rifampicin	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Ethambutol	S	Unknown	Unk	Not Reported
Streptomycin	S	Unknown	Unk	Not Reported
Praziquantel	S	Unknown	Unk	Not Reported
Artesunate	S	Oral	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12340122	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2016US04484			Unknown	MWI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malnutrition	Stavudine			S	Unknown	Unk		Cipla
	Nevirapine			S	Unknown	Unk		Cipla
	Zidovudine			S	Unknown	Unk		Cipla
	Lamivudine			S	Unknown	Unk		Cipla
	Ritonavir			S	Unknown	Unk		Cipla
	Abacavir			S	Unknown	Unk		Cipla
	Tenofovir			S	Unknown	Unk		Cipla
	Efavirenz			S	Unknown	Unk		Cipla
	Bleomycin			S	Unknown	15 Units/M2 Via Intramuscular Or Intravenous Injection		Cipla
	Bleomycin			S	Intravenous (not otherwise specified)	10 Units/M2, Every 3 Weeks As Salvage Regimen		Cipla
	Vincristine			S	Intravenous (not otherwise specified)	1.4 Mg/M2, Unk		Cipla
	Vincristine			S	Intravenous (not otherwise specified)	1.4 Mg/M2, Every 3 Weeks As Salvage Regimen		Cipla
	Doxorubicin			S	Intravenous (not otherwise specified)	35 Mg/M2, Every 3 Weeks As Salvage Regimen		Cipla
	Paclitaxel			S	Intravenous (not otherwise specified)	75 Mg/M2, Infusion Every 3 Weeks		Cipla
	Ciprofloxacin			S	Oral	Unk		Cipla
	Amoxicillin			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Cipla
	Fluconazole			S	Oral	Unk		Cipla

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

Quinine	S	Parenteral	Unk	Not Reported
Albendazole	S	Unknown	Unk	Not Reported
Mebendazole	S	Unknown	Unk	Not Reported
Lopinavir	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S			Not Reported
Ceftriaxone	S	Parenteral	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Metronidazole	S			Not Reported
Rifampicin	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Ethambutol	S	Unknown	Unk	Not Reported
Streptomycin	S	Unknown	Unk	Not Reported
Praziquantel	S	Unknown	Unk	Not Reported
Artesunate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12340134	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2016US04482			Unknown	MWI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sepsis	Stavudine			S	Unknown	Unk		Cipla
	Nevirapine			S	Unknown	Unk		Cipla
	Zidovudine			S	Unknown	Unk		Cipla
	Lamivudine			S	Unknown	Unk		Cipla
	Ritonavir			S	Unknown	Unk		Cipla
	Abacavir			S	Unknown	Unk		Cipla
	Tenofovir			S	Unknown	Unk		Cipla
	Efavirenz			S	Unknown	Unk		Cipla
	Bleomycin			S	Unknown	15 Units/M2 Via		Cipla

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

			Intramuscular Or Intravenous Injection	
Bleomycin	S	Intramuscular	10 Units/M2, Every 3 Weeks	Cipla
Vincristine	S	Intravenous (not otherwise specified)	1.4 Mg/M2, Unk	Cipla
Vincristine	S	Intravenous (not otherwise specified)	1.4 Mg/M2, Every 3 Weeks	Cipla
Doxorubicin	S	Intravenous (not otherwise specified)	35 Mg/M2, Unk	Cipla
Paclitaxel	S	Intravenous (not otherwise specified)	75 Mg/M2, Infusion Every 3 Weeks	Cipla
Ciprofloxacin	S	Oral	Unk	Cipla
Amoxicillin	S	Oral	Unk	Not Reported
Azithromycin	S	Oral	Unk	Cipla
Fluconazole	S	Oral	Unk	Cipla
Quinine	S	Parenteral	Unk	Not Reported
Albendazole	S	Unknown	Unk	Not Reported
Mebendazole	S	Unknown	Unk	Not Reported
Lopinavir	S	Unknown	Unk	Not Reported
Co-Trimoxazole	S	Oral	Unk	Not Reported
Co-Trimoxazole	S			Not Reported
Ceftriaxone	S	Parenteral	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Metronidazole	S			Not Reported
Rifampicin	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Ethambutol	S	Unknown	Unk	Not Reported
Streptomycin	S	Unknown	Unk	Not Reported
Praziquantel	S	Unknown	Unk	Not Reported
Artesunate	S	Unknown	Unk	Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2016	12343124	EXPEDITED (15-DAY)		OT	US-LUNDBECK-DKLU2013262			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Renal Failure	Northera			S	Unknown			Lundbeck	
	Zithromax			S	Unknown			Not Reported	
	Aspirin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2016	12345523	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2016US04345			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Condition Aggravated; Death; Drug Ineffective	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Azithromycin			S				Cipla	
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Cipla	
	Vancomycin			S	Unknown	Unk		Cipla	
	Cefepime			S	Unknown	Unk		Not Reported	
	Methylprednisolone			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2016	12346007	NON-EXPEDITED		HO, OT	US-APOTEX-2016AP008279		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Atenolol			C	Unknown	Unk		Not Reported	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Famotidine			C	Unknown	Unk		Not Reported	

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

	Prednisone		C	Unknown	Unk			Not Reported	
	Hydroxyzine		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2016	12349928	DIRECT		OT			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Drug Hypersensitivity; Insomnia; Pneumonia; Stevens-Johnson Syndrome	Azithromycin			S	Oral	6 Tablet(S) 2 Tablets 1st Day Taken By Mouth		Greenstone	
	Zoloft			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2016	12350134	EXPEDITED (15-DAY)		HO, LT	US-RANBAXY-2013US-65712		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	Unk		Sun	
	Methadone			S	Unknown	10 Mg, Tid		Not Reported	
	Lisinopril/Hydrochlorothiazide			C	Unknown	Unk Unk, Qd		Not Reported	
	Benzonatate			C	Unknown	100 Mg, Tid As Needed		Not Reported	
	Acetaminophen/Dextromethorphan/Doxylamine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2016	12352649	EXPEDITED (15-DAY)		HO	JP-WATSON-2016-09407		15 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Potentiating Drug Interaction	Oseltamivir (Unknown)			S	Unknown	(5 Doses Of 2 Mg/Kg Every Twelve Hours		Not Reported	
	Azithromycin (Unknown)			S	Unknown	Unk		Not Reported	
	Clarithromycin (Unknown)			S	Unknown	Unk		Actavis	
	Dihydrocodeine			C	Unknown	Unk		Not Reported	

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

	Ambroxol		C	Unknown	Unk			Not Reported	
	Benproperine		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2016	12352720	EXPEDITED (15-DAY)		OT	CH-OTONOMY INC.- 2016OTO00017		68 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Medication Error	Ciprofloxacin			S	Oral	500 Mg, 1x/Day		Otonomy	
	Azithromycin			S	Oral	250 Mg, 3x/Week		Not Reported	
	Domperidone			S	Oral	30 Mg, 1x/Day		Not Reported	
	Citalopram			S	Oral	10 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2016	12355453	DIRECT	Y	HO			21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Coronary Syndrome; Acute Myocardial Infarction; Chest Pain; Rash	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2016	9603529	NON-EXPEDITED			US-PFIZER INC- 2013283263		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Chloromycetin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ampicillin			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2016	12322714	NON-EXPEDITED			US-PFIZER INC-2016223556		69 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Daypro			S		Unk		Pfizer	
	Prilosec /00661201/			S		Unk		Not Reported	
	Crestor			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Norflex			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12365387	EXPEDITED (15-DAY)		LT, OT	US-PFIZER INC-2016251100			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Left Ventricular Dysfunction; Long Qt Syndrome	Azithromycin			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12369341	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2016-01872		18 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Linezolid			S	Intravenous (not otherwise specified)			Not Reported	
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported	
	Linezolid			S	Oral	600 Mg 2x/Day At Least 15 Days Per Month		Not Reported	
	Linezolid			S	Unknown			Not Reported	

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

Azithromycin	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2016	12369378	NON-EXPEDITED			US-PERRIGO-16US001455		6 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Back Pain; Gait Inability; Headache; Off Label Use; Oropharyngeal Pain; Pain In Extremity; Product Administered To Patient Of Inappropriate Age; Sensory Disturbance	Famotidine			S	Oral	10 Mg, Bid		Perrigo
	Azithromycin			S	Oral	Unknown, Unknown		Not Reported
	Probiotic /06395501/			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2016	12371210	NON-EXPEDITED			US-PFIZER INC-2016226480			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Compazine			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2016	12371408	NON-EXPEDITED			US-TEVA-649937USA			Female	USA

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

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

Drug Hypersensitivity	Amiloride W/Hydrochlorothiazide	S	Unknown	Barr
	Azithromycin	S	Unknown	Not Reported
	Tramadol	S	Unknown	Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2016	12372584	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016253322			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Liver Disorder; Pain; Rectal Haemorrhage; Weight Increased	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2016	12375861	DIRECT					46 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S				Not Reported	
	Zoloft			C				Not Reported	
	Wellbutrin			C				Not Reported	
	Trazadone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12373856	EXPEDITED (15-DAY)		HO	JP-ROCHE-1758684		67 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Rocephin			S	Intravenous (not otherwise specified)	Dosage Is Uncertain.		Not Reported	
	Zithromac			S	Oral			Not Reported	
	Acetaminophen			C	Unknown	Dosage Is Uncertain.		Not Reported	
	Flomox (Japan)			C	Unknown	Dosage Is Uncertain.		Not Reported	
	Astomin (Japan)			C	Unknown	Dosage Is Uncertain.		Not Reported	
	Cravit			C	Unknown	Dosage Is Uncertain.		Not Reported	

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

	Mucodyne	C	Unknown	Dosage Is Uncertain.	Not Reported
	Loxonin	C	Unknown	Dosage Is Uncertain.	Not Reported
	Huscode	C	Oral	Dosage Is Uncertain.	Not Reported
	Brocin	C	Oral		Not Reported
	Apricot Kernel Water	C	Unknown	Dosage Is Uncertain.	Not Reported
	Senega	C	Oral	Dosage Is Uncertain.	Not Reported
	Norvasc	C	Oral	Dosage Is Uncertain.	Not Reported
	Exforge	C	Unknown	Dosage Is Uncertain.	Not Reported
	Loxoprofen Sodium	C			Not Reported
	Methylephedrine Hydrochloride	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12374686	NON-EXPEDITED			US-PFIZER INC-2016228691			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12374749	NON-EXPEDITED			US-PFIZER INC-2016257030			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Not Reported	
	Metformin Hcl			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12377616	NON-EXPEDITED			US-JNJFOC-20140417870		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Ibuprofen	Y	S	Unknown	Not Reported
	Ibuprofen		S	Unknown	Not Reported
	Risperdal		S	Unknown	Not Reported
	Azithromycin		S	Unknown	Not Reported
	Solu-Medrol		S	Unknown	Not Reported
	Prednisone		S	Unknown	Not Reported
	Abilify		S	Unknown	Not Reported
	Wellbutrin		S	Unknown	Not Reported
	Chantix		S	Unknown	Not Reported
	Asa		S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2016	12378920	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-660440USA		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Death; Cardiac Arrest; Death	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2016	12380416	NON-EXPEDITED			US-PFIZER INC-2015475629			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Levaquin			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2016	12381038	EXPEDITED (15-DAY)		HO	GH-PFIZER INC-2016260005		22 YR	Female	GHA

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

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

Cough; Diarrhoea; Hypotension; Wheezing	Zmax	S	2 G, Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2016	12382531	EXPEDITED (15-DAY)		DS, HO, OT	US-TEVA-659973USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Autoimmune Hepatitis; Blood Disorder; Cholestasis; Confusional State; Fibrosis; Hepatic Cirrhosis; Hepatic Encephalopathy; Hepatitis Acute; Hepatitis Cholestatic; Jaundice; Liver Disorder; Liver Disorder; Liver Function Test Abnormal; Liver Function Test Increased; Metabolic Disorder; Nausea; Ocular Icterus; Oedema Peripheral; Pelvic Inflammatory Disease; Perihepatitis; Skin Abrasion; Tachycardia	Azithromycin			S	Unknown	Prescribed 6 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2016	12383933	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED- 2016SP001595			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Strides
	Oseltamivir			S		Unk		Not Reported
	Heparin			S		Unk		Not Reported
	Furosemide			S		Unk		Not Reported

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

Meropenem	S	Unk	Not Reported
Azithromycin	S	Unk	Not Reported
Phenylephrine	S	Unk	Not Reported
Betamethasone	S	Unk	Not Reported
Norepinephrine	S	Unk	Not Reported
Vasopressin	S	Unk	Not Reported
Linezolid	S	Unk	Not Reported
Ceftriaxone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2016	12385861	NON-EXPEDITED			US-PFIZER INC-2016242096			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Benzathine Benzylpenicillin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2016	12386022	NON-EXPEDITED			US-PFIZER INC-2016258905			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12387513	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2016-06170			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Azithromycin			S	Unknown			Aurobindo
	Clarithromycin			S	Unknown			Aurobindo

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

Linezolid 600 Mg	S	Oral	600 Mg, Unk	Not Reported
Linezolid	S	Intravenous (not otherwise specified)	10 Mg/Kg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12388152	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2016SP001054			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Vancomycin			S		Unk		Strides
	Hydralazine Hcl			S		Unk		Strides
	Metoprolol			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Triiodothyronine			S	Intravenous (not otherwise specified)			Not Reported
	Triiodothyronine			S	Intravenous bolus	10 Mcg, Unk		Not Reported
	Triiodothyronine			S	Intravenous drip	2.5 Mcg/H		Not Reported
	Nitric Oxide			S		20 Ppm, Unk		Not Reported
	Nitric Oxide			S		20 Ppm, Unk		Not Reported
	Milrinone			S		0.375 Mcg/Kg/Min		Not Reported
	Piperacillin/Tazobactam			S		Unk		Not Reported
	Oseltamivir			S		Unk		Not Reported
	Vasopressin			S		0.1 Ut/Min		Not Reported
	Dobutamine			S		Unk		Not Reported
	Dopamine			S		Unk		Not Reported
	Furosemide			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Heparin			S		Unk		Not Reported
	Organic Nitrates			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2016	12391145	NON-EXPEDITED		OT	US-PFIZER INC-2016265024			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12294040	EXPEDITED (15-DAY)		OT	US-BEH-2016061344		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Pyrexia; Rash	Hizentra			S				Not Reported	
	Hizentra			S				Not Reported	
	Hizentra			S	Subcutaneous			Not Reported	
	Hizentra			S	Subcutaneous			Not Reported	
	Zithromax			S				Not Reported	
	Acetaminophen			C				Not Reported	
	Diphenhydramine			C				Not Reported	
	Lidocaine			C				Not Reported	
	Prilocaine			C				Not Reported	
	Epipen			C				Not Reported	
	Benadryl			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Losartan-Hctz			C				Not Reported	
	Fish Oil			C				Not Reported	
	Folic Acid			C				Not Reported	
	Methotrexate			C				Not Reported	
	One-A-Day			C				Not Reported	
	Aspirin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12343163	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016243096		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Agranulocytosis	Zithromax	S	Oral	500 Mg, Unk	Pfizer
	Zithromax	S	Oral	250 Mg, Daily	Pfizer
	Inipomp	S	Oral	40 Mg, 1x/Day	Pfizer
	Levothyrox	C		75 Ug, Unk	Not Reported
	Cortancyl	C		10 Mg, Unk	Not Reported
	Flecaine	C		100 Mg, Unk	Not Reported
	Lasilix	C		20 Mg, Unk	Not Reported
	Speciafoldine	C		Unk	Not Reported
	Diffu K	C		Unk	Not Reported
	Triatec (Ramipril)	C		5 Mg, Unk	Not Reported
	Spiriva	C		Unk	Not Reported
	Cacit [Calcium Carbonate]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12386459	NON-EXPEDITED			US-PFIZER INC-2016263167		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Swelling	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12393233	NON-EXPEDITED			US-PFIZER INC-2016266943		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer
	Biaxin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12395248	NON-EXPEDITED			US-PFIZER INC-2016265020		54 YR	Female	USA

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

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

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2016	12395333	EXPEDITED (15-DAY)		DE, OT	GH-PFIZER INC-2016266434		83 YR	Female	GHA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperpyrexia	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Rocephin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2016	12397235	NON-EXPEDITED			US-PFIZER INC-2016254979		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2016	12397281	NON-EXPEDITED			US-PFIZER INC-2016255195		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2016	12398224	NON-EXPEDITED			US-PFIZER INC-2016255007		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12331990	NON-EXPEDITED			US-PFIZER INC-2016236634		2 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Psychomotor Hyperactivity; Reaction To Excipient	Azithromycin			S	Oral	7 MI, Daily (The First Day)		Pfizer	
	Azithromycin			S	Oral	3.5 MI, Daily (The Following Days)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12401893	NON-EXPEDITED			US-PFIZER INC-2016248238			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12401899	NON-EXPEDITED			US-PFIZER INC-2016253951			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12404372	EXPEDITED (15-DAY)		HO	ES-G&W LABS-GW2016US000015			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Acetaminophen			S	Unknown	750 Mg, Qd		G And W Lab	
	Acetaminophen			S	Unknown	Every 6-8 Hours		G And W Lab	
	Ibuprofen			S	Unknown	1 Df, Single		Not Reported	
	Azithromycin			S	Unknown	3 Doses (Not Otherwise Specified)		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12404937	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-039196		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Pneumonia	Sprycel			S	Oral	100 Mg, Qd		Bristol Myers Squibb	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12405294	EXPEDITED (15-DAY)		HO, OT	US-ASTRAZENECA- 2016SE54794		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Acute	Toprol XL			S	Oral			Not Reported	
Respiratory Failure; Back Pain; Blood Pressure	Zithromax			S	Unknown			Not Reported	
Increased; Chest Pain; Chronic Obstructive	Revatio			S	Oral			Not Reported	
Pulmonary Disease; Cough; Drug	Sutent			C				Not Reported	
Hypersensitivity; Idiopathic	Aromasin			C				Not Reported	
Pulmonary Fibrosis; Oedema Peripheral; Pain;	Xalkori			C				Not Reported	
Pain In Extremity; Pulmonary Hypertension;	Xalkori			C				Not Reported	
Rosacea	Inlyta			C		Two Times A Day		Not Reported	
	Bosulif			C				Not Reported	
	Emcyt			C				Not Reported	
	Vfend			C				Not Reported	
	Vfend			C				Not Reported	
	Elelyso			C		Every Week		Not Reported	
	Rapamune			C				Not Reported	
	Rapamune			C				Not Reported	
	Rapamune			C				Not Reported	
	Rapamune			C	Oral			Not Reported	
	Ibrance			C				Not Reported	
	Ibrance			C				Not Reported	
	Ibrance			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12405530	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2016-01969		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Atenolol			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Famotidine			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Hydroxazine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2016	12405531	NON-EXPEDITED		HO	US-LUPIN PHARMACEUTICALS INC.-2016-00977		1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2016	9972753	NON-EXPEDITED			US-PFIZER INC- 2014059544			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Demerol			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Decadron		S		Unk			Not Reported	
	Lortab		S		Unk			Not Reported	
	Phernergan		S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2016	12407215	NON-EXPEDITED			US-PFIZER INC-2016247916		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Aspartame			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2016	12410425	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Zithromax Z-Pak			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2016	12413927	EXPEDITED (15-DAY)		OT	PHHY2016FR071802		53 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Erythema; Vasoconstriction	Azithromycin Sandoz			S	Oral	2 Df, Qd		Novartis	
	Prednisolone Sandoz			S	Oral	2 Df, Qd		Not Reported	
	Valsartan			C	Unknown	80 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2016	8290107	EXPEDITED (15-DAY)		CA, HO, OT	US-JNJFOC-20111204756			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Atrial Septal Defect; Cleft Lip And Palate; Cryptorchism; Dacryostenosis	Topamax	S	Transplacental	Not Reported
Congenital; Deafness	Cymbalta	S	Transplacental	Not Reported
Bilateral; Dysphagia; Failure To Thrive; Feeding Disorder;	Inderal	S	Transplacental	Not Reported
Gastroesophageal Reflux Disease; Inguinal Hernia; Nose Deformity; Sensory Integrative Dysfunction;	Lortab	S	Transplacental	Not Reported
Sleep Apnoea Syndrome; Syndactyly; Weight Decreased	Amox	S	Transplacental	Not Reported
	Camila	S	Transplacental	Not Reported
	Sulfamethoxazole	S	Transplacental	Not Reported
	Promethazine	S	Transplacental	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Fluconazole	S	Transplacental	Not Reported
	Nitrofurantoin	S	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2016	12415375	NON-EXPEDITED			US-PFIZER INC-2016276273			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Phenobarbital			S		Unk		Unknown
	Zithromax			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Dilantin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Benadryl			S				Not Reported
	Vicodin			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Tylenol /00020001/			S		Unk		Not Reported
	Tegretol			S		Unk		Not Reported
	Percocet /00446701/			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Zocor			S		Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12417878	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2016-06528			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Adrenal Haemorrhage; Flank Pain; Nausea	Azithromycin			S	Unknown			Aurobindo	
	Methylprednisolone			S	Oral			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12418723	EXPEDITED (15-DAY)		DE, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-116809		182 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Circulatory Collapse; Off Label Use; Overdose; Product Prescribing Error	Azithromycin			S	Intravenous (not otherwise specified)	Approximately 62.5 Mg/Kg		Sun	
	Ceftriaxone			C	Intravenous (not otherwise specified)	50 Mg/Kg, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12419324	NON-EXPEDITED			US-PFIZER INC-2016279748			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Diflucan			S		Unk		Pfizer	
	Metoclopramide Hcl			S		Unk		Pfizer	
	Zinc Chloride			S		Unk		Unknown	
	Lyrica			S		Unk		Pfizer	
	Tramadol			S		Unk		Not Reported	

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

Imitrex	S	Unk	Not Reported
Meperidine Hcl	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Metozolv	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Cubicin	S	Unk	Not Reported
Iodine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12421973	NON-EXPEDITED			US-PFIZER INC-2016280189			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Doxycycline Calcium			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Januvia			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Avandia			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12423405	DIRECT		OT			38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Fatigue; Nausea; Tachycardia	Azithromycin Tablets, Usp, 250 Mg			S	Oral	6 Tablet (S) 2 Day 1; 1 4 Days Taken By Mouth		Sandoz
	Levothyroxine			C				Not Reported

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

	Digestive Enzymes	C	Not Reported
	Motrin Ib	C	Not Reported
	Prenatal Vitamins	C	Not Reported
	Vitamin D3	C	Not Reported
	Zyrtec	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2016	12466160	EXPEDITED (15-DAY)		OT	US-TEVA-661189USA		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Product Dose Omission	Bisoprolol			S	Unknown	Unknown		Duramed
	Azithromycin			S		Take Two Pills; Then One Pill For 5 Days		Not Reported
	Carbidopa And Levodopa			S		3 Dosage Forms Daily; 20/100 Mg		Not Reported
	Carbidopa And Levodopa Extended Release			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2016	12390289	EXPEDITED (15-DAY)		DE, OT	GH-PFIZER INC-2016266362		33 YR	Male	GHA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conversion Disorder; Hyperhidrosis; Incorrect Route Of Product Administration; Loss Of Consciousness; Nasopharyngitis; Palpitations	Zithromax			S	Intravenous bolus	500 Mg, Daily		Pfizer
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Stat (At Once)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2016	12419137	EXPEDITED (15-DAY)		OT	FR-ABBVIE-16K-056-1614843-00			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bursitis; Drug Ineffective;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported

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

Hepatocellular Injury; Rheumatoid Arthritis; Synovitis	Humira 40mg/0.8ml	S	Subcutaneous	Not Reported
	Novatrex	S	Unknown	Not Reported
	Novatrex	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Folic Acid	C		Not Reported
	Topalgic (France)	C		Not Reported
	Calcium	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2016	12423024	NON-EXPEDITED			US-PFIZER INC- 2016254613		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Nasopharyngitis; Sinusitis	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2016	12425813	NON-EXPEDITED			US-PFIZER INC- 2016278537			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Erythromycin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Macitentan			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2016	12431561	DIRECT		DE			54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Defaecation Urgency; Diarrhoea; Rectal Cancer; Rectal Polyp	Zithromax 250 Mg Pfizer	S	3 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2016	12439711	EXPEDITED (15-DAY)		HO, LT	PL-TEVA-662444ISR		94 YR	Male	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphasia; Arrhythmia; Coma; Hypoacusis; Visual Impairment; Vocal Cord Inflammation	Sumamed			S	Oral	500 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12429631	EXPEDITED (15-DAY)		HO	IT-MYLANLABS- 2016M1022747			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Lesion	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Doxycycline			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12431123	NON-EXPEDITED			US-JAZZ-2015-US- 016940		28 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Xyrem			S	Oral	2.25 G, Bid		Jazz
Abdominal Pain;	Xyrem			S	Oral	4.5 G, Bid		Jazz
Decreased Appetite;	Z-Pak			S		Unk		Not Reported
Diarrhoea; Dry Eye; Eye Swelling; Eyelid Disorder;	Adderall			C	Oral	Unk		Not Reported
Eyelid Irritation; Nausea;	Lamictal			C	Oral	Unk		Not Reported
Night Sweats; Sinusitis;	Topamax			C	Oral	Unk		Not Reported
Swelling Of Eyelid; Weight Decreased	Cymbalta			C	Oral	Unk		Not Reported

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

Prozac	C	Oral	Unk	Not Reported
Depo-Provera	C		Unk	Not Reported
Hyoscyamine Sulfate	C		Unk	Not Reported
Melatonin	C	Oral	Unk	Not Reported
Tylenol Extra-Strength	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2016	12432188	EXPEDITED (15-DAY)		OT	HR-TEVA-663172ACC		45 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Enterocolitis	Sumamed			S	Oral	500 Milligram Daily;		Not Reported
	Dasselta			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12421636	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2016273973		79 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Application Site Erythema; Pemphigoid; Pruritus; Rash	Azithromycin			S		250 Mg, Total 6 Tablets		Pfizer
	Augmentin /00756801/			S	Oral	1 G, 2x/Day (1-0-1)		Not Reported
	Neupro			S	Transdermal	3 Mg/24 H In Reserve		Not Reported
	Ketralgin /00068902/			C	Oral	5 Mg, 1x/Day (0-0-1-0)		Not Reported
	Propycil			C	Oral	50 Mg, Every Third Day (1-0-0-0)		Not Reported
	Sifrol			C		0.25 Mg, 3x/Day (0-1-1-1)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12439146	NON-EXPEDITED			US-PFIZER INC-2016256937		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Disorder; Ear Infection; Epistaxis; Nasal	Zithromax			S		Unk		Pfizer

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

Congestion

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12439204	NON-EXPEDITED			US-PFIZER INC-2016273270			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Ultram			S		Unk		Not Reported	
	Z-Pak			S		Unk		Not Reported	
	Nizoral			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2016	12442839	DIRECT		OT			52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Depression; Panic Attack	Zithromax Z-Pak			S	Oral			Pfizer	
	Lexapro			C				Not Reported	
	Xanax			C				Not Reported	
	B-12			C				Not Reported	
	Probiatic			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	10246683	EXPEDITED (15-DAY)		HO	FR-ROCHE-1420103		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Condition Aggravated; Enterobacter Sepsis; Secondary Immunodeficiency	Mabthera			S	Intravenous (not otherwise specified)	D1 And D15		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported	
	Novatrex			S	Oral	2 Df In Mornig And 2 Df In Evening Per Week		Not Reported	
	Prednisone			S	Oral			Not Reported	
	Prednisone			S	Oral	In The Morning		Not Reported	

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

Imeth	S	Oral	2.5 Mg Tablet	Not Reported
Forsteo	C	Unknown		Not Reported
Folic Acid	C	Unknown	5 Mg Per Week	Not Reported
Rabeprazole	C	Unknown		Not Reported
Insulin	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Methotrexate	C	Unknown		Not Reported
Fluindione	C	Unknown		Not Reported
Cacit (France)	C	Unknown	D3 500mg 2 Df Every Mornings	Not Reported
Teriparatide	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	12441448	NON-EXPEDITED			US-PFIZER INC-2016263221		32 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Nuvigil			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	12441502	NON-EXPEDITED			US-PFIZER INC-2016280456			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2016	12445219	NON-EXPEDITED			US-PFIZER INC-2016258337			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2016	12447119	DIRECT	Y	RI			13 YR	Male	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash; Urticaria	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12331672	EXPEDITED (15-DAY)		HO, LT	AT-PFIZER INC-2016233945		53 YR	Female	AUT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypothermia; Product Use Issue; Thrombocytopenia	Zithromax			S		500 Mg, Daily			Pfizer
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12401981	NON-EXPEDITED			US-PFIZER INC-2016271635			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Zithromax			S		Unk			Pfizer
	Cipro			S		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2016	12446758	NON-EXPEDITED			US-PFIZER INC-2016275202		41 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Effexor Xr			S		Unk			Pfizer
	Zithromax			S		Unk			Pfizer
	Bactrim			S		Unk			Not Reported
	Wellbutrin			S		Unk			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2016	12447325	EXPEDITED (15-DAY)		HO	US-RECORDATI RARE DISEASES-US-R13005-16-00142		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Kounis Syndrome; Off Label Use	Ibuprofen			S	Unknown			Not Reported	
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported	
	Midazolam Hydrochloride			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Rhogam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2016	12447807	EXPEDITED (15-DAY)		DE, HO, OT	AU-APOTEX-2016AP008889		69 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Condition Aggravated; Drug Ineffective; Haematemesis; Hypercapnia; Melaena; Respiratory Gas Exchange Disorder; Thrombocytopenia	Imatinib			S	Unknown	100 Mg, Tid		Not Reported	
	Salbutamol			S	Unknown	Unk Unk, Unknown		Apotex	
	Azithromycin			S	Unknown	Unk Unk, Unknown		Apotex	
	Acyclovir			S	Unknown	Unk, Unknown		Apotex	
	Sulfamethoxazole W/Trimethoprim			S	Unknown	Unk, Unknown		Not Reported	
	Piperacillin And Tazobactam			S	Unknown	Unk, Unknown		Not Reported	
	Anidulafungin			S	Unknown	Unk Unk, Unknown		Not Reported	
	Prednisolone			S	Unknown	75 Mg Daily		Not Reported	
	Enoxaparin Sodium			S	Unknown	40 Mg, Qd		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported	
	Cisatracurium			S	Unknown	Unk, Unknown		Not Reported	
	Cisatracurium			S				Not Reported	
	Esomeprazole			C	Unknown	Unk, Unknown		Not Reported	

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

Hydrocortisone			C	Unknown	Unk, Unknown	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2016	12447936	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015R1-113627		81 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Glossitis	Azithromycin			S	Unknown	500 Mg, Qd		Sun	
	Sulphamethoxazole/Trimethoprim			S	Unknown	960 Mg, Bid		Sun	
	Prednisolone			C	Unknown	7.5 Mg, Qd		Not Reported	
	Methotrexate			C	Unknown	12.5 Mg, 1/Week		Not Reported	
	Valaciclovir			C	Unknown	1 G, Tid		Not Reported	
	Valganciclovir			C	Unknown	900 Mg, Bid		Not Reported	
	Foscarnet			C	Ophthalmic	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2016	12448526	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2016286720			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Hyperpyrexia	Zithromax			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2016	11246581	EXPEDITED (15-DAY)		HO	PHHY2015CA077102		49 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Middle Insomnia; Respiratory Rate Increased	Onbrez Breezhaler			S	Respiratory (inhalation)	75 Ug, Qd (1 Capsule Once Daily)		Not Reported	
	Seebri Breezhaler			S	Respiratory (inhalation)	50 Ug, Qd		Not Reported	
	Azithromycin			S	Oral	2 Tabs At Once Then 1		Novartis	

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

Acetylcysteine	S	Unknown	Tab Od	Not Reported
Symbicort	C	Unknown	Use 3-4 MI In Nebulizer Up To 3-4 Times Daily	Not Reported
Singulair	C	Unknown	Unk	Not Reported
Spiriva	C	Unknown	10 Mg, Qd	Not Reported
Zenhale	C	Unknown	18 Ug, Qd	Not Reported
Ventolin /00942701/	C	Respiratory (inhalation)	200/5 Ug 4 Inh, Bid	Not Reported
Ventolin /00942701/	C	Unknown	Unk , Prn	Not Reported
Ventolin /00942701/	C	Unknown	Six To Eight Puffs Per Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2016	12445093	NON-EXPEDITED			US-PFIZER INC- 2016260976		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Benadryl			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2016	12450618	NON-EXPEDITED			US-PFIZER INC- 2016292689			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Not Reported	
	Procaine			S		Unk		Not Reported	
	Hibiclens			S		Unk		Not Reported	
	Macrobid			S		Unk		Not Reported	
	Prevacid			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2016	12453081	EXPEDITED (15-DAY)		OT	PHHY2016AT032998		17 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extraocular Muscle Paresis; Headache; Visual Impairment	Azithromycin Sandoz			S	Oral			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	11781464	NON-EXPEDITED		OT	US-APOTEX-2015AP014821			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12438554	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2014163532		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis Bacterial; Bronchitis; Condition Aggravated; Enterobacter Sepsis; Secondary Immunodeficiency	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Imeth			S	Oral	7.5 Mg, Weekly		Pfizer	
	Prednisone			S	Oral	40 Mg, Daily		Not Reported	
	Prednisone			S	Oral	15 Mg, 1x/Day		Not Reported	
	Prednisone			S	Oral	Unk		Not Reported	
	Mabthera			S	Parenteral	1 G, Once Every 15 Days		Not Reported	
	Folic Acid			C		5 Mg, Weekly		Not Reported	
	Rabeprazole Sodium			C		20 Mg, Daily		Not Reported	
	Cacit D3			C		500 Mg, 2x/Day		Not Reported	
	Forsteo			C	Subcutaneous	20 Ug, Daily		Not Reported	
	Umuline			C		7 lu, 1x/Day		Not Reported	
	Kardegic			C				Not Reported	

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

	Inexium /01479302/	C	Not Reported
	Diffu K	C	Not Reported
	Doliprane	C	Not Reported
	Seresta	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12447839	EXPEDITED (15-DAY)		OT	IT-TEVA-665828ACC		81 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Dyspnoea; Hypersensitivity; Throat Tightness	Azithromycin			S	Oral	500 Mg Total		Not Reported
	Blopress - 32 Mg Compresse			C	Oral	1 Df		Not Reported
	Eutirox - 100 Microgrammi Compresse			C	Oral	1 Df		Not Reported
	Pancleus - 20 Mg Compresse			C	Oral	1 Df		Not Reported
	Gastroresistenti Aloneb - 5 Mg/12.5 Mg Compresse Rivestite Con Film			C	Oral	1 Df=Nebivolol Hydrochloride5mg/Hydroc hlorothiazide12.5mg		Not Reported
	Zyllt - 75 Mg Compresse Rivestite Con Film			C	Oral	1 Df		Not Reported
	Citalopram			C	Oral	20 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12454941	NON-EXPEDITED			US-PFIZER INC- 2016267432		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12454944	NON-EXPEDITED			US-PFIZER INC- 2016274200			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

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

Codeine			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
10-Jun-2016	12454997	NON-EXPEDITED			US-PFIZER INC-2016289051		66 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer		
	Azithromycin			S		Unk		Pfizer		
	Flector			S		Unk		Pfizer		
	Sulfadiazine Silver			S		Unk		Pfizer		
	Morphine Sulfate			S				Pfizer		
	Metronidazole			S		Unk		Pfizer		
	Erythromycin			S		Unk		Pfizer		
	Levofloxacin			S		Unk		Not Reported		
	Lortab /00607101/			S		Unk		Not Reported		
	Bupropion			S		Unk		Not Reported		
	Pentasa			S		Unk		Not Reported		
	Tylox /00867901/			S		Unk		Not Reported		
	Wellbutrin			S		Unk		Not Reported		
	Levaquin			S		Unk		Not Reported		
	Crestor			S		Unk		Not Reported		
	Arformoterol			S		Unk		Not Reported		
	Trazodone			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
10-Jun-2016	12455902	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-16-00		45 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cardiac Arrest; Drug	Diphenhydramine			S	Unknown			Eurohealth		

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

Interaction; Drug	Methadone	S	Unknown	International
Withdrawal Syndrome;	Ondansetron	S	Unknown	Roxane
Loss Of Consciousness;	Azithromycin	S	Unknown	Roxane
Torsade De Pointes;	Fluoxetine	S	Unknown	Not Reported
Ventricular Tachycardia	Sertraline	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12455958	EXPEDITED (15-DAY)		OT	PHHY2016US076828		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Recurrence;	Clofazimine			S	Unknown			Novartis
Mycobacterium Abscessus	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
Infection	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imipenem			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2016	12456900	EXPEDITED (15-DAY)		DE, HO, OT	AU-BAUSCH-BL-2016-013690		69 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress	Acyclovir			S	Unknown			Not Reported
Syndrome; Condition	Prednisolone			S	Unknown			Bausch And Lomb
Aggravated; Drug	Salbutamol			S	Unknown			Not Reported
Ineffective;	Azithromycin			S	Unknown			Not Reported
Haematemesis;	Imatinib			S	Unknown			Not Reported
Hypercapnia; Melaena;	Sulfamethoxazole W/			S	Unknown			Not Reported
Respiratory Gas	Trimethoprim			S	Unknown			Not Reported
Exchange Disorder;	Piperacillin And Tazobactam			S	Unknown			Not Reported
Thrombocytopenia	Anidulafungin			S	Unknown			Not Reported

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

Enoxaparin Sodium	S	Unknown	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
Cisatracurium	S	Unknown	Not Reported
Cisatracurium	S		Not Reported
Hydrocortisone	C	Unknown	Not Reported
Esomeprazole	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12147176	NON-EXPEDITED			US-PFIZER INC-2016078565		50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Hypertension; Nervousness; Palpitations; Tinnitus	Zithromax			S	Oral	500 Mg, (250 Mg, Little Pill, 2 On The First Day)		Pfizer
	Zithromax			S	Oral	250 Mg, 1x/Day 250 Mg, Little Pill, 1 For Next Four Days		Pfizer
	Prednisone			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12290731	NON-EXPEDITED			US-PFIZER INC-2016192286		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Arthrotec			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Ampicillin Sodium			S		Unk		Unknown
	Erythromycin Ethylsuccinate			S		Unk		Pfizer
	Ketoprofen			S		Unk		Not Reported
	Inapsine			S		Unk		Not Reported
	Anaprox			S		Unk		Not Reported

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

Bactrim	S	Unk	Not Reported
Lodine	S	Unk	Not Reported
Naprelan	S	Unk	Not Reported
Pyridium	S	Unk	Not Reported
Relafen	S	Unk	Not Reported
Suprax /00821801/	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12372336	EXPEDITED (15-DAY)		OT	CI-PFIZER INC-2016253176		11 YR	Male	CIV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Near Death Experience	Zithromax			S		Two Doses Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12454112	EXPEDITED (15-DAY)		DE	NG-ROCHE-1769018		33 YR	Male	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conversion Disorder; Hyperhidrosis; Loss Of Consciousness; Nasopharyngitis; Palpitations	Ceftriaxone			S		2g Stat		Not Reported	
	Zithromax			S		2g Stat		Not Reported	
	Zithromax			S	Intravenous bolus			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12458126	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US06578			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Loss Of Consciousness; Self-Medication; Torsade De Pointes; Ventricular Tachycardia	Sertraline			S				Invagen	
	Fluoxetine			S				Not Reported	
	Azithromycin			S				Not Reported	
	Ondansetron			S				Not Reported	
	Diphenhydramine			S				Not Reported	

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

Methadone			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460008	NON-EXPEDITED			US-PFIZER INC-2016273528			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin				S		Unk		Pfizer
	Humira				S		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460019	NON-EXPEDITED			US-PFIZER INC-2016276472			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer
	Amoxicillin				S		Unk		Pfizer
	Daypro				S		Unk		Pfizer
	Procardia XL				S		Unk		Pfizer
	Ceclor				S		Unk		Not Reported
	Tetanus Vaccine				S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460033	NON-EXPEDITED			US-PFIZER INC-2016274541		63 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460075	NON-EXPEDITED			US-PFIZER INC-2016275447		67 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460095	NON-EXPEDITED			US-PFIZER INC-2016276588		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Protonix			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460177	NON-EXPEDITED			US-PFIZER INC-2016297029			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12460583	NON-EXPEDITED			US-AKORN-29176			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Oedema; Exophthalmos; Eye Pain; Lacrimation Increased	Azasite			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2016	12463991	DIRECT					63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Dysuria; Paraesthesia; Penis Disorder	Azithromycin Tablets Usp, 250 Mg Teva			S	Oral	4 Tablet(S) Once A Day Taken By Mouth		Teva	
	Glucosamine			C				Not Reported	
	Chondroitin			C				Not Reported	

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

Calcium Citrate W/ Vitamin D			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12463638	NON-EXPEDITED			US-PFIZER INC-2016273191		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Avelox			S		Unk		Not Reported	
	Anaprox			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12465780	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2016292269		47 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Eosinophilia; Leukocytosis	Zithromax			S	Oral	Unk		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12465944	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016198518		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hiatus Hernia; Intercepted Product Prescribing Error	Novatrex			S		15 Mg, (6 Tablets)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2016	12466856	DIRECT		OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Azithromycin, 250 Mg			S	Oral	6 Tablet (S) 2 Today Then 5 DAY		Teva	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hearing Aids			C			1 Tab Taken By Mouth			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Jun-2016	12466889	DIRECT						Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Atrial Fibrillation; Drug Interaction; Drug Resistance; Hypertension; Hypotension; Respiratory Failure; Unresponsive To Stimuli	Azithromycin 500 Mg			S				Not Reported		
	Diltiazem Hcl Diltiazem			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2016	12416856	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016278482		4 YR	Male	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cystitis Haemorrhagic	Zithromac			S	Oral	Unk		Pfizer		
	Zithromac			S	Oral	Unk		Pfizer		
	Seihaito			C	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2016	12467139	EXPEDITED (15-DAY)		HO, LT, OT	US-ACTAVIS-2016-12275		45 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Intentional Product Misuse; Loss Of Consciousness; Self-Medication; Torsade De Pointes; Ventricular Tachycardia	Azithromycin (Unknown)			S	Unknown	Unk		Not Reported		
	Ondansetron (Unknown)			S	Unknown	Unk		Unknown		
	Diphenhydramine (Watson Laboratories)			S	Unknown	Unk		Watson		
	Fluoxetine (Watson Laboratories)			S	Unknown	Unk		Watson		
	Sertraline Hydrochloride (Watson Laboratories)			S	Unknown	Unk		Watson		

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

Methadone			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2016	12470835	DIRECT	Y					Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Product Dispensing Error; Product Dispensing Error	Azithromycin 500 Mg			S	Oral				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
16-Jun-2016	12397253	NON-EXPEDITED			US-PFIZER INC- 2016244597			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Discomfort; Drug Hypersensitivity; Drug Intolerance	Zithromax			S		Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
16-Jun-2016	12471300	NON-EXPEDITED			US-PFIZER INC- 2016298182		57 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer	
	Azithromycin			S		Unk			Pfizer	
	Codeine			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
16-Jun-2016	12471347	NON-EXPEDITED			US-PFIZER INC- 2016298291			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2016	12473563	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-667837USA		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Death; Electrocardiogram Qt Prolonged; Status Epilepticus	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2016	12474198	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC- 20160612076		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Intentional Product Misuse; Loss Of Consciousness; Medication Error; Torsade De Pointes; Ventricular Tachycardia	Diphenhydramine		Y	S	Unknown			Not Reported	
	Ondansetron			S	Unknown			Not Reported	
	Methadone			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12460864	EXPEDITED (15-DAY)		HO	US-SA-2016SA109795		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Arteriospasm Coronary; Blood Lactic Acid Increased; Blood Pressure Decreased; Chest Pain; Electrocardiogram Abnormal; Fibrin D Dimer Increased; Heart Rate Increased; Kounis	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Epinephrine			S	Unknown			Not Reported	
	Epinephrine			S	Unknown			Not Reported	

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

Syndrome; Lactic Acidosis; Magnetic Resonance Imaging Brain Abnormal; Nicotine Dependence; Paraesthesia; Reversible Cerebral Vasoconstriction Syndrome; Thunderclap Headache; Troponin Increased	Epinephrine	S	Intramuscular	1:1000	Not Reported
	Epinephrine	S	Intramuscular	1:1000	Not Reported
	Fentanyl	S	Intravenous (not otherwise specified)		Not Reported
	Nicotine	S	Unknown		Not Reported
	Rhogam	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12474644	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2016-02595		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Sertraline			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Fluoxetine			S	Unknown	Double The Prescribed Dose		Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Ondansetron			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12475101	EXPEDITED (15-DAY)		DE	GH-ROCHE-1769018		33 YR	Male	GHA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conversion Disorder; Hyperhidrosis; Loss Of Consciousness; Nasopharyngitis; Palpitations	Ceftriaxone			S	Intravenous (not otherwise specified)	2g Stat		Not Reported
	Zithromax			S	Intravenous bolus			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12476151	NON-EXPEDITED			US-WOCKHARDT USA, LLC-1053916		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anorectal Discomfort; Diarrhoea; Diarrhoea; Proctalgia	Azithromycin			S	Oral			Wockhardt	
	Lisinopril			C				Not Reported	
	Atenolol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2016	12478222	NON-EXPEDITED		HO	US-PFIZER INC-2016301143		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Disorder; Vomiting	Zithromax			S	Oral	250 Mg, Cyclic (2 To Start And Then 1 Tablet Daily For The Next 4 Days)		Pfizer	
	Eliquis			C	Oral	5 Mg, 2x/Day		Not Reported	
	Atorvastatin			C	Oral	10 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2016	12479596	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2016-02645		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Kounis Syndrome	Azithromycin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported	
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Rhogam			C	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2016	12481618	NON-EXPEDITED			US-PFIZER INC-2016075689		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Product Use In Unapproved Indication; Respiratory Tract Congestion	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2016	12483028	EXPEDITED (15-DAY)		HO, LT, OT	US-EDGEMONT-2016EDG00020		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Abnormal; Intentional Product Misuse; Loss Of Consciousness; Torsade De Pointes; Ventricular Tachycardia	Fluoxetine			S	Unknown			Edgemont	
	Methadone			S	Unknown			Not Reported	
	Ondansetron			S	Unknown			Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2016	12484330	DIRECT	Y	HO			6 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Malaise; Product Taste Abnormal; Vomiting	Azithromycin For Oral Suspension Usp 200 Mg Per 5 MI Ndc 00093-2026-23			S	Oral	7.1 MI (284 Mg) Once Daily By Mouth		Teva	
	Azithromycin			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2016	12447653	EXPEDITED (15-DAY)		HO, OT	US-SA-2016SA105101		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Cardiac Arrest; Drug Interaction; Drug Withdrawal Headache; Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; Electrocardiogram St Segment Abnormal; Intentional Product Misuse; Loss Of Consciousness; Malaise; Myalgia; Mydriasis; Nausea; Pulse Absent; Pyrexia; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Tachycardia	Sertraline			S	Unknown			Not Reported	
	Diphenhydramine		Y	S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Methadone Hydrochloride			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ondansetron			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2016	12484599	EXPEDITED (15-DAY)		DS	US-AKORN-32908		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Kounis Syndrome	Azasite 1%			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2016	12486343	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016300742		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Acute Kidney Injury;	Novatrex	S	Oral	12.5 Mg, Weekly	Pfizer
Anaemia Folate	Previscan (Fluindione)	C		Unk	Not Reported
Deficiency; Escherichia	Cortancyl	C		5 Mg, Daily	Not Reported
Sepsis; Pyelonephritis;	Lamaline	C		6 Df, Daily	Not Reported
Renal Tubular Necrosis;	(Acetaminophen\Caffeine\Opium)				
Septic Shock; Shock;	Amlor	C		5 Mg, Daily	Not Reported
Thrombocytopenia	Rasilez	C		150 Mg, Daily	Not Reported
	Fosavance	C		Unk	Not Reported
	Pantoprazole	C		Unk	Not Reported
	Allopurinol	C		Unk	Not Reported
	Atarax	C		Unk	Not Reported
	Temesta (Lorazepam)	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2016	12486411	NON-EXPEDITED			US-PFIZER INC-2015450638		82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Robitussin Maximum Strength Cough		Y	S				Pfizer
	Robitussin Maximum Strength Cough		Y	S				Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2016	12422173	EXPEDITED (15-DAY)		DS	PHHY2015GB092285			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Disturbance In	Azithromycin			S	Oral	1500 Mg, Qd		Novartis
Attention; Headache;	Prednisolone			C	Oral	5 Mg, Unk		Not Reported
Hypoacusis; Overdose	Methotrexate			C	Oral	10 Mg, Qw		Not Reported
	Etanercept			C	Subcutaneous	50 Mg, Qw		Not Reported

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

Metformin	C	Oral	1 G, Qd	Not Reported
Lansoprazole	C	Oral	15 Mg, Qd	Not Reported
Simvastatin	C	Oral	20 Mg, Qd	Not Reported
Co-Amoxiclav	C		625 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2016	12463792	EXPEDITED (15-DAY)	HO		US-DRREDDYS- USA/USA/16/0080586		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Kounis Syndrome; Lactic Acidosis	Ibuprofen			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Copper			S	Unknown			Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported
	Rhogam			S	Unknown			Not Reported
	Nicotine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2016	12487610	EXPEDITED (15-DAY)	HO, OT		US-GLENMARK PHARMACEUTICALS INC, USA.- 2016GMK02329			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Loss Of Consciousness; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Unknown	Unk		Glenmark
	Azithromycin			S	Unknown	Unk		Not Reported
	Diphenhydramine			S	Unknown	Unk		Not Reported
	Methadone			S	Unknown	Unk		Not Reported
	Fluoxetine			S	Unknown	Unk		Not Reported
	Sertraline			S	Unknown	Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2016	12489153	EXPEDITED (15-DAY)		OT	CA-BAYER-2016-113767		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mycobacterial Peritonitis; Pericarditis; Rash; Rash Maculo-Papular	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Moxifloxacin Oral			S	Unknown	400 Mg, Qd		Bayer
	Cefoxitin			S	Unknown	2 G, Qd		Not Reported
	Linezolid			S	Unknown	600 Mg, Bid		Not Reported
	Revlimid			S	Oral	15 Mg, Tiw		Not Reported
	Revlimid			S	Oral	10 Mg, Tiw		Not Reported
	Tigecycline			S	Unknown	100 Mg, Qd		Not Reported
	Alfacalcidol			C	Unknown	0.25 Mg, Unk		Not Reported
	Aranesp			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
	Asa			C	Unknown	81 Mg, Unk		Not Reported
	Calcium Carbonate			C	Unknown	1250 Mg, Tid		Not Reported
	Furosemide			C	Unknown	60 Mg, Qd		Not Reported
	Pantoprazole			C	Unknown	40 Mg, Bid		Not Reported
	Replavite			C	Oral	Unk Unk, Qd		Not Reported
	Valtrex			C	Unknown	500 Mg, Tiw		Not Reported
	Valtrex			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2016	12490287	EXPEDITED (15-DAY)		HO	US-FRESENIUS KABI-FK201603785		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Cardiac Arrest; Potentiating Drug Interaction; Torsade De Pointes	Diphenhydramine Injection (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Ondansetron (Manufacturer Unknown)			S	Unknown			Not Reported

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

Unknown)				
Methadone	S	Unknown		Not Reported
Fluoxetine	S	Unknown		Not Reported
Sertraline	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12464309	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS- USA/USA/16/0080605		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Intentional Product Misuse; Loss Of Consciousness; Medication Error; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S	Unknown			Not Reported
	Sertraline			S	Unknown			Not Reported
	Fluoxetine			S	Unknown			Not Reported
	Methadone			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12469028	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC- 2016297355		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Prescription Drug Used Without A Prescription; Torsade De Pointes; Ventricular Tachycardia	Azithromycin			S		Unk		Pfizer
	Diphenhydramine Hcl			S		Unk		Unknown
	Ondansetron			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Methadone			S		Unk		Not Reported
	Fluoxetine			S		Doubling His Prescribed Dose Of Fluoxetine		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2016	12491364	EXPEDITED (15-DAY)		HO, OT	US-ACCORD-041652		45 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Intentional Product Misuse; Loss Of Consciousness; Medication Error; Torsade De Pointes; Ventricular Tachycardia	Sertraline Ondansetron Azithromycin Diphenhydramine Methadone Fluoxetine			S S S S S S				Accord Accord Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2016	12465214	EXPEDITED (15-DAY)		OT	US-JNJFOC-20160608689		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Kounis Syndrome; Lactic Acidosis; Reversible Cerebral Vasoconstriction Syndrome	Ibuprofen Ibuprofen Fentanyl Midazolam Hydrochloride Azithromycin Rhogam Copper		Y	S S S S S S S	Unknown Unknown Intravenous (not otherwise specified) Intravenous (not otherwise specified) Unknown Unknown Intra-uterine	100 Mcg		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2016	12495702	EXPEDITED (15-DAY)		HO, OT	US-TARO PHARMACEUTICALS USA.,INC-2016SUN00325		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Torsade De	Ondansetron Hydrochloride Methadone Fluoxetine			S S S	Unknown	Unk Unk Dose Doubled		Taro Not Reported Not Reported

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

Pointes	Sertraline	S	Unk	Not Reported
	Azithromycin	S		Not Reported
	Diphenhydramine	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2016	12497352	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2016M1026365			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Kounis Syndrome; Reversible Cerebral Vasoconstriction Syndrome	Fentanyl			S	Intravenous (not otherwise specified)	100 Microg		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Epinephrine			S	Intramuscular	0.3mg (1:1000)		Not Reported
	Midazolam Hydrochloride			S	Unknown	2mg		Mylan
	Rhogam			S	Unknown			Mylan
	Copper			S	Other			Mylan
	Ibuprofen			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12275757	EXPEDITED (15-DAY)		OT	BR-ROCHE-793670		51 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Anxiety; Arthralgia; Arthralgia; Blood Pressure Decreased; Blood Urine Present; Drug Hypersensitivity; Fear; Hypotension; Immunodeficiency; Immunodeficiency; Influenza; Influenza; Infusion Related Reaction; Limb Discomfort; Pain; Pain; Pneumonia; Pneumonia; Product Dose	Mabthera			S	Intravenous (not otherwise specified)	9 Mabthera Infusions Cycles In Feb-2009, Oct- 2009, May-2010, Nov- 2010, Jul-2011, Apr-2012, Nov-2012		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Berotec			S	Unknown	During Seven Days		Not Reported

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

Omission; Somnolence; Tooth Infection; Tremor; Urinary Tract Infection; Weight Increased; Weight Increased	Atrovent	S	Unknown	During Seven Days	Not Reported
	Tylenol	C	Oral		Not Reported
	Rivotril	C	Unknown		Not Reported
	Rivotril	C		1 Tablet At Night	Not Reported
	Rivotril	C			Not Reported
	Amytril	C	Unknown		Not Reported
	Amytril	C			Not Reported
	Citalopram	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12499151	EXPEDITED (15-DAY)		OT	US-PERRIGO- 16US017090		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Kounis Syndrome	Ibuprofen			S	Oral	Unknown, Unknown		Perrigo
	Rhogam			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Fentanyl			S	Intravenous (not otherwise specified)	100 Mcg, Single		Not Reported
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	2 Mg, Single		Not Reported
	Iud Nos			S	Intra-uterine			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12499887	EXPEDITED (15-DAY)		HO	US-MYLANLABS- 2016M1025652			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Cardiac Arrest; Drug Interaction; Intentional Product Misuse; Torsade De Pointes	Methadone			S	Unknown			Not Reported
	Fluoxetine			S	Unknown	Doubling His Prescribed Dose		Not Reported
	Sertraline			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

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

Ondansetron		S	Unknown		Not Reported				
Diphenhydramine		S	Unknown		Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12500274	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2016296186		11 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Injury	Azithromycin			S	Intravenous (not otherwise specified)			Pfizer	
	Doxycycline Hyclate			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12500395	NON-EXPEDITED			US-PFIZER INC-2016302577		16 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Zithromax			S		1 G, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12501660	NON-EXPEDITED			GXBR2016US001754			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin 250 Mg			S	Unknown	Unk Df, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12502226	NON-EXPEDITED			GXBR2016US001758			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Decreased	Azithromycin 250 Mg			S	Oral	250 Mg, 2 Tabs On Day 1 Then 1 Tab Qd For 4 Days		Novartis	
	Amlodipine			C	Oral	Unk Df, Unk		Not Reported	
	Finasteride			C	Oral	Unk Df, Unk		Not Reported	

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

Prevacid	C	Oral	Unk Df, Unk	Not Reported
Remeron	C	Oral	Unk Df, Unk	Not Reported
Inderal	C	Oral	Unk Df, Unk	Not Reported
Multiple Vitamins	C	Oral	Unk Df, Unk	Not Reported
Fish Oil	C	Oral	Unk Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2016	12502371	EXPEDITED (15-DAY)		DE, HO, OT	AR-ABBVIE-16P-007-1662379-00		49 YR	Male	ARG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Castleman'S Disease; Kaposi'S Sarcoma; Night Sweats; Pulmonary Mass; Pyrexia; Pyrexia; Skin Lesion; Synovial Cyst	Norvir			S	Unknown			Not Reported
	Tenofovir			S	Unknown			Not Reported
	Lamivudine			S	Unknown			Not Reported
	Atazanavir			S	Unknown			Not Reported
	Fluconazol			S	Unknown			Not Reported
	Co Trimoxazole			S	Unknown			Not Reported
	Leucovorin Calcium			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12368475	NON-EXPEDITED			US-PFIZER INC-2016242800			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12461751	EXPEDITED (15-DAY)		DS	GB-PFIZER INC-2016287573			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Disturbance In	Azithromycin			S	Oral	500 Mg, Thrice Per Week		Pfizer

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

Attention; Headache;
Hypoacusis; Overdose

Azithromycin	S	Oral	(Mondays, Wednesdays, And Fridays)	Pfizer
Co-Amoxiclav	C		1500 Mg, Three Times A Week	Not Reported
Etanercept	C	Subcutaneous	625 Mg, Three Times A Day	Not Reported
Lansoprazole	C	Oral	50 Mg, Weekly	Not Reported
Metformin	C	Oral	15 Mg, Once Daily	Not Reported
Methotrexate	C	Oral	1 G, Once Daily	Not Reported
Prednisolone	C	Oral	10 Mg, Weekly	Not Reported
Simvastatin	C	Oral	5 Mg, Unk	Not Reported
			20 Mg, Once Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12503153	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2016AP009270		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Intentional Product Misuse; Torsade De Pointes	Sertraline Hydrochloride			S	Unknown	Unk		Apotex
	Fluoxetine Oral Solution Usp			S	Unknown	Doubling His Prescribed Dose		Apotex
	Azithromycin			S	Unknown	Two Courses		Apotex
	Ondansetron Injection Usp			S	Unknown	Unk		Apotex
	Methadone			S	Unknown	Unk		Not Reported
	Diphenhydramine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12503444	NON-EXPEDITED			US-PFIZER INC- 2016301023		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Inappropriate Schedule Of Product Administration	Azithromycin			S		Unk, 3x/Day		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2016	12506050	NON-EXPEDITED			GXBR2016US002051			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Vertigo	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	9821601	NON-EXPEDITED			US-PFIZER INC-2014011774		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12454245	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2016-044464			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Interaction; Upper Respiratory Tract Infection	Sprycel			S	Oral	100 Mg, Qd		Bristol Myers Squibb	
	Sprycel			S	Oral	100 Unk, Unk		Bristol Myers Squibb	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12457407	EXPEDITED (15-DAY)		DS	GB-MYLANLABS-2016M1023652			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Disturbance In Attention; Headache; Hypoacusis; Overdose	Azithromycin			S	Oral	500 Mg, Qw		Not Reported	
	Azithromycin			S	Oral	1500 Mg, Qd (1500 Mg, Qd)		Not Reported	
	Co-Amoxiclav /00756801/			C		625 Mg, Tid (625 Mg, Tid)		Mylan	
	Etanercept			C	Subcutaneous	50 Mg, Qw		Mylan	

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

Lansoprazole	C	Oral	15 Mg, Qd (15 Mg, Qd)	Mylan
Metformin	C	Oral	1 G, Qd (1 G, Qd)	Mylan
Methotrexate	C	Subcutaneous	50 Mg, Qw (50 Mg, Qw)	Mylan
Methotrexate	C	Oral	10 Mg, Qw (10 Mg, Qw)	Mylan
Prednisolone	C	Oral	5 Mg, Unk	Mylan
Simvastatin	C	Oral	20 Mg, Qd (20 Mg, Qd)	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12506975	EXPEDITED (15-DAY)	HO		FR-ROCHE-1785109		76 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Transient Ischaemic Attack	Lucentis			S	Other	10 Mg/MI		Not Reported
	Novatrex			S	Oral	4 Df Per Week		Not Reported
	Cortancyl			S	Oral			Not Reported
	Speciafoldine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12507822	NON-EXPEDITED			US-PFIZER INC-2016319323			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Nexium 24hr			S		Unk		Unknown
	Duricef			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Macrochantin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2016	12508419	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2016312832		76 YR	Female	FRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transient Ischaemic Attack	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Lucentis			S	Oral	Unk		Not Reported	
	Cortancyl			S	Oral	5 Mg, Daily		Not Reported	
	Speciafoldine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12426685	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2016-0211457		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Hypertension; Upper Respiratory Tract Infection	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead	
	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12471073	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-118567		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Intentional Product Misuse; Loss Of Consciousness; Medication Error; Self-Medication; Torsade De Pointes; Ventricular Tachycardia	Azithromycin			S	Unknown	Unk		Sun	
	Diphenhydramine			S	Unknown	Unk		Sun	
	Fluoxetine			S	Unknown	Unk		Sun	
	Ondansetron			S	Unknown	Unk		Natco Pharma	
	Sertraline			S	Unknown	Unk		Sun	
	Methadone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12516906	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2016AP009490		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Anaphylactic Reaction; Chest Pain; Kounis Syndrome; Reversible Cerebral Vasoconstriction Syndrome	Midazolam Hydrochloride Injection	S	Unknown	2 Mg, Unk	Apotex
	Azithromycin	S	Unknown	Unk	Apotex
	Fentanyl	S	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Rhogam	S	Unknown	Unk	Not Reported
	Copper	S	Other	Unk	Not Reported
	Epinephrine	S	Intramuscular	0.3mg (1:1000)	Not Reported
	Ibuprofen	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12517048	NON-EXPEDITED			US-PFIZER INC- 2016283385		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Bone Disorder; Dyspepsia; Dyspnoea; Flatulence; Gastric Disorder; Heart Rate Increased; Hyperchlorhydria; Inappropriate Schedule Of Product Administration; Muscle Tightness; Throat Tightness; Wrong Technique In Product Usage Process	Zithromax			S	Oral	500 Mg, Daily (Loading Dose Of Two 250 Mg Tablets)		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	250 Mg, Daily (Split The Tablet And Took It Every Two Hours)		Pfizer	
	Zithromax			S		1 Df, 3x/Day (Take A Third Of A Tablet 3 Times A Day)		Pfizer	
	Probiotic			C		Unk, 2x/Day (About 2 Billion Units In The Am And 2 Billion Units In The Pm)		Not Reported	
	Zovirax			C	Oral	200 Mg, 1x/Day		Not Reported	
	Chlorhexidine			C	Oral	Unk (Oral Swish And Spit Twice A Day)		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12517116	NON-EXPEDITED			US-PFIZER INC-2016285634		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12518117	NON-EXPEDITED		HO	US-DRREDDYS-USA/USA/16/0077779		85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Myasthenia Gravis; Rash Erythematous	Moxifloxacin			S	Unknown			Not Reported
	Aztreonam			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Pyridostigmine			C	Oral			Not Reported
	Azathioprine			C	Oral			Not Reported
	Prednisone			C	Oral			Not Reported
	Rivaroxaban			C	Oral			Not Reported
	Digoxin			C	Oral			Not Reported
	Aspirin			C	Oral			Not Reported
	Omeprazole			C	Oral			Not Reported
	Lisinopril			C	Oral			Not Reported
	Carvedilol			C	Oral			Not Reported
	Furosemide			C	Oral			Not Reported
	Exemestane			C	Oral			Not Reported
	Calcium Carbonate			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2016	12520013	NON-EXPEDITED			US-PFIZER INC-2016292993		65 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S				Pfizer
	Etodolac			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Plaquenil /00072603/			S				Not Reported
	Imuran /00001501/			S				Not Reported
	Lactose			S				Not Reported
	Nabumetone			S				Not Reported
	Seldane			S				Not Reported
	Sulindac			S				Not Reported
	Terfenadine			S				Not Reported
	Azathioprine			S				Not Reported
	Clinoril			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	10860637	EXPEDITED (15-DAY)		OT	CA-ROCHE-1542745		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphonia; Arthralgia; Blood Pressure Increased; Bronchitis; Diarrhoea; Fall; Fatigue; Haematoma; Influenza; Injection Site Haematoma; Laryngitis; Ligament Sprain; Lower Respiratory Tract Congestion; Nasopharyngitis; Oropharyngeal Pain; Pain In Extremity; Paronychia; Rhinorrhoea; Sinus Pain; Sinusitis; Sputum Discoloured; Torticollis;	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
Zithromax Z-Pack	Zithromax Z-Pack			S	Unknown	375 Mg, Biw		Not Reported
	Zithromax Z-Pack			S	Subcutaneous	Unk		Not Reported

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

Weight Decreased	Zithromax Z-Pack	S	Subcutaneous	Unk	Not Reported
	Zithromax Z-Pack	S	Subcutaneous	Unk	Not Reported
	Zithromax Z-Pack	S	Subcutaneous	Unk	Not Reported
	Zithromax Z-Pack	S	Subcutaneous	Unk	Not Reported
	Zithromax Z-Pack	S	Subcutaneous	Unk	Not Reported
	Zithromax Z-Pack	S	Subcutaneous	Unk	Not Reported
	Alvesco	C	Respiratory (inhalation)	2 Df, Bid	Not Reported
	Advair	C	Respiratory (inhalation)	1 Df, Qd	Not Reported
	Nasonex	C	Respiratory (inhalation)	2 Df, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12453013	EXPEDITED (15-DAY)		OT	GB-TEVA-665854ACC			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Disturbance In Attention; Headache; Hypoacusis; Overdose	Azithromycin			S	Oral	500 Mg, Qw3		Not Reported
	Azithromycin			S	Oral	1500 Milligram Daily; 1500 Mg, Qd		Not Reported
	Co-Amoxiclav			C		1875 Milligram Daily; 625 Mg, Tid		Not Reported
	Etanercept			C	Subcutaneous	50 Mg, Qw		Not Reported
	Lansoprazole			C	Oral	15 Milligram Daily; 15 Mg, Qd		Not Reported
	Metformin			C	Oral	1 Gram Daily; 1 G, Qd		Not Reported
	Methotrexate			C	Oral	10 Mg, Qw		Not Reported
	Prednisolone			C	Oral	5 Mg, Unk		Not Reported
	Simvastatin			C	Oral	20 Milligram Daily; 20 Mg, Qd		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2016	12520839	NON-EXPEDITED			US-PFIZER INC-2016292134			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Limb Discomfort; Skin Exfoliation	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2016	12523200	EXPEDITED (15-DAY)		LT, OT	US-ZYDUS-011482		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Magnesium Decreased; Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Headache; Loss Of Consciousness; Malaise; Myalgia; Mydriasis; Nausea; Pulse Absent; Pupil Fixed; Pyrexia; Self-Medication; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Tachycardia	Sertraline			S	Unknown			Zydus Pharm	
	Methadone			S	Unknown			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ondansetron			S	Unknown			Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2016	11246358	EXPEDITED (15-DAY)		HO	CA-ROCHE-1605352		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Middle Insomnia; Respiratory Rate Increased	Onbrez			S	Respiratory (inhalation)			Not Reported	
	Azithromycin			S	Oral	2 Tabs At Once And Then 1 Tab Od Orally For The Duration Of 1 Days		Not Reported	
	Acetylcysteine			S	Unknown	Dose Of 200 Mg/ML, 3-4 ML		Not Reported	

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

						In Nebulizer Up To 3-4 Times Daily			
	Seebri			S	Respiratory (inhalation)				Not Reported
	Symbicort Forte			C					Not Reported
	Singulair Junior			C					Not Reported
	Spiriva			C					Not Reported
	Zenhale			C					Not Reported
	Tudorza			C					Not Reported
	Ventolin			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12503858	EXPEDITED (15-DAY)		HO, LT, OT	BR-PFIZER INC- 2016307425		23 YR	Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Electrocardiogram Qt Prolonged; Systolic Dysfunction; Ventricular Fibrillation	Zitromax			S	Intravenous (not otherwise specified)	500mg, 1 Ampoule In Afternoon		Pfizer
	Nausedron			S	Intravenous (not otherwise specified)	4mg,1 Ampoule /6hrs		Not Reported
	Nausedron			S				Not Reported
	Ceftriaxone Sodium			C		Unk		Not Reported
	Bactrim			C		Unk		Not Reported
	Amikacin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12529938	DIRECT		DS			60 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Substitution Issue	Z-Pack			S				Pfizer
	Sertraline Camber Pharmaceuticals			S				Camber

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2016	12530382	DIRECT		OT			20 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dizziness; Headache; Nausea	Azithromycin 250 Mg, 250 Mg Teva			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	11560517	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2015-058921			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Off Label Use; Pregnancy On Contraceptive	Opdivo			S	Unknown			Bristol Myers Squibb	
	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12457060	EXPEDITED (15-DAY)		OT	PHHY2016CH078265			Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Cerebrovascular Accident; Hypoaesthesia	Azithromycin Sandoz			S	Oral	500 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12502347	EXPEDITED (15-DAY)		OT	CA-GILEAD-2016- 0220464		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ascites; Bronchitis; Drug Interaction; Drug-Induced Liver Injury; Hyperbilirubinaemia; Malaise; Pharyngitis; Pyrexia	Harvoni			S	Oral	1 Df, Unk		Gilead	
	Azithromycin			S	Oral	250 Mg, Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Amoxicillin			S	Oral	500 Mg, Unk		Not Reported	
	Amoxicillin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12529785	EXPEDITED (15-DAY)		OT	GB-LUPIN		20 YR	Female	GBR

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

PHARMACEUTICALS
INC.-2016-02944

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Electrocardiogram Qt Prolonged	Ethambutol			S	Unknown			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Prothionamide			S	Unknown			Not Reported
	Linezolid			S	Unknown			Not Reported
	Linezolid			S	Unknown			Not Reported
	Para-Aminosalicylic Acid			S	Unknown			Not Reported
	Para-Aminosalicylic Acid			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Bedaquiline			S	Unknown			Not Reported
	Clofazimine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12530305	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2016US08051			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction	Warfarin			S	Unknown	Unk		Invagen
	Levofloxacin			S	Unknown	Unk		Cipla
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Cipla
	Ciprofloxacin			S	Unknown	Unk		Cipla
	Fluconazole			S	Unknown	Unk		Cipla
	Azithromycin			S	Unknown	Unk		Cipla

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

	Metronidazole	S	Unknown	Unk	Not Reported
	Nafcillin	S	Unknown	Unk	Not Reported
	Rifampin	S	Unknown	Unk	Not Reported
	Aspirin	S	Unknown	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12530319	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2016US08068			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Warfarin			S	Unknown	Unk		Invagen	
	Levofloxacin			S	Unknown	Unk		Cipla	
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Cipla	
	Ciprofloxacin			S	Unknown	Unk		Cipla	
	Fluconazole			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Metronidazole			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Not Reported	
	Aspirin			S	Unknown	Unk		Not Reported	
	Acetaminophen			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12530321	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2016US08053			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Warfarin			S	Unknown	Unk		Invagen	
	Warfarin			S				Invagen	
	Levofloxacin			S	Unknown	Unk		Cipla	
	Ciprofloxacin			S	Unknown	Unk		Cipla	
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Cipla	

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

	Fluconazole	S	Unknown	Unk	Cipla
	Azithromycin	S	Unknown	Unk	Cipla
	Metronidazole	S	Unknown	Unk	Not Reported
	Nafcillin	S	Unknown	Unk	Not Reported
	Rifampin	S	Unknown	Unk	Not Reported
	Aspirin	S	Unknown	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12530364	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2016US08074			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Warfarin			S	Unknown	Unk		Invagen	
	Levofloxacin			S	Unknown	Unk		Cipla	
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk		Cipla	
	Ciprofloxacin			S	Unknown	Unk		Cipla	
	Fluconazole			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Metronidazole			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Not Reported	
	Aspirin			S	Unknown	Unk		Not Reported	
	Acetaminophen			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12531765	NON-EXPEDITED			US-PFIZER INC- 2016326857		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lyrice			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	

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

Estradiol	S	Unk	Pfizer
Furosemide	S	Unk	Unknown
Morphine Sulfate	S	Unk	Pfizer
Lisinopril	S	Unk	Not Reported
Percocet	S	Unk	Not Reported
Sotalol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12531934	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016328331		83 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Respiratory Failure	Azithromycin			S		Unk		Pfizer	
	Piperacillin/Tazobactam			S		Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2016	12533790	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201604080		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	Midazolam (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
	Fentanyl			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S				Not Reported	
	Anti-D Immunoglobulin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12420149	EXPEDITED (15-DAY)		HO	CH-UCBSA-2016019434		79 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Application Site Erythema; Pemphigoid; Pruritus; Rash	Neupro			S	Transdermal	3mg/24hr, As Needed (Prn)		Ucb	

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

Augmentin	S	Oral	1 G, 2x/Day (Bid)	Not Reported
Azithromycin	S		250 Mg	Not Reported
Ketalarin	C	Oral	5 Mg, Once Daily (Qd)	Not Reported
Propycil	C	Oral	50 Mg, Ev 3 Days	Not Reported
Sifrol	C		0.25 Mg, 3x/Day (Tid)	Not Reported
Finasterax	C		Unk	Not Reported
Prednisolone	C		25 Mg, Once Daily (Qd)	Not Reported
Prednisolone	C		50 Mg, Once Daily (Qd)	Not Reported
Xyzal	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12464527	EXPEDITED (15-DAY)		HO, OT	US-TEVA-668425USA		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Intentional Product Misuse; Loss Of Consciousness; Medication Error; Torsade De Pointes; Ventricular Tachycardia	Ondansetron			S				Teva
	Fluoxetine			S				Barr
	Diphenhydramine			S				Barr
	Azithromycin			S				Not Reported
	Sertraline			S				Not Reported
	Methadone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12535088	EXPEDITED (15-DAY)		HO	AU-ROCHE-1788012		75 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oedema Peripheral; Pruritus; Rash Erythematous	Bactrim			S	Oral			Not Reported
	Oseltamivir			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Cefepime			S	Intravenous (not otherwise specified)			Not Reported

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

	Lenalidomide	S	Oral						Not Reported
	Tazocin	S	Intravenous (not otherwise specified)						Not Reported
	Trimethoprim	S	Oral						Not Reported
	Dexamethasone	C							Not Reported
	Fluconazole	C							Not Reported
	Heparin Sodium	C	Unknown						Not Reported
	Irbesartan	C							Not Reported
	Lansoprazole	C							Not Reported
	Thyroxine	C							Not Reported
	Valaciclovir	C							Not Reported
	Hydrochlorothiazide	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12536527	NON-EXPEDITED			US-PFIZER INC-2016302318			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Tetanus Toxoid			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12536602	NON-EXPEDITED			US-PFIZER INC-2016295314			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria	Zmax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12536628	NON-EXPEDITED			US-PFIZER INC-2016295257			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Chromaturia; Dysuria; Paraesthesia	Zmax			S		Unk		Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2016	12538095	EXPEDITED (15-DAY)		DE, LT	AU-BAUSCH-BL-2016-016175		26 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Vancomycin			S	Unknown			Not Reported	
	Tobramycin			S	Intravenous (not otherwise specified)			Bausch And Lomb	
	Trimethoprim 1600mg, Sulfamethoxazole 320mg			S	Intravenous (not otherwise specified)			Not Reported	
	Imipenem			S	Intravenous (not otherwise specified)			Not Reported	
	Caspofungin			S	Unknown			Not Reported	
	Caspofungin			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Piperacillin / Tazobactam			S	Intravenous drip	12 G Of Piperacillin Component/24 H		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12322705	NON-EXPEDITED			US-PFIZER INC-2016222213		11 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Oxygen Saturation Abnormal; Sleep Apnoea Syndrome	Azithromycin			S		Unk		Pfizer	
	Quillivant Xr			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12463292	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2016SP006489			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Chest Pain; Dyspnoea; Kounis Syndrome; Lactic	Ibuprofen			S		Unk		Unknown	
	Fentanyl			S	Intravenous (not	100 Mcg, Unk		Not Reported	

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

Acidosis; Swelling Face; Urticaria		Azithromycin	S			otherwise specified)	Unk		Not Reported
		Midazolam Hydrochloride	S			Intravenous (not otherwise specified)	2 Mg, Unk		Not Reported
		Rhogam	S				Unk		Not Reported
		Copper	S			Intra-uterine	Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2016	12543468	DIRECT	Y				2 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Amoxicillin			S	Oral				Not Reported
	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12543647	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2016-08408			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	250 Mg, Unk			Aurobindo
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12544273	EXPEDITED (15-DAY)		LT	AU-ACTAVIS PTY LTD- 2016-14762		26 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Pathogen Resistance; Pleural Effusion; Pneumothorax; Respiratory Failure; Treatment Failure	Piperacillin-Tazobactam (Unknown)			S	Intravenous drip	12 G Of Piperacillin Component/24 H			Not Reported
	Tobramycin (Unknown)			S	Intravenous (not otherwise specified)	560 Mg, Qhs			Watson
	Azithromycin (Unknown)			S	Oral	500 Mg, 3/Week			Not Reported
	Vancomycin Hydrochloride			S	Unknown	1.5 G, Q8h			Not Reported
	Caspofungin (Unknown)			S	Unknown	70 Mg, Loading Dose			Not Reported

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

Caspofungin (Unknown)	S	Unknown	50 Mg, Daily	Not Reported
Imipenem	S	Intravenous (not otherwise specified)	1 G, Q6h	Not Reported
Trimethoprim Sulfamethoxazole	S	Intravenous (not otherwise specified)	1600/320 Mg, 6 Hourly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12544375	NON-EXPEDITED			US-PFIZER INC-2016307165		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Enbrel			C		50 Mg, Unk		Not Reported	
	Nexium			C		Unk		Not Reported	
	Crestor			C		Unk		Not Reported	
	Avalide			C		Unk		Not Reported	
	Cardiazem			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12544397	NON-EXPEDITED			US-PFIZER INC-2016301918		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Levoquin			S		X7ds		Not Reported	
	Levoquin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2016	12544634	EXPEDITED (15-DAY)		HO, OT	US-SCIEGEN PHARMACEUTICALS INC-2016SCILIT00283		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Blood Magnesium Decreased; Cardiac Arrest; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Mydriasis; Pulse Absent; Torsade De Pointes; Unresponsive To Stimuli; Ventricular Tachycardia	Fluoxetine Capsules, Usp	S	Unknown	Doubling The Prescribed Dose	Sciegen
	Methadone	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Ondansetron	S	Unknown	Unk	Not Reported
	Diphenhydramine	S	Unknown	Unk	Not Reported
	Sertraline	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12546281	NON-EXPEDITED			US-PFIZER INC-2016328363			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Effexor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Hydrochlorothiazide			S		Unk		Not Reported	
	Zestril			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12549574	NON-EXPEDITED			US-PFIZER INC-2016306143		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S				Pfizer	
	Neosporin			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12549592	NON-EXPEDITED			US-PFIZER INC-2016304150		2 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose;	Azithromycin			S		200 Mg, Unk		Pfizer	
Decreased Appetite;	Azithromycin			S		100 Mg, Unk		Pfizer	
Product Dispensing Error									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12549638	EXPEDITED (15-DAY)		OT	US-BAYER-2016-131863			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Cipro			S		Unk		Bayer	
Bronchitis; Candida	Zithromax Z-Pack			S	Subcutaneous	Unk		Not Reported	
Infection; Candida	Humira			C		40 Mg, Unk		Not Reported	
Infection; Depression;	Spironolacton			C		Unk		Not Reported	
Diarrhoea; Dyskinesia;	Cerebrex			C		Unk		Not Reported	
Gastric Ulcer; Hiatus	Furosemide			C		Unk		Not Reported	
Hernia; Memory	Imuran			C		Unk		Not Reported	
Impairment; Nausea;	Atenolol			C		Unk		Not Reported	
Parasomnia; Product Use	Cymbalta			C		Unk		Not Reported	
In Unapproved Indication;	Osteo Bi-Flex			C		Unk		Not Reported	
Pyrexia; Rash Pruritic;									
Rash Pruritic; Sleep									
Disorder									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2016	12550569	NON-EXPEDITED			US-PFIZER INC-2016329137		65 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Demerol			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Albuterol			S		Unk		Not Reported	
	Darvocet-N			S		Unk		Not Reported	
	Darvon			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
	Irbesartan			S		Unk		Not Reported	

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

Lisinopril	S	Unk	Not Reported
Omeprazole	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Torsemide	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Valium	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12394201	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016267218		68 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis Bacterial; Bronchitis; Condition Aggravated; Enterobacter Sepsis; Hypogammaglobulinaemia ; Immunodeficiency; Product Use In Unapproved Indication; Secondary Immunodeficiency; Urosepsis	Imeth			S	Oral	2.5 Mg, (3 Dosage Form, 1 In 1 W)		Pfizer
	Novatrex			S	Oral	4 Df, Weekly (1 In 1 W)		Pfizer
	Prednisone			S		10 Mg, Daily		Not Reported
	Prednisone			S	Oral	40 Mg, Daily		Not Reported
	Prednisone			S		15 Mg, Daily (Morning)		Not Reported
	Prednisone			S		13 Mg, Daily		Not Reported
	Mabthera			S		1000 Mg, Day 1 And Day 3		Not Reported
	Mabthera			S	Parenteral	1 G Once Every 15 Days		Not Reported
	Previscan (Fluindione)			C		20 Mg, Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Inexium			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported
	Calcidose [Calcium Carbonate]			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported
	Seresta			C		Unk		Not Reported
	Forsteo			C	Subcutaneous	20 Micrograms/80 Microlitres (1 Dosage Form,1 D)		Not Reported

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

Folic Acid	C	5 Mg, Weekly	Not Reported
Rabeprazole	C	20 Mg, Daily	Not Reported
Cacit D3	C	500 Mg, 2x/Day (In The Morning)	Not Reported
Human Insulin	C	7 lu, Daily In The Morning	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12520855	NON-EXPEDITED			US-PFIZER INC-2016324905			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Dilantin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Epinephrine			S		Unk		Unknown
	Doxycycline Hyclate			S		Unk		Pfizer
	Cipro /00697201/			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Lamictal			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Risperidone			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12551800	EXPEDITED (15-DAY)		CA	IL-STRIDES ARCOLAB LIMITED-2016SP009448			Unknown	ISR

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

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

Foetal Exposure During Pregnancy; Ventricular Septal Defect	Ibuprofen	S	Transplacental	Unk	Unknown
	Paracetamol	S	Transplacental	Unk	Not Reported
	Azithromycin	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12552474	NON-EXPEDITED			US-PFIZER INC-2016321194			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12552484	NON-EXPEDITED			US-PFIZER INC-2016333949		34 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Norco			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
	Paxil			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12552810	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016338437		2 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Gastrointestinal Pain	Zithromax			S	Oral	0.1 G, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12553592	EXPEDITED (15-DAY)		HO, LT, OT	BR-WATSON-2016-15044		20 YR	Female	BRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Diazepam (Unknown)			S	Unknown	Unk		Watson	
	Haloperidol (Unknown)			S	Unknown	Unk		Watson	
	Amoxicillin-Clavulanic Acid (Unknown)			S	Unknown	Unk		Not Reported	
	Azithromycin (Unknown)			S	Unknown	Unk		Not Reported	
	Valproic Acid			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12554110	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2016337266		2 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash Maculo-Papular	Methylprednisolone Sodium Succinate			S	Intravenous drip	15 Mg, Twice A Day		Pfizer	
	Qixian			S	Intravenous drip	100 Mg, 2x/Day		Not Reported	
	Glucose			S	Intravenous drip	100 MI, Twice A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2016	12554914	NON-EXPEDITED			US-ASTRAZENECA-2016SE33787		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity; Drug Ineffective; Feeling Abnormal	Prilosec			S	Oral			Not Reported	
	Seroquel			S	Oral			Not Reported	
	Sertraline			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Daypro			S	Unknown			Not Reported	
	Protonix			S	Unknown			Not Reported	
	Levoxyl			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2016	11895946	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2015478539		4 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Toxicity To Various Agents; Vomiting	Zithromax			S		Unk		Pfizer	
	Colchicine Opocalcium			S		8 Mg Of Colchicine 2 Times A Day (16 Tablets Of 0.5 Mg Crushed With A Bit Of Water).		Not Reported	
	Paracetamol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2016	12555433	EXPEDITED (15-DAY)		OT	US-ABBVIE-16K-163-1671529-00			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Asacol			S	Unknown			Not Reported	
	Aza (Azithromycin Dihydrate)			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2016	12555697	NON-EXPEDITED			US-PFIZER INC-2016308469		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Augmentin /00852501/			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	

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

Levaquin			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Jul-2016	12555698	NON-EXPEDITED			US-PFIZER INC-2016303722		53 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Arthralgia; Rash	Azithromycin			S	Oral	250 Mg, Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Jul-2016	12556637	NON-EXPEDITED			US-PFIZER INC-2016308580			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Decreased Appetite; Swelling Face	Zithromax			S		Unk; 2 Pills Last Night And The Night Before		Pfizer		
	Zithromax			S			Pfizer			
	Zithromax			S			Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jul-2016	12559482	NON-EXPEDITED			US-PFIZER INC-2016310943		70 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective	Zithromax			S		Unk		Pfizer		
	Zithromax			S			Pfizer			
	Zithromax			S			Pfizer			
	Zithromax			S			Pfizer			
	Zithromax			S			Pfizer			
	Enbrel			C	Subcutaneous	50 Mg, Weekly		Not Reported		
	Calcium			C				Not Reported		
	Vitamin C /00008001/			C				Not Reported		
	Magnesium			C				Not Reported		
	Vitamin D3			C				Not Reported		

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12561244	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016334924		28 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Breast Swelling; Discomfort; Tremor	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12561842	EXPEDITED (15-DAY)		OT	HR-TEVA-675935ACC		35 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chest Pain; Dyspnoea; Musculoskeletal Discomfort	Sumamed			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12562538	NON-EXPEDITED			US-NOVOPROD-489132		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Eye Pruritus; Pruritus	Tresiba Flextouch U100			S	Subcutaneous	50 U, Qd		Novo Nordisk	
	Amoxicillin			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Keflex-C			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2016	12563151	NON-EXPEDITED			US-PFIZER INC-2016311600		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dizziness; Inappropriate Schedule Of	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	

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

Product Administration;
Nausea

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2016	12487718	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2016-08074		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction;	Ibuprofen			S	Unknown	Unk		Aurobindo
Chest Pain; Dyspnoea;	Azithromycin			S	Unknown	Unk		Aurobindo
Kounis Syndrome; Lactic	Copper			S	Intra-uterine	Unk		Not Reported
Acidosis; Swelling Face;	Fentanyl			S	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported
Urticaria	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	2 Mg, Unk		Not Reported
	Rhogam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	10138264	NON-EXPEDITED			US-PFIZER INC- 2014114179			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Dizziness; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	12565170	NON-EXPEDITED			US-PFIZER INC- 2016314800		23 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Histussin Hc			S		Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	12567102	NON-EXPEDITED			US-PFIZER INC-2016330786			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Interaction	Sertraline Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2016	12567109	NON-EXPEDITED			US-PFIZER INC-2016330827			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Interaction	Sertraline Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	10089642	NON-EXPEDITED			US-PFIZER INC-2014106287			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Asa			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12568893	EXPEDITED (15-DAY)		HO, OT	BR-PAR PHARMACEUTICAL COMPANIES-2016SCPR015634			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Treatment Noncompliance	Diazepam			S	Unknown	Unk Unk, Unknown		Par	
	Haloperidol			S	Unknown	Unk Unk, Unknown		Not Reported	
	Valproic Acid			S	Unknown	Unk Unk, Unknown		Not Reported	

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

	Amoxicillin W/Clavulanate	S	Unknown	Unk Unk, Unknown		Not Reported			
	Potassium Azithromycin	S	Unknown	Unk Unk, Unknown		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12570777	NON-EXPEDITED			US-WATSON-2015-25167		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Headache; Loss Of Personal Independence In Daily Activities; Nausea; Pain	Norco			S	Oral	1 Tablet, Daily		Watson	
	Azithromycin			S	Oral	500 Mg, Daily		Not Reported	
	Diphenhydramine Hydrochloride			C		25 Mg, Qhs		Not Reported	
	Mucinex D			C	Unknown	1 Unk, Qam		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12571488	NON-EXPEDITED			US-BAUSCH-BL-2015-027481			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Choking; Diarrhoea; Dysphagia; Faeces Discoloured; Insomnia; Pelvic Floor Muscle Weakness; Product Dose Omission	Xifaxan (Rifaximin) Tablets 550mg			S	Oral			Valeant	
	Xifaxan (Rifaximin) Tablets 550mg			S	Oral			Valeant	
	Zithromax			S	Oral			Not Reported	
	Atenolol			C	Oral			Not Reported	
	Estrace			C				Not Reported	
	Florastor			C	Oral			Not Reported	
	Vitamin D Nos			C	Oral			Not Reported	
	Vitamin B			C	Oral			Not Reported	
	Oxycodone			C	Oral			Not Reported	
	Xanax			C	Oral	As Needed		Not Reported	
	Percodan			C				Not Reported	
	Estrogens			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2016	12572019	NON-EXPEDITED			US-BAUSCH-BL-2015-027088			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Drug Hypersensitivity; Haematochezia; Malaise; Off Label Use; Rash Pruritic; Sinusitis	Xifaxan (Rifaximin) Tablets 550mg			S	Unknown			Valeant	
	Bactrim			S	Unknown			Not Reported	
	Z-Pac			S	Unknown			Not Reported	
	Doxycycline Hyclate			C				Not Reported	
	Probiotics			C				Not Reported	
	Vitamin B12			C				Not Reported	
	Vitamin D3			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12454908	NON-EXPEDITED			US-PFIZER INC-2016262543		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abnormal Faeces; Chills; Condition Aggravated; Decreased Appetite; Drug Ineffective; Fatigue; Gastrointestinal Disorder; Muscle Fatigue	Azithromycin			S	Oral	500 Mg, 1x/Day (250mg Capsule By Mouth Two First Day Then Once Daily)		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day (250mg Capsule By Mouth Two First Day Then Once Daily)		Pfizer	
	Hydroxyzine			C	Oral	25mg Tablet By Mouth Twice Daily		Not Reported	
	Hydroxyzine			C		Usually Takes It Only Once A Day		Not Reported	
	Zyrtec			C	Oral	10 Mg, 1x/Day		Not Reported	
	Zyrtec			C	Oral	5 Mg, 2x/Day (5mg Liquid By Mouth Twice Daily)		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12569368	EXPEDITED (15-DAY)		HO	PHHY2016IT091815		47 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Urticaria	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Metformin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12573493	NON-EXPEDITED			US-PFIZER INC-2016316552		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		250 Mg, Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12573552	NON-EXPEDITED			US-PFIZER INC-2016318792			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12573795	NON-EXPEDITED		OT	US-PFIZER INC-2016337159		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin Hcl			S	Intravenous (not otherwise specified)	Unk		Unknown	
	Tobramycin			C		Unk		Not Reported	
	Fluticasone W/Salmeterol			C		Unk		Not Reported	

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

Montelukast			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12573854	EXPEDITED (15-DAY)		DE	EG-PFIZER INC-2016339962		40 DAY	Unknown	EGY
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspiration; Cyanosis	Zithromax			S	Oral	17 Mg/Kg, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2016	12575921	EXPEDITED (15-DAY)		OT	PHHY2016GB098087		20 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neuropathy Peripheral	Azithromycin			S	Unknown			Novartis	
	Linezolid			S	Unknown			Not Reported	
	Cycloserine			S	Unknown			Not Reported	
	Pyrazinamide			S	Unknown			Not Reported	
	Para-Aminosalicylic Acid			S	Unknown			Not Reported	
	Bedaquiline			S	Unknown	400 Mg, Qd,For 2 Weeks,		Not Reported	
	Bedaquiline			S	Unknown	200 Mg, Three Times Weekly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	11811897	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2015423396		57 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
Diabetes Mellitus;	Deflan			S	Oral	1 Df, Daily		Not Reported	
Hypertensive Crisis; Liver Disorder	Torvast			C	Oral	20 Mg, Unk		Not Reported	
	Cardura			C	Oral	1 Df, Unk		Not Reported	

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

		Triatec (Ramipril)	C	Oral	5 Mg, Unk			Not Reported	
		Norvasc	C	Oral	5 Mg, Unk			Not Reported	
		Cardioaspirin	C	Oral	100 Mg, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12577700	EXPEDITED (15-DAY)		HO	CH-ROCHE-1797485			Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestatic Liver Injury	Rocephin			S	Intravenous drip				Not Reported
	Tavanic			S	Intravenous drip				Not Reported
	Zithromax			S	Parenteral				Not Reported
	Amlodipine			C	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578676	NON-EXPEDITED			US-PFIZER INC-2016349923		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk			Pfizer
	Zithromax			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12578739	NON-EXPEDITED			US-PFIZER INC-2016321414		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Rash	Zithromax			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2016	12580687	EXPEDITED (15-DAY)		HO	AU-APOTEX-2016AP007728			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Heart Rate Increased; Nausea	Azithromycin	S	Oral	2 Df, Single	Apotex
	Zoloft	C	Unknown	Unk	Not Reported
	Flu Vaccine Vii	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2016	9857048	EXPEDITED (15-DAY)		DE, OT	ET-PFIZER INC-2014025394		30 YR	Female	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S	Oral	1000 Mg (4x250mg Tablets) , Single		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2016	10918005	EXPEDITED (15-DAY)		HO, OT	ET-PFIZER INC-2015036219		21 YR	Female	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Altered State Of Consciousness; Anaphylactic Shock; Foetal Heart Rate Abnormal	Zithromax			S	Oral	1000 Mg, Single (4 Tablets Of 250 Mg Stat Dose)		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2016	12586542	DIRECT		HO			36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Chest Pain; Diarrhoea; Dizziness; Nightmare; Palpitations	Azithromycin Pliva			S	Oral			Pliva	
	Vistaril			C				Not Reported	
	Iron Sulfate			C				Not Reported	
	Vitamin D Nos			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	9837420	NON-EXPEDITED			US-PFIZER INC-2014020339			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Zestril			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	11815615	EXPEDITED (15-DAY)		HO, OT	PHHY2015IT158567		57 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diabetes Mellitus; Hypertensive Crisis; Liver Disorder	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Deflan			S	Oral	1 Df, Qd		Not Reported	
	Torvast			C	Oral	20 Mg, Unk		Not Reported	
	Triatec (Ramipril)			C	Oral	5 Mg, Unk		Not Reported	
	Cardioaspirin			C	Oral	100 Mg, Unk		Not Reported	
	Norvasc			C	Oral	5 Mg, Unk		Not Reported	
	Cardura			C	Oral	1 Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12419956	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2016195553		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Conjunctivitis; Cough; Disease Recurrence; Dry Eye; Glaucoma; Visual Impairment	Novatrex			S		15 Mg, Weekly		Pfizer	
	Novatrex			S		15 Mg, Weekly		Pfizer	
	Novatrex			S		2.5 Mg, Weekly		Pfizer	
	Metoject			S				Not Reported	
	Cortancyl			C		Unk		Not Reported	
	Speciafoldine			C		Unk		Not Reported	
	Eliquis			C		Unk		Not Reported	
	Flecaine Coversyl /00790703/			C C		 Unk		 Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12580718	EXPEDITED (15-DAY)		OT	PHHO2016US010154		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase; Aspartate Aminotransferase; Blood Alkaline Phosphatase	Dabrafenib			S	Oral	150 Mg, Bid		Novartis	
	Trametinib			S	Oral	2 Mg, Bid (Qam)		Not Reported	
	Hydroxychloroquine			S	Oral	600 Mg, Bid		Not Reported	
	Azithromycin			S	Oral	500 Mg, Qd (250 Mgd) 2-5		Not Reported	
	Tylenol			S	Oral	650 Mg, Q6h		Not Reported	
	Tylenol			S	Oral	325 Mg, Prn (Q12h)		Not Reported	
	Coq10			C	Unknown			Not Reported	
	Vitamiin C			C	Unknown			Not Reported	
	Vitamin D Nos			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12586556	NON-EXPEDITED			US-PFIZER INC- 2016324591		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Sulfadiazine Silver			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Augmentin /00756801/			S		Unk		Not Reported	
	Mmr			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Tiazac /00489702/			S		Unk		Not Reported	
	Keflex /00145501/			S		Unk		Not Reported	
	Pyridium			S		Unk		Not Reported	
	Sucralose			S		Unk		Not Reported	
	Neotracin /00038301/			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12587091	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-057935			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia	Pravastatin Sodium			S	Unknown			Bristol Myers Squibb	
	Lyrica			S	Oral	100 Mg, Bid		Not Reported	
	Zithromax			S	Oral	250 Mg, Unk		Not Reported	
	Protonix /00661201/			S	Oral	40 Mg, Bid		Not Reported	
	Crestor			S	Unknown			Not Reported	
	Aldactone /00006201/			S	Oral	25 Mg, Qd		Not Reported	
	Spiriva			S	Other	18 Mg, Qd		Not Reported	
	Effexor			S	Oral	75 Mg, Qd		Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Simvastatin			C	Unknown			Not Reported	
	Lovastatin			C	Unknown			Not Reported	
	Ventoline /00139502/			C	Other	2.5 Mg, Prn		Not Reported	
	Biotene /03475601/			C	Oral			Not Reported	
	Aspirin /00002701/			C	Oral	81 Mg, Qd		Not Reported	
	Symbicort			C	Other	Unk, Bid		Not Reported	
	Calcium			C	Oral	500 Mg, Prn		Not Reported	
	Keflex /00145501/			C	Oral	500 Mg, Q6h		Not Reported	
	Vitamin D3			C	Oral	5000 Unit, Qd		Not Reported	
	Cymbalta			C	Oral	60 Mg, Qd		Not Reported	
	Dilt-Xr			C	Oral	120 Mg, Qd		Not Reported	
	Norco			C	Oral	Unk Unk, Q8h		Not Reported	
	Synthroid			C	Oral	100 Mg, Qd		Not Reported	
	Robaxin			C	Oral	500 Mg, Qd		Not Reported	
	Zaroxolyn			C	Unknown	0.5 Df, Unk		Not Reported	

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

Lopressor	C	Oral	25 Mg, Qd	Not Reported
Remeron	C	Oral	15 Mg, Qd	Not Reported
Ditropan	C	Oral	15 Mg, Qd	Not Reported
Oxygen	C	Other		Not Reported
Helium	C	Other		Not Reported
K-Dur	C	Unknown	1 Df, Qd	Not Reported
Deltasone /00016001/	C	Unknown	20 Mg, Unk	Not Reported
Rythmol /00546301/	C	Oral	325 Mg, Bid	Not Reported
Requip	C	Oral	1 Mg, Tid	Not Reported
Saline /00075401/	C	Nasal		Not Reported
Demadex /01036501/	C	Oral	80 Mg, Qd	Not Reported
Ultram /00599202/	C	Unknown	50 Mg, Prn	Not Reported
Coumadin /00014802/	C	Oral	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2016	12589871	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016349304		67 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Arthritis; Back Pain; Blood Disorder; Disease Progression; Hypermetabolism; Overdose; Pancytopenia; Pleural Effusion; Toxicity To Various Agents	Novatrex			S	Oral	12.5 Mg Weekly (5 Df Of 2.5 Mg On Tuesdays)		Pfizer
	Pyostacine			S		Unk		Not Reported
	Speciafoldine			C		1 Df, Weekly		Not Reported
	Kaleorid 1000			C		1 Df In The Morning And 1 Df In The Evening		Not Reported
	Cotareg 160/25			C		1 Df In The Morning		Not Reported
	Amlor			C		Strength 10 Mg 1 Df In The Morning		Not Reported
	Fosavance			C		Strength 60/5600 1 Df, Weekly		Not Reported
	Levothyrox			C		62.5 Ug Daily In The Morning		Not Reported

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

Lexomil	C	Strength 6mg 0.5 Df In The Evening	Not Reported
Lasilix	C	40 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	9372745	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2013SE47427		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Discomfort; Arrhythmia; Blood Pressure Fluctuation; Body Height Decreased; Bronchitis; Dyspnoea; Dyspnoea; Escherichia Infection; Flatulence; Intentional Product Misuse; Lower Respiratory Tract Infection; Myocardial Infarction; Pyrexia; Seasonal Allergy	Tenormin			S	Oral	50 Daily In The Am And 25 Mg In The Evening As Needed		Not Reported
	Brilinta			S	Oral			Not Reported
	Amoxicillin			S	Unknown	3 Courses Of 500 Mg Three Times A Day For 10 Days		Not Reported
	Amoxicillin			S	Unknown	2000.0mg As Required		Not Reported
	Biaxin			S	Unknown	500 Mg Two Times A Day For 5 Days		Not Reported
	Zithromax			S	Unknown	Non Az Product		Not Reported
	Levoquin			S	Unknown			Not Reported
	Other Antibiotics			S	Unknown			Not Reported
	Aspirin			C				Not Reported
	Viagra			C		25.0mg As Required		Not Reported
	Nasocort			C		1 -2 Sprays, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12459591	EXPEDITED (15-DAY)		OT	US-ACTAVIS-2016-12035		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Kounis Syndrome; Lactic Acidosis	Fentanyl Patch			S	Intravenous (not otherwise specified)	100 Mg, Unknown		Watson
	Midazolam (Unknown)			S	Intravenous (not	2 Mg, Unknown		Not Reported

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

	otherwise specified)			
Azithromycin (Unknown)	S	Unknown	Unk	Not Reported
Ibuprofen (Amallic)	S	Unknown	Unk	Watson
Anti-D Immunoglobulin	S	Unknown	Unk	Not Reported
Copper	S	Intra-uterine	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12592404	NON-EXPEDITED			US-PFIZER INC-2016325634		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ampicillin Sodium			S		Unk		Unknown
	Amoxicillin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12592430	NON-EXPEDITED			US-PFIZER INC-2016326859			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Diarrhoea	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12593661	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2016341346		75 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abscess; Acute	Azithromycin			S	Oral	Unk		Pfizer
Generalised	Padmed Circosan			C		Unk		Not Reported
Exanthematous	Vitamin D Nos			C		Unk		Not Reported
Pustulosis; Rash								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12593792	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2016353557		34 YR	Male	CHE

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestatic Liver Injury	Zithromax Uno			S	Parenteral	500 Mg, 2x/Day		Pfizer	
	Amlodipine Besilate			S		10 Mg, Daily		Pfizer	
	Tavanic			S	Intravenous drip	500 Mg, 2x/Day		Not Reported	
	Rocephin-Roche			S	Intravenous drip	2 G, 1x/Day		Roche	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12593793	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016349243		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Hyponatraemia; Vertigo	Zithromax			S	Oral	1 Df, 3x/Week		Pfizer	
	Seroplex			S	Oral	5 Mg, 1x/Day		Not Reported	
	Tenstaten			S	Oral	50 Mg, 1x/Day		Not Reported	
	Kardegic			C		Unk		Not Reported	
	Temerit			C		Unk		Not Reported	
	Fenofibrate			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12596368	NON-EXPEDITED			US-UNITED THERAPEUTICS-UNT-2016-006443			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Ear Disorder; Ear Infection; Epistaxis; Nasal Congestion	Tyvaso			S		24 Micrograms, Qid		United Therapeutics	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2016	12597179	DIRECT					68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cold Sweat; Diarrhoea; Dizziness; Dizziness; Loss	Azithromycin			S	Oral	6 Tablet(S) Once A Day		Greenstone	

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

Of Consciousness; Malaise	Metoprolol Tart Potachloride Ranitidine Hydrochlorothiazide Losartan Potassium Ventolin Hfa (Inhaler) Vitamin B12 Vitamin D3	C C C C C C C C	Taken By Mouth	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2016	12462169	EXPEDITED (15-DAY)		HO, OT	US-TEVA-668422USA		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Kounis Syndrome; Lactic Acidosis; Reversible Cerebral Vasoconstriction Syndrome	Azithromycin Rhogam Midazolam Hydrochloride Copper Ibuprofen Fentanyl Epinephrine			S S S S S S S	Unknown Unknown Intravenous (not otherwise specified) Intra-uterine Intravenous (not otherwise specified) Intramuscular			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
						0.3mg (1:1000)		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2016	12564399	EXPEDITED (15-DAY)		OT	CN-ROCHE-1793843		5 YR	Unknown	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Platelet Count Decreased	Rocephin Azithromycin			S S	Intravenous drip Unknown			Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2016	12591304	NON-EXPEDITED			US-UNITED THERAPEUTICS-UNT-		55 YR	Female	USA

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

2016-005816

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; Conjunctivitis; Diarrhoea; Drug Hypersensitivity; Fluid Retention; Infection; Oedema Peripheral; Pain In Extremity; Weight Decreased	Remodulin			S	Subcutaneous	0.05 Mg/Kg, Continuing		United Therapeutics
	Metformin			S	Unknown	500 Mg, Bid		Not Reported
	Metolazone			S				Not Reported
	Azithromycin			S				Not Reported
	Adcirca			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	11621515	EXPEDITED (15-DAY)		DE, HO, OT	BR-ROCHE-1642561			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Aspiration; Cataract; Dizziness; Fall; Gait Disturbance; Gastric Disorder; Mass; Pelvic Fracture; Pneumonia; Seizure; Septic Shock; Spinal Fracture; Upper Limb Fracture; Weight Decreased	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)			Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Route: Endovenous; Dose: 100mg/10ml, Frequency: 1000 Mg, Second Infusion Was Given On 01 Oct 2012.		Not Reported
	Mabthera			S	Intravenous (not otherwise specified)	Latest Infusion Was Given On 14/Aug/2013		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported
	Buscopan			C				Not Reported
	Diclofenac			C	Unknown			Not Reported
	Cyclobenzaprine			C	Unknown			Not Reported
	Lyrca			C	Unknown			Not Reported
	Tramal			C	Unknown			Not Reported

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

Penicillamine	C	Unknown		Not Reported
Omeprazole	C	Unknown		Not Reported
Omeprazole	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Tylenol	C	Unknown		Not Reported
Celebra	C	Unknown		Not Reported
Losartan	C	Unknown	Drug: Losartana	Not Reported
Diurisa	C	Unknown		Not Reported
Pentalac	C	Unknown	3 Or 4 Times/Day, Other Indication Stomach Crisis	Not Reported
Pentalac	C			Not Reported
Neomycin	C	Unknown		Not Reported
Domperidone	C	Unknown	When Necessary	Not Reported
Amlodipine	C	Unknown		Not Reported
Aceclofenac	C	Unknown		Not Reported
Lipless	C	Unknown		Not Reported
Domperidone	C	Unknown	Indication: Stomach Crisis	Not Reported
Cortisone	C	Unknown		Not Reported
Bamifix	C			Not Reported
Avamys	C			Not Reported
Losartan	C	Unknown		Not Reported
Diupress	C	Unknown		Not Reported
Acetaminophen	C			Not Reported
Pregabalin	C	Unknown		Not Reported
Diurex (Brazil)	C	Unknown		Not Reported
Higroton	C			Not Reported
Lactulona	C			Not Reported
Prednisone	C	Unknown		Not Reported
Prednisone	C	Unknown		Not Reported
Neomycin	C			Not Reported
Diupress	C			Not Reported
Losartan	C			Not Reported

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

	Omeprazole	C		Not Reported
	Nexium	C		Not Reported
	Tramal	C	Unknown	Not Reported
	Depura	C		Not Reported
	Collyrium (Drug Name Unknown)	C		Not Reported
	Aldactone (Brazil)	C	Unknown	Not Reported
	Supradyn	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	11831752	EXPEDITED (15-DAY)		OT	IT-TEVA-615413ACC		57 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Diabetes Mellitus; Hypertensive Crisis; Liver Disorder	Azithromycin			S	Oral	500 Mg Daily		Not Reported
	Deflan - Laboratori Guidotti S.P.A.			S	Oral	1 Df Daily		Not Reported
	Torvast - 40 Mg Compresse Masticabili			C	Oral	20 Mg		Not Reported
	Triatec - 5 Mg Compresse			C	Oral	5 Mg		Not Reported
	Norvasc - 10 Mg Compresse			C	Oral	5 Mg		Not Reported
	Cardura			C	Oral	1 Df		Not Reported
	Cardioaspirin - 100 Mg Compresse Gastroresistenti			C		100 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	12605086	EXPEDITED (15-DAY)		HO	US-TEVA-678705USA		70 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Aggression; Feeling Abnormal; Hallucination; Loss Of Personal Independence In Daily Activities; Speech Disorder	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Cefalexin			S				Ivax
	Levothyroxine			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2016	12605993	DIRECT		OT			79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Substitution Issue; Rash	Azithromycin			S				Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2016	12456910	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2016294115		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Kounis Syndrome; Reversible Cerebral Vasoconstriction Syndrome	Azithromycin			S		Unk		Pfizer	
	Fentanyl Citrate			S	Intravenous (not otherwise specified)	100 Ug, Unk		Unknown	
	Ibuprofen			S		Unk		Pfizer	
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	2 Mg, Unk		Pfizer	
	Copper			S	Intra-uterine	Unk		Not Reported	
	Rhogam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2016	12607802	EXPEDITED (15-DAY)		DE, OT	HN-PFIZER INC- 2016358557		87 YR	Female	HND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	10160250	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2013194152		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Abdominal Discomfort; Abdominal Discomfort; Arrhythmia; Blood Pressure Fluctuation; Body Height Decreased; Bronchitis; Dyspnoea; Dyspnoea; Escherichia Infection; Flatulence; Intentional Product Misuse; Lower Respiratory Tract Infection; Myocardial Infarction; Pyrexia; Seasonal Allergy	Tenormin Amoxicillin Amoxicillin Zithromax Brilinta Biaxin Levoquin Aspirin Viagra Nasocort	S S S S S S S C C C	Oral Unknown Unknown Unknown Oral Unknown Unknown Unknown Unknown Unknown	50 Daily In The Am And 25 Mg In The Evening As Needed 3 Courses Of 500 Mg Three Times A Day 2000 Mg, As Needed Unk,Non Az Product 90 Mg, 2x/Day 500 Mg, 2x/Day Unk 325 Mg, 1x/Day 25 Mg, As Needed 1 -2 Sprays,As Needed	Pfizer Pfizer Pfizer Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12589966	EXPEDITED (15-DAY)		OT	GXKR2016DE003479		69 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Palatal Oedema; Pharyngeal Swelling; Tongue Movement Disturbance	Azithromycin - 1 A Pharma			S		500 Mg/Day		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12609389	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2016-09750		82 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Azithromycin			S	Unknown			Aurobindo
	Clindamycin			S	Unknown			Aurobindo
	Metronidazole			S	Unknown			Aurobindo
	Vancomycin			S	Unknown			Aurobindo
	Piperacillin/Tazobactam			S	Unknown			Not Reported

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

Imipenem And Cilastatin	S	Intravenous (not otherwise specified)	1 Gram Every 6 Hours	Not Reported
Linezolid	S	Intravenous (not otherwise specified)	600 Mg, Every 12 Hours	Not Reported
Cefepime	S	Unknown	Unk	Not Reported
Amikacin	S	Unknown		Not Reported
Ampicillin W/Sulbactam /00892601/	S	Unknown		Not Reported
Cefoxitin	S	Unknown		Not Reported
Ertapenem	S	Unknown	Unk	Not Reported
Meropenem	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12609654	EXPEDITED (15-DAY)		HO, LT	FR-ABBVIE-16K-056-1687793-00		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Aortic Thrombosis; Breast Enlargement; Hepatic Infarction; Renal Infarct; Splenic Infarction	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Novatrex			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Oxycodone			S	Oral			Not Reported
	Alprazolam			S	Oral			Not Reported
	Striverdi Respimat			S	Respiratory (inhalation)			Not Reported
	Spiriva			S	Respiratory (inhalation)			Not Reported
	Inexium			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12610558	EXPEDITED (15-DAY)		OT	US-BAYER-2016-144303		31 YR	Female	USA

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

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

Genital Haemorrhage;	Skyla	S	Intra-uterine	14 Mcg/24hr, Cont	Bayer
Nephrolithiasis;	Azithromycine	S		Unk	Not Reported
Pneumonia; Post					
Procedural Haemorrhage					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12612200	EXPEDITED (15-DAY)		LT	FR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2016- BI-49		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aortic Thrombosis;	Spiriva			S	Respiratory	5 Mcg		Boehringer Ingelheim
Hepatic Infarction; Renal	Striverdi Respimat			S	Respiratory	2 Puf		Not Reported
Infarct; Splenic Infarction					(inhalation)			
	Humira			S	Subcutaneous	40 Mg		Not Reported
	Novatrex			S	Oral	17.5 Mg		Not Reported
	Prednisone			S	Oral	20 Mg		Not Reported
	Oxycodone			S	Oral	60 Mg		Not Reported
	Alprazolam			S	Oral	0.25 Mg		Not Reported
	Inexium			S	Oral	20 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2016	12612308	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2016361090		24 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia	Zithromac 500mg			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2016	12536483	NON-EXPEDITED			US-PFIZER INC- 2016299926			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12615625	NON-EXPEDITED			US-PFIZER INC-2016339756		41 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12615964	NON-EXPEDITED			US-PFIZER INC-2016338626		10 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Urticaria	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2016	12618140	DIRECT		HO			17 YR	Unknown	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Aggression; Agitation; Hallucination; Rash; Swelling	Azithromycin, 200 Mg Teva Vitamin E			S C	Oral		4 DAY	Teva Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	11091094	NON-EXPEDITED			US-PFIZER INC-2015147915		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax Codeine			S S		Unk Unk		Pfizer Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Aug-2016	11121459	EXPEDITED (15-DAY)		OT	JP-JNJFOC-20150510980		35 YR	Male	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Eosinophilic Pustular Folliculitis; Gastroesophageal Reflux Disease; Non-Alcoholic Steatohepatitis	Prezista	S	Oral	Not Reported
	Norvir	S	Oral	Not Reported
	Truvada	S	Oral	Not Reported
	Zithromac	S	Oral	Not Reported
	Benambax	C	Unknown	Not Reported
	Venetlin	C	Respiratory (inhalation)	Not Reported
	Clarith	C	Oral	Not Reported
	Singulair	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2016	12619180	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC- 2016363921		42 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aortic Thrombosis; Hepatic Infarction; Renal Infarct; Splenic Infarction	Alprazolam			S	Oral	0.25 Mg, 1x/Day		Pfizer
	Novatrex			S	Oral	17.5 Mg, Weekly		Pfizer
	Inexium			S	Oral	20 Mg, 1x/Day		Unknown
	Humira			S	Subcutaneous	40 Mg, Every 2 Weeks		Not Reported
	Prednisone			S	Oral	10 Mg, 2x/Day		Not Reported
	Oxycodone			S	Oral	60 Mg, 1x/Day		Not Reported
	Spiriva Respimat			S	Respiratory (inhalation)	2 Df, 1x/Day		Not Reported
	Striverdi Respimat			S	Respiratory (inhalation)	2 Df, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2016	12619821	NON-EXPEDITED			US-TAKEDA- 2016TUS013347			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Ulcerative	Entyvio			S	Unknown			Takeda

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

Azithromycin	S	Unknown		Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Simponi	S	Unknown		Not Reported
Remicade	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2016	12621432	DIRECT	Y				52 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Dysarthria; Hallucination	Azithromycin			S	Oral	Mg Po		Not Reported
	Dextromethorphan/Guaifenesin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2016	12461447	EXPEDITED (15-DAY)		LT, OT	US- ELI_LILLY_AND_COMP ANY-US201606003898		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Cardiac Arrest; Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Headache; Intentional Product Misuse; Loss Of Consciousness; Malaise; Myalgia; Nausea; Pyrexia; Torsade De Pointes; Ventricular Tachycardia	Fluoxetine Hydrochloride			S	Unknown	Unk, Unknown		Eli Lilly And Co
	Diphenhydramine			S	Unknown	Unk, Unknown		Not Reported
	Methadone			S	Unknown	Unk, Unknown		Not Reported
	Azithromycin			S	Unknown	Unk, Unknown		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Ondansetron			S	Unknown	Unk, Unknown		Not Reported
	Ondansetron			S				Not Reported
	Ondansetron			S				Not Reported
	Ondansetron			S				Not Reported
	Sertraline			S	Unknown	Unk, Unknown		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2016	12561777	EXPEDITED (15-DAY)		OT	JP-009507513-1607JPN006620			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Stromectol Tablets 3 Mg			S	Oral	Daily Dosage Unknown		Merck	
	Azithromycin			S	Unknown	Daily Dose Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2016	12621156	NON-EXPEDITED			US-PFIZER INC-2016348681			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2016	12621184	NON-EXPEDITED			US-PFIZER INC-2016349104			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Erythromycin Base			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2016	12622832	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2016369493		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Anxiety	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Bisoprolol			C		Unk		Not Reported	
	Simvastatin			C		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2016	12622979	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016365586		46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Crohn'S Disease; Diarrhoea; Nasal Congestion; Pharyngeal Inflammation; Pharyngitis; Respiratory Tract Congestion; Weight Decreased	Zithromax			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
	Clarithromycin			S		Unk		Not Reported	
	Humira			C	Subcutaneous	40 Mg, Unk (40 Mg, 1 In 2 Wk)		Not Reported	
	Apriso			C		Unk		Not Reported	
	Vitamin D Nos			C		Unk		Not Reported	
	Vitamin B12			C		Unk		Not Reported	
	Nadolol			C		Unk		Not Reported	
	Oxybutynin			C		Unk		Not Reported	
	Ditropan			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12470610	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-118411		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Kounis Syndrome; Lactic Acidosis	Azithromycin			S	Unknown	Unk		Sun	
	Ibuprofen			S	Unknown	Unk		Ranbaxy	
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Sun	
	Fentanyl			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rhogam			S	Unknown	Unk		Not Reported	
	Copper			S	Intra-uterine	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12550699	EXPEDITED (15-DAY)		HO, LT, OT	BR-BAUSCH-BL-2016-016400		20 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Diazepam			S	Unknown			Not Reported	
	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported	
	Haloperidol			S	Unknown			Not Reported	
	Valproic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12570288	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016306349		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Feeling Abnormal; Headache; Hypoacusis; Nausea	Zithromax			S	Oral	Unk		Pfizer	
	Mycobutin			S	Oral	300 Mg, Daily [150 Mg; 2 Caps Per Day]		Pfizer	
	Ethambutol			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12626865	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016367809		78 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection; Pancytopenia; Prinzmetal Angina	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Metoject			S	Intramuscular	15 Mg, Weekly		Not Reported	
	Lexomil			C		3 Mg, Daily		Not Reported	
	Tildiem			C		60 Mg, Daily		Not Reported	
	Cortancyl			C		6 Mg, Daily		Not Reported	
	Levothyrox			C		100 Ug, Daily		Not Reported	

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

Atacand	C	8 Mg, Daily	Not Reported
Calcidose Vitamine D	C	1 Df, 1x/Day	Not Reported
Stagid	C	700 Mg, 2x/Day	Not Reported
Paracetamol	C	1 G, 4x/Day	Not Reported
Pantoprazole	C	40 Mg, Daily	Not Reported
Mirtazapine	C	30 Mg, Daily	Not Reported
Stilnox	C	10 Mg, Daily	Not Reported
Previscan /00789001/	C	0.5 Tablet Alternately To 0.75 Tablet Every 2 Days	Not Reported
Durogesic	C	25 Ug, 3x/Day	Not Reported
Speciafoldine	C	15 Mg, Weekly	Not Reported
Speciafoldine	C	5 Mg 48h Following Methotrexate Injection	Not Reported
Speciafoldine	C	10 Mg 48h Following Methotrexate Injection	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12626892	NON-EXPEDITED			US-PFIZER INC- 2016356705			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Doxycycline Hyclate			S		Unk		Pfizer
	Vicodin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2016	12628718	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Packaging Confusion	Pantoprazole Sodium			S	Intravenous (not otherwise specified)			Auromedics

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

Azithromycin

S

Intravenous (not
otherwise specified)

Auromedics

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	11589074	NON-EXPEDITED			US-PFIZER INC- 2015325744		29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Chills; Diarrhoea; Genitourinary Symptom; Injection Site Pain; Myalgia; Pyrexia	Zithromax			S	Oral	Unk (Took The Double Dose On Saturday But Did Not Take Again, As Directed)		Pfizer
	Ceftriaxone Sodium			S	Intramuscular	1 G, Once		Pfizer
	Zofran			S	Oral	Unk (As Prescribed)		Not Reported
	Zofran			S				Not Reported
	Duexis			C	Oral	800 Mg, As Needed (Has Been Taking For A Couple Months But Not Every Day)		Not Reported
	Duexis			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12376040	EXPEDITED (15-DAY)		HO, LT, OT	FR-PFIZER INC- 2016170363		79 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bowen'S Disease; Chest Pain; Neuroendocrine Carcinoma Of The Skin	Novatrex			S	Oral	5 Mg, Weekly		Pfizer
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported
	Cortancyl			S	Oral	5 Mg, Weekly		Not Reported
	Levothyrox			C				Not Reported
	Lasilix /00032601/			C				Not Reported
	Bisoprolol			C				Not Reported
	Tahor			C				Not Reported
	Coumadine			C				Not Reported
	Cordarone			C				Not Reported
Esomeprazole			C				Not Reported	

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

		Zyloric		C					Not Reported
		Cymbalta		C					Not Reported
		Lyrica		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12454959	NON-EXPEDITED			US-PFIZER INC-2016270512		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12550888	EXPEDITED (15-DAY)		HO, LT	BR-ROCHE-1792614		20 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Diazepam			S	Unknown			Not Reported	
	Haloperidol			S	Unknown			Not Reported	
	Valproic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Amoxicillin/Clavulanate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12630443	NON-EXPEDITED			PR-PFIZER INC-2016342331			Female	PRI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12630449	NON-EXPEDITED			US-PFIZER INC-2016343842		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia; Chills; Diarrhoea;	Zithromax			S	Oral	1 Df, Daily, 500		Pfizer	

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

Hyperhidrosis; Malaise; Mobility Decreased; Nausea; Tremor; Vomiting	Flovent	C	Respiratory (inhalation)	220 Ug, As Needed, 110 Mcg Per Actuation, Two Puffs In The Morning	Not Reported
	Calcium	C		600 Mg, Unk	Not Reported
	Vitamin D Nos	C		2000 Iu, 2x/Day	Not Reported
	Lisinopril	C		2.5 Mg, Daily	Not Reported
	Synthroid	C		112 Ug, Daily	Not Reported
	Singulair	C		10 Mg, Unk	Not Reported
	Singulair	C			Not Reported
	Red Yeast Rice	C		600 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12630462	NON-EXPEDITED			US-PFIZER INC- 2016343178		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12630470	NON-EXPEDITED			US-PFIZER INC- 2016340533		42 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2016	12630520	NON-EXPEDITED			US-PFIZER INC- 2016351403		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Macrodantin			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

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

	Cipro		S		Unk		Not Reported		
	Keflex		S		Unk		Not Reported		
	Aceon		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2016	12361776	NON-EXPEDITED			US-SA-2016SA083235		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Malaise; Rash; Urticaria	Praluent			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Alirocumab Prefilled Pen			C	Unknown			Not Reported	
	Levothyroxine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2016	12459830	EXPEDITED (15-DAY)		DE	ET-PFIZER INC-2016288337		60 YR	Female	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S	Oral	1 G (4 Tablets), Stat (At Once) Early In The Morning		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2016	12548809	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2016GSK093910		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Cardiac Failure; Compression Fracture; Drug Hypersensitivity; Pneumonia	Advair			S				Glaxosmithkline	
	Advair			S				Glaxosmithkline	
	Flagyl			S				Glaxosmithkline	
	Robitussin			S				Glaxosmithkline	
	Codeine Phosphate			S				Glaxosmithkline	
	Levaquin			S				Glaxosmithkline	
	Avalox			S				Glaxosmithkline	
	Sudafed			S				Glaxosmithkline	

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

	Azithromycin	S		Glaxosmithkline
	Bactrim	S		Glaxosmithkline
	Biaxin	S		Glaxosmithkline
	Ceftin	S		Glaxosmithkline
	Clindamycin	S		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2016	12638225	NON-EXPEDITED			US-SA-2016SA084071		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash; Unevaluable Event	Praluent			S	Unknown			Not Reported
	Praluent			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Alirocumab Prefilled Pen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2016	12390976	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2016263893			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aortic Dissection	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2016	12639764	EXPEDITED (15-DAY)		HO	CH-GLENMARK PHARMACEUTICALS INC, USA.-2016GMK02388			Unknown	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Medication Error	Citalopram Hydrobromide			S	Oral	10 Mg, Qd		Glenmark
	Azithromycin			S	Oral	250 Mg/3× Per Week		Not Reported
	Ciprofloxacin			S	Oral	500 Mg, Qd		Not Reported
	Domperidone			S	Oral	30 Mg, Qd		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2016	12641219	NON-EXPEDITED			US-PFIZER INC-2016350687		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Tramadol			S		Unk		Not Reported	
	Amitriptyline			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2016	12641233	NON-EXPEDITED			US-PFIZER INC-2016368501		61 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2016	12642473	EXPEDITED (15-DAY)		HO	FR-MEDAC PHARMA, INC.-1056176		78 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection; Pancytopenia; Prinzmetal Angina	Metoject			S	Intramuscular			Medac	
	Novatrex			S	Oral			Not Reported	
	Folic Acid			C				Not Reported	
	Lexomil			C				Not Reported	
	Tildiem			C				Not Reported	
	Prednisone			C				Not Reported	
	Levothyroxine Sodium			C				Not Reported	
	Atacand			C				Not Reported	
	Calcidose Vitamin D3			C				Not Reported	
	Stagid			C				Not Reported	
	Paracetamol			C				Not Reported	
	Pantoprazole Sodium			C				Not Reported	
	Mirtazapine			C				Not Reported	
	Zolpidem			C				Not Reported	
	Fluindione			C				Not Reported	

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

Fentanyl			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12171323	NON-EXPEDITED			US-PFIZER INC-2016102007		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Eye; Product Use In Unapproved Indication	Azithromycin			S		250 Mg, Unk		Pfizer	
	Azithromycin			S		250 Mg, 1x/Day (250 Mg - 6 Tablets One A Day)		Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12565137	NON-EXPEDITED			US-PFIZER INC-2016310817		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12603639	NON-EXPEDITED			US-PFIZER INC-2016335647		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12626050	EXPEDITED (15-DAY)		HO, LT	FR-ASTRAZENECA-2016SE82272		42 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aortic Thrombosis; Breast Oedema; Hepatic Infarction; Renal Infarct; Splenic Infarction	Inexium			S	Oral			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Novatrex			S	Oral			Not Reported	

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

Prednisone	S	Oral	Not Reported
Oxycodone	S	Oral	Not Reported
Alprazolam	S	Oral	Not Reported
Spiriva Respimat	S	Respiratory (inhalation)	Not Reported
Striverdi Respimat	S	Respiratory (inhalation)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12644253	EXPEDITED (15-DAY)		OT	AU-009507513-1608AUS005984			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Recurrence	Montelukast Sodium			S		Unk		Merck	
	Azithromycin			S		Unk		Not Reported	
	Cyclosporine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12644326	NON-EXPEDITED		OT	US-AKORN-36150			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Instillation Site Pain; Liquid Product Physical Issue; Product Container Issue	Azasite 1% (Azithromycin Ophthalmic Solution)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2016	12647191	DIRECT	Y				66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Nausea; Palpitations	Zithromax			S	Intracavernous			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12646738	EXPEDITED (15-DAY)		OT	IT-TEVA-683575ACC			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pelvic Inflammatory Disease	Azithromycin			S				Not Reported	
	Doxycycline			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12647246	EXPEDITED (15-DAY)		DE	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-121367		6 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Oedema; Toxicity To Various Agents	Azithromycin			S	Oral	Unk		Sun	
	Azithromycin			S				Sun	
	Codeine			S	Unknown	10 To 20 Mg, Q4h		Ranbaxy	
	Codeine			S				Ranbaxy	
	Guaifenesin/Codeine			S	Unknown	Unk		Not Reported	
	Guaifenesin/Codeine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12647834	EXPEDITED (15-DAY)		DS, HO, OT	CA-APOTEX- 2016AP010432			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Dyspnoea; Forced Expiratory Volume Decreased; Product Use Issue	Apo-Azithromycin			S	Oral	250 Mg, Unk		Apotex	
	Seebri Breezhaler			S	Respiratory (inhalation)	Once Daily		Not Reported	
	Advair			C	Unknown	Twice Daily		Not Reported	
	Guaifenesin W/Salbutamol			C	Unknown	Twice Daily		Not Reported	
	Nifedipine			C	Unknown	20 Mg, Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12648685	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20160809200			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Angioedema; Conjunctival Haemorrhage; Drug Reaction With Eosinophilia And Systemic Symptoms; Fixed Eruption; Flushing; Gingival Hypertrophy; Mouth Ulceration; Photosensitivity Reaction; Pruritus; Rash Maculo-Papular; Rash Pustular; Stevens-Johnson Syndrome; Sunburn; Urticaria	Domperidone			S	Unknown			Not Reported
	Ofloxacin			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Cefuroxime			S	Unknown			Not Reported
	Cephalexine			S	Unknown			Not Reported
	Cefoperazone			S	Unknown			Not Reported
	Cephadrine			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Norfloxacin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Tinidazole			S	Unknown			Not Reported
	Amikacin			S	Unknown			Not Reported
	Gentamicin			S	Unknown			Not Reported
	Gliclazide			S	Unknown			Not Reported
	Metformin			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Phenytoin			S	Unknown			Not Reported
Valproate			S	Unknown			Not Reported	
Atorvastatin			S	Unknown			Not Reported	
Drotaverine			S	Unknown			Not Reported	
Calcium			S	Unknown			Not Reported	
Cefixime			S	Unknown			Not Reported	

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

	Esomeprazole	S	Unknown	Not Reported
	Tamsulosin	S	Unknown	Not Reported
	Naproxen	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Budesonide	S	Unknown	Not Reported
	Co-Trimoxazole	S	Unknown	Not Reported
	Levosulpiride	S	Unknown	Not Reported
	Multivitamins	S	Unknown	Not Reported
	Ranitidine	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12648712	NON-EXPEDITED			US-PFIZER INC-2016368916			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12649238	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP010377		83 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Erythema; Monoplegia; Nausea; Pain; Peripheral Swelling; Rheumatoid Arthritis; Varicophlebitis; Vomiting	Apo-Azithromycin			S	Oral	Unk, Qd		Apotex
	Apo-Azithromycin			S	Oral	Unk, Bid		Apotex
	Apo-Azithromycin			S	Unknown	Unk		Apotex
	Cholecalciferol			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Teveten /01347302/			C	Unknown			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2016	12649404	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP010382			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Candida Infection; Chronic Obstructive Pulmonary Disease; Dyspnoea; Hospitalisation; Wheezing	Apo-Azithromycin			S	Oral	250 Mg, Q.3w		Apotex	
	Alvesco			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Tiotropium Bromide			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12586503	NON-EXPEDITED			US-PFIZER INC-2016322870		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		500 Mg, Unk		Pfizer	
	Levofloxacin			S		500 Mg, Unk		Unknown	
	Amoxicillin			S		500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12630510	NON-EXPEDITED			US-PFIZER INC-2016350507		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12651528	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP010380		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Photodermatitis;	Atorvastatin			S	Oral			Apotex	
	Apo-Lansoprazole			S	Oral			Not Reported	

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

Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Apo-Mycophenolate	S	Oral			Apotex
	Pantoprazole	S	Oral			Apotex
	Prednisone	S	Oral			Apotex
	Apo-Sulfatrim	S	Oral			Not Reported
	Apo-Voriconazole	S	Oral	Unk		Not Reported
	Apo-Voriconazole	S	Oral	Unk		Not Reported
	Azithromycin	S	Oral			Not Reported
	Tacrolimus	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12652391	NON-EXPEDITED			US-PFIZER INC- 2016369368			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Compazine			S		Unk		Not Reported	
	Cozaar			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12652437	NON-EXPEDITED			US-PFIZER INC- 2016381899			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Vancomycin Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Choline Magnesium Salicylate			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12652450	NON-EXPEDITED			US-PFIZER INC- 2016365574			Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12652458	NON-EXPEDITED			US-PFIZER INC-2016380189			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Ineffective; Rash; Rash Erythematous; Skin Disorder; Thermal Burn	Zithromax			S	Oral	Unk, 1x/Day		Pfizer	
	Viibryd			S	Oral	20 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12652829	EXPEDITED (15-DAY)		DE	US-MYLANLABS-2016M1033366			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2016	12654173	DIRECT		HO, OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis; Dyspnoea; Headache; Hyperhidrosis; Malaise; Pruritus; Tinnitus	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	11453315	NON-EXPEDITED			US-PFIZER INC-2015292021		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Chantix			S		Unk		Pfizer	

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

Rash	Azithromycin	S	Unk	Pfizer
	Tricor	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12181402	NON-EXPEDITED		DE	JP-AKORN-24102		95 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperthermia Malignant; Pneumonia Anthrax; Urinary Tract Infection Bacterial	Azasite			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12181678	NON-EXPEDITED		HO	JP-AKORN-24108		88 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hip Fracture	Azasite			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12520060	NON-EXPEDITED			US-PFIZER INC- 2016323801		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Zyvox			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Compazine			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Methadone			S		Unk		Not Reported

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

	Paxil	S	Unk	Not Reported
	Toprol XL	S	Unk	Not Reported
	Zofran	S	Unk	Not Reported
	Asa	S	Unk	Not Reported
	Kytril	S	Unk	Not Reported
	Parnate	S	Unk	Not Reported
	Zantac	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12642347	NON-EXPEDITED			US-PFIZER INC-2016353181			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12655784	NON-EXPEDITED			US-PFIZER INC-2016376157			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Butorphanol Tartrate			S		Unk		Unknown	
	Codeine			S		Unk		Not Reported	
	Acetaminophen W/Propoxyphene Napsylate			S		Unk		Not Reported	
	Dilaudid			S		Unk		Not Reported	
	Hydrocodone/Acetaminophen			S		Unk		Not Reported	
	Hydroxychloroquine			S		Unk		Not Reported	
	Naproxen			S		Unk		Not Reported	
	Quinacrine			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12655796	NON-EXPEDITED			US-PFIZER INC-2016376654		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Ultram			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12655819	NON-EXPEDITED			US-PFIZER INC-2016383650			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Advair			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Cipro /00697201/			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2016	12657706	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016380637		35 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactoid Reaction; Drug-Induced Liver Injury	Zithromac 250mg			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2016	12657908	NON-EXPEDITED			US-AMGEN-USASL2016104374		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Sinusitis	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	

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

Z-Pak			S		Unknown		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
17-Aug-2016	12658767	EXPEDITED (15-DAY)		HO, OT	MX-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-122134		71 YR	Female	MEX	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Hypoglycaemia	Azithromycin			S	Oral	500 Mg, Unk		Sun		
	Metoprolol			C	Unknown			Not Reported		
	50/12.5 Mg Losartan/Hydrochlorothiazide			C	Unknown	50/12.5 Mg Losartan/Hydrochlorothiazide de Every 24 Hours		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
17-Aug-2016	12661365	NON-EXPEDITED			US-AKORN-37008			Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Eye Inflammation	Azasite (Azithromycin Ophthalmic Solution) 1%			S				Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
17-Aug-2016	12662249	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI- FK201605543			Male	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Cardiac Arrest; Ventricular Tachycardia	Azithromycin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care		
	Licorice Root			S	Unknown			Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
18-Aug-2016	12664515	NON-EXPEDITED			US-PFIZER INC- 2016387964			Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		

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

Drug Hypersensitivity	Zithromax		S			Unk		Pfizer	
	Glipizide		S			Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2016	12664769	EXPEDITED (15-DAY)		HO, OT	MX-PFIZER INC-2016385707		71 YR	Female	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoglycaemia	Azithromycin			S	Oral	500 Mg / 24 Hrs		Pfizer	
	Losartan/Hydrochlorothiazide			C		50 / 12.5 Mg Losartan/Hydrochlorothiazide Every 24 Hours		Not Reported	
	Metoprolol			C		100 Mg, Every 24 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2016	12665601	EXPEDITED (15-DAY)		DE, OT	US-TEVA-686097USA		91 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2016	12665636	NON-EXPEDITED		OT	US-PFIZER INC-2016387320			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		250 Mg		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2016	12503909	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016311806		57 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Abdominal Pain; Diarrhoea; Dyspepsia; Faeces Soft; Hyperhidrosis; Loss Of Consciousness; Syncope; Thirst; Vomiting	Zithromac Sr 2g	S	Oral	2 G, 1x/Day	Pfizer
	Aciclovir	C	Oral	200 Mg, 1x/Day	Not Reported
	Olmotec	C	Oral	10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2016	12655548	EXPEDITED (15-DAY)		OT	US-GALDERMA- US16005571		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	Doxycycline			S				Not Reported	
	Azithromycin			S				Not Reported	
	Penicillin			S				Not Reported	
	Tenofovir			C				Not Reported	
	Efavirenz			C				Not Reported	
	Emtricitabine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2016	12666888	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2016AP010373			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Erythema; Monoplegia; Peripheral Swelling; Rheumatoid Arthritis	Apo-Azithromycin			S	Unknown	1 Df, Bid		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2016	12666904	EXPEDITED (15-DAY)		DE, HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-121328		91 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes; Ventricular	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Single		Sun	

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

Tachycardia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2016	12671017	DIRECT		OT			89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Disorientation; Dizziness; Dysgeusia; Eye Pain; Facial Paralysis; Hypophagia; Nausea; Tendon Disorder; Vertigo; Weight Decreased	Azithromysin			S		250mg Tab 4 Pills (T) Mouth		Not Reported	
	Levaquin			S		10 Pills (T)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2016	12671024	DIRECT		OT			66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dizziness; Dyspepsia; Fall; Feeling Abnormal; Heart Rate Increased; Hyperacusis; Hypertension; Hypoaesthesia; Insomnia; Nausea; Neck Pain; Oropharyngeal Pain; Panic Attack; Personality Change; Vertigo	Ciprofloxacin			S	Oral	20 Pills 1 Tab 2x Day Mouth		Not Reported	
	Azithromycin			S	Oral	6 Pills 2 Tab Then 1 For 4 Days Mouth		Greenstone	
	Armour Thyroid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2016	12545490	EXPEDITED (15-DAY)		HO, OT	BR-PFIZER INC- 2016327676		20 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S		Unk		Pfizer	
	Clavulanate Amoxicillin			S		Unk		Not Reported	

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

	Diazepam	S	Unk	Not Reported
	Haloperidol	S	Unk	Not Reported
	Haloperidol	S		Not Reported
	Valproic Acid	S	Unk	Not Reported
	Valproic Acid	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2016	12670585	NON-EXPEDITED			US-ASTRAZENECA-2016SE74678		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tumour Marker Increased	Faslodex			S	Intramuscular			Astrazeneca
	Ibrance			S	Oral	100mg/Day On Days 1-21 Every 28 Days		Not Reported
	Ibrance			S	Oral			Not Reported
	Zolof			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Calcium			C				Not Reported
	Hydrocodone-Homalropine			C				Not Reported
	Lovenox			C				Not Reported
	Multivitamin			C				Not Reported
	Ranitidine			C				Not Reported
	Turmeric Root Extract			C				Not Reported
	Vitamin D3			C				Not Reported
	Vitamin E			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2016	12672981	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2016389798		4 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rectal Haemorrhage	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2016	12673540	EXPEDITED (15-DAY)		HO	RU-TEVA-670902ISR		48 YR	Female	RUS

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Limb Discomfort; Overdose	Sumamed			S		2 Gram Daily; For 4,5 Days		Not Reported	
	Ryzodeg			C		30 Units X 2 Times A Day		Not Reported	
	Novorapid			C		10 Units At Daytime		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2016	12674641	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-087		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Maximum Strength Mucinex D Tablets Z-Pak			S	Unknown	1200 Mg, Qd		Not Reported	
				S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2016	10752028	EXPEDITED (15-DAY)		DE, OT	ET-PFIZER INC-2015035997		60 YR	Male	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S	Oral	1000 Mg, Single (4 Tablets Of 250 Mg Stat Dose)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2016	12661588	NON-EXPEDITED			US-PFIZER INC-2016389220			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2016	12669792	EXPEDITED (15-DAY)		HO	US-ABBVIE-13P-163-1054536-00		59 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Bronchitis; Cough; Diverticulum; Feeling Hot; Influenza; Meniscus Injury; Pain; Pain; Polyp; Psoriasis; Rotator Cuff Syndrome; Therapeutic Product Effect Decreased; Upper Respiratory Tract Infection; Urticaria	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Z-Pak			S	Unknown			Not Reported	
	Z-Pak			S				Not Reported	
	Lunesta			C	Oral	Bedtime		Not Reported	
	Sprix			C	Nasal	Spray Daily		Not Reported	
	Prilosec			C	Oral			Not Reported	
	Senokot			C	Oral			Not Reported	
	Hydrocodone			C	Oral	10/325mg 4-6 Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2016	12676306	NON-EXPEDITED			US-PFIZER INC- 2016391222			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity; Dyspepsia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2016	12676611	NON-EXPEDITED			US-PFIZER INC- 2016396585			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Headache; Nausea; Palpitations	Zithromax			S		250 Mg, Tablet		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2016	12676723	EXPEDITED (15-DAY)		DE, OT	US-LUPIN PHARMACEUTICALS INC.-2016-03756		91 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest	Azithromycin			S	Intravenous (not	500 Mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2016	12621065	NON-EXPEDITED			US-PFIZER INC-2016350699		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash; Swelling	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2016	12641257	NON-EXPEDITED			US-PFIZER INC-2016365390			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Darvocet-N			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2016	12680008	EXPEDITED (15-DAY)		OT	CH-MYLANLABS-2016M1035690			Unknown	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	250 Mg/3 X Per Week		Not Reported	
	Ciprofloxacin			S	Oral	500mg/Day		Not Reported	
	Citalopram			S	Oral	10mg/Day		Not Reported	
	Domperidone			S	Oral	30mg/Day		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2016	12682263	EXPEDITED (15-DAY)		OT	PHHY2016CH115602		68 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy; Drug Interaction; Electrocardiogram Qt	Azithromycin			S	Oral	250 Mg/3x Per Week		Novartis	
	Ciprofloxacin			S	Oral	500 Mg, Qd		Not Reported	

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

Prolonged	Citalopram	S	Oral	10 Mg, Qd	Not Reported
	Domperidone	S	Oral	30 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2016	12552096	EXPEDITED (15-DAY)		HO	PL-TEVA-674605ISR			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pyrexia	Cefuroxime			S				Not Reported
	Azithromycin			S				Not Reported
	Cefaclor			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2016	12673576	EXPEDITED (15-DAY)		HO, LT, OT	BR-TEVA-2016-15044		20 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Diazepam			S	Unknown	Unk		Not Reported
	Haloperidol			S	Unknown	Unk		Not Reported
	Amoxicillin W/Clavulanic Acid			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Valproic Acid			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2016	12682916	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2016US17436			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Leukopenia; Pericardial Cyst; Pericardial Effusion; Treatment Failure	Levofloxacin			S	Unknown	Unk		Cipla
	Levofloxacin			S				Cipla
	Levofloxacin			S				Cipla
	Levofloxacin			S				Cipla
	Emtricitabine			S	Unknown	Unk		Cipla
	Tenofovir			S	Unknown	Unk		Cipla
	Azithromycin			S	Unknown	Unk		Cipla

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

Azithromycin	S			Cipla
Azithromycin	S			Cipla
Azithromycin	S			Cipla
Ciprofloxacin	S	Unknown	Unk	Cipla
Sulfamethoxazole/ Trimethoprim	S	Unknown	Unk	Cipla
Sulfamethoxazole/ Trimethoprim	S			Cipla
Sulfamethoxazole/ Trimethoprim	S			Cipla
Sulfamethoxazole/ Trimethoprim	S			Cipla
Amphotericin B	S	Intravenous (not otherwise specified)	Unk	Cipla
Amphotericin B	S			Cipla
Amphotericin B	S			Cipla
Doxycycline	S	Unknown	Unk	Cipla
Doxycycline	S			Cipla
Doxycycline	S			Cipla
Doxycycline	S			Cipla
Vancomycin	S	Unknown	Unk	Cipla
Vancomycin	S			Cipla
Vancomycin	S			Cipla
Vancomycin	S			Cipla
Piperacillin-Tazobactam	S	Unknown	Unk	Not Reported
Piperacillin-Tazobactam	S			Not Reported
Piperacillin-Tazobactam	S			Not Reported
Piperacillin-Tazobactam	S			Not Reported
Atovaquone	S	Unknown	Unk	Not Reported
Raltegravir	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2016	12684700	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2015399654		6 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Idiosyncratic Drug Reaction	Zithromac 10%			S	Oral	10 Mg/Kg, Daily		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2016	12686346	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016277847		86 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2016	11791684	EXPEDITED (15-DAY)		DS	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-079942			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Discomfort; Nasopharyngitis; Pain In Extremity; Prescribed Underdose; Vomiting	Sprycel			S	Oral	70 Mg, Unk		Bristol Myers Squibb	
	Lisinopril			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2016	12603636	EXPEDITED (15-DAY)		HO, OT	FR-MEDAC PHARMA, INC.-1055666		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Bronchitis; Cardiac Disorder; Conjunctivitis; Cough; Dizziness; Dry Eye; Dyspnoea; Fall; General Physical Health	Metoject			S	Subcutaneous			Medac	
Deterioration; Glaucoma; Limb Discomfort; Pharyngitis; Rash; Somnolence; Visual Impairment	Novatrex			S	Oral			Not Reported	
	Prednisone			C				Not Reported	
	Folic Acid			C				Not Reported	
	Eliquis			C				Not Reported	
	Flecainide Acetate			C				Not Reported	
	Perindopril Erbumine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2016	12326259	EXPEDITED (15-DAY)		DE, HO	US-AUROBINDO-AUR-APL-2016-05554		91 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest; Ventricular Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2016	12693864	NON-EXPEDITED			US-PFIZER INC-2016398511		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Combivent			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Metformin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2016	12694177	NON-EXPEDITED			US-PFIZER INC-2016403014		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zosyn			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2016	12695893	NON-EXPEDITED			US-PFIZER INC-2016397629		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Condition Aggravated; Dizziness; Hyperhidrosis; Loss Of Personal Independence In Daily Activities; Malaise; Migraine; Palpitations	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12563221	EXPEDITED (15-DAY)		OT	NG-PFIZER INC-2016340164			Male	NGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Status Asthmaticus	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12645928	NON-EXPEDITED			US-PFIZER INC-2016160652			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Enbrel			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Not Reported	
	Sulphur			S		Unk		Not Reported	
	Zithromycin			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Arava			S		Unk		Not Reported	
	Humira			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12696618	NON-EXPEDITED		HO	US-JNJFOC-20141004311		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Diflucan		Y	S	Unknown			Not Reported	
	Levaquin			S	Unknown			Not Reported	
	Simvastatin			S	Unknown			Not Reported	
	Cleocin			S	Unknown			Not Reported	
	Lipitor			S	Unknown			Not Reported	
	Bactrim			S	Unknown			Not Reported	

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

Biacin	S	Unknown	Not Reported
Zithromax	S	Unknown	Not Reported
Ampicillin	S	Unknown	Not Reported
Cipro	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12696818	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2016-02722		59 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; International Normalised Ratio Increased; Prothrombin Time Prolonged	Azithromycin			S	Unknown	Single Dose		Not Reported
	Warfarin Potassium			S	Unknown	2.5 Mg		Not Reported
	Warfarin Potassium			S	Unknown	1 Mg		Not Reported
	Warfarin Potassium			S	Unknown	2 Mg		Not Reported
	Tamsulosin Hydrochloride			C	Unknown			Not Reported
	Furosemide			C	Unknown			Not Reported
	Iron Sulfate			C	Unknown			Not Reported
	Fluvoxamine Maleate			C	Unknown			Not Reported
	Olopatadine Hydrochloride			C	Unknown			Not Reported
	Etizolam			C	Unknown			Not Reported
	Mosapride Salt			C	Unknown			Not Reported
	Morphine Hydrochloride			C	Unknown			Not Reported
	Morphine Sulfate			C	Unknown			Not Reported
	Flunitrazepam			C	Unknown			Not Reported
	Magnesium Oxide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12696821	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2016-02733		85 YR	Female	JPN

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

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

Drug Interaction; International Normalised Ratio Increased; Prothrombin Time Prolonged	Azithromycin	S	Unknown		Not Reported
	Azithromycin	S			Not Reported
	Warfarin Potassium	S	Unknown		Not Reported
	Warfarin Potassium	S	Unknown		Not Reported
	Warfarin Potassium	S	Unknown		Not Reported
	Urapidil	C	Unknown	15 Mg	Not Reported
	Digoxin	C	Unknown	0.125 Mg	Not Reported
	Verapamil Hydrochloride	C	Unknown	40 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12696826	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2016-03853		50 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12697304	NON-EXPEDITED		OT	US-JNJFOC- 20160727534			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Ulcerative	Simponi			S	Subcutaneous				Not Reported
	Remicade			S	Intravenous (not otherwise specified)				Not Reported
	Humira			S	Subcutaneous				Not Reported
	Azithromycin Dihydrate			S	Unknown				Not Reported
	Entyvio			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12697499	EXPEDITED (15-DAY)		HO, LT, OT	BR-AUROBINDO-AUR- APL-2016-10753		20 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Reaction With Eosinophilia And Systemic Symptoms	Amoxicillin+Clavulanic Acid 1.2g	S	Unknown	Unk	Aurobindo
	Diazepam	S		Unk	Not Reported
	Haloperidol	S			Not Reported
	Valproic Acid	S			Not Reported
	Azithromycin	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2016	12698608	NON-EXPEDITED			US-PFIZER INC-2016392995			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Atenolol			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Hydrochlorothiazide			S		Unk		Unknown
	Norvasc			S		Unk		Pfizer
	Atenol			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2016	9019402	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2013018562		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastroenteritis	Celecoxib			S	Oral	Unk		Pfizer
	Zithromax			S	Oral	Day1, 500 Mg, 1x/Day		Pfizer
	Zithromax			S	Oral	Day2 - Day5, 250 Mg, 1x/Day		Pfizer
	Amoxal			S	Oral	875 Mg, 2x/Day		Not Reported
	Nexium			C	Oral	20 Mg, 1x/Day		Not Reported
	Hydrocodone			C	Oral	Unk		Not Reported
	Zanaflex			C	Oral	Unk		Not Reported

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

Theo-Dur	C	Oral	Unk	Not Reported
Glucophage	C	Oral	Unk	Not Reported
Humulin	C	Subcutaneous	70/30, Unk	Not Reported
Amaryl	C	Oral	Unk	Not Reported
Zyloprim	C	Oral	Unk	Not Reported
Benadryl	C	Oral	Unk	Not Reported
Prinivil	C	Oral	20 Mg, 1x/Day	Not Reported
Novolin 70/30	C	Subcutaneous	20 Mg, Hs	Not Reported
Nasal Saline	C	Nasal	1 Df, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2016	12701022	EXPEDITED (15-DAY)		OT	US-AMGEN- USASL2016110510		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Facial Paralysis; Head Discomfort; Intentional Product Misuse; Pain; Rash Erythematous; Sinusitis	Enbrel			S	Unknown	Unk Unk, Q3wk		Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	
	Vitamin D3			C	Unknown	2000 Iu, Unk		Not Reported	
	Calcium			C		1200 Mg, Unk		Not Reported	
	Valaciclovir			C	Oral	1 Mg, Tid		Not Reported	
	Prednisone			C		6 Day Taper		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2016	12702305	EXPEDITED (15-DAY)		HO, OT	JP-TEVA-688864ISR		75 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Purpura; Rhabdomyolysis	Azithromycin			S		Single Dose		Not Reported	
	Pregabalin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2016	12705013	DIRECT		DS, RI			62 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Eyelid Ptosis; Impaired Driving Ability; Palpitations; Vision Blurred	Azithromycin			S	Oral			Sandoz	
	Synthroid			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2016	12705710	DIRECT		HO			17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Crying; Hallucination; Inappropriate Affect; Lethargy; Product Quality Issue; Pyrexia; Rash; Viral Infection; Vision Blurred	Azithromycin			S	Oral	200mg/5ml 11ml First Day 5.5 From Day 2 To Day 5 Once A Day By Mouth		Teva	
	Enalapril			C				Not Reported	
	Tylenol			C				Not Reported	
	Advil			C				Not Reported	
	Motrin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2016	12705447	NON-EXPEDITED			US-ASTRAZENECA- 2016SE76437			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia	Symbicort			S	Respiratory (inhalation)			Astrazeneca	
	Crestor			S		Oral		Not Reported	
	Lyrca			S		Oral		Not Reported	
	Spiriva			S		Unknown		Not Reported	
	Zithromax			S		Unknown		Not Reported	
	Effexor			S		Unknown		Not Reported	
	Protonix			S		Unknown		Not Reported	
	Aldactone			S		Unknown		Not Reported	
	Ventolin			C				Not Reported	
	Biotene			C				Not Reported	

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

Aspirin	C	Not Reported
Keflex	C	Not Reported
Vitamin D3	C	Not Reported
Cymbalta	C	Not Reported
D/Lt-Xr	C	Not Reported
Norco	C	Not Reported
Freestyle Lancets	C	Not Reported
Synthroid	C	Not Reported
Robaxin	C	Not Reported
Zaroxolyn	C	Not Reported
Lopressor	C	Not Reported
Remeron	C	Not Reported
Ditropan XI	C	Not Reported
Deltasone	C	Not Reported
Rythmol Sr	C	Not Reported
Requip	C	Not Reported
Saline Mist	C	Not Reported
Demadex	C	Not Reported
Ultram	C	Not Reported
Coumadin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2016	12708827	NON-EXPEDITED			US-PFIZER INC-2016409769		92 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	9793286	NON-EXPEDITED			US-PFIZER INC-2013370971			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Darvon			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported

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

Demerol			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-Sep-2016	12160980	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2016134734		58 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Eosinophilia; Pulmonary Eosinophilia	Zithromax			S	Oral	250 Mg, 3x/Week		Pfizer		
	Cymbalta			S		30 Mg, 1x/Day		Not Reported		
	Spiriva			C		Unk		Not Reported		
	Innovair			C		Unk		Not Reported		
	Bricanyl			C		Unk		Not Reported		
	Atrovent			C		Unk		Not Reported		
	Bronchodual			C		Unk		Not Reported		
	Paracetamol			C				Not Reported		
	Tramadol			C				Not Reported		
	Augmentin /00756801/			C		2 G, 3x/Day		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-Sep-2016	12709900	DIRECT		LT			55 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anaphylactic Shock	Azasite			S	Ophthalmic			Akorn		
	Lisiniprol			C				Not Reported		
	Vitamin D Nos			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-Sep-2016	12711473	EXPEDITED (15-DAY)		OT	FR-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2016-BI-14		4 YR	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Atrioventricular Block Second Degree	Catapressan			S	Intravenous (not	24 Anz		Not Reported		

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

Atrovent	S	otherwise specified)			Boehringer Ingelheim
Zithromax	S	Respiratory (inhalation)	3 Anz		Not Reported
Aerius (Desloratadine)	C	Intravenous (not otherwise specified)			Not Reported
Morphine	C	Oral			Not Reported
Morphine	C	Intravenous (not otherwise specified)	26136 Anz		Not Reported
Claforan	C	Intravenous (not otherwise specified)			Not Reported
Midazolam Hydrochloride	C	Intravenous (not otherwise specified)			Not Reported
Midazolam	C	Intravenous (not otherwise specified)			Not Reported
Ventoline	C	Intravenous (not otherwise specified)	6 Anz		Not Reported
Acupan	C	Intravenous (not otherwise specified)			Not Reported
Paracetamol	C	Unknown			Not Reported
Budesonide	C	Respiratory (inhalation)	2 Anz		Not Reported
Tracrium	C	Intravenous (not otherwise specified)			Not Reported
Gentamicine	C	Unknown			Not Reported
Lasilix	C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12711649	DIRECT		OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Nausea; Pain	Azithromycin			S	Oral	250 Mg 2 Day 1 Then 1		Pliva

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

Days 2-5 By Mouth

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12712891	NON-EXPEDITED			US-APOTEX-2016AP009757		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Apotex	
	Acyclovir			S	Unknown			Apotex	
	Piperacillin/Tazobactam			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12712926	NON-EXPEDITED			US-APOTEX-2016AP006042		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Amoxicillin And Clavulanate			S	Unknown	Unk		Apotex	
	Potassium								
	Azithromycin			S	Unknown	Unk		Apotex	
	Lubiprostone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12712933	NON-EXPEDITED			US-APOTEX-2015AP012378		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dry Throat; Nausea	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12712961	NON-EXPEDITED			US-APOTEX-2016AP006881			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Pruritus; Rash	Azithromycin			S	Unknown	Unk		Apotex	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12712965	NON-EXPEDITED			US-APOTEX-2016AP009795			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12712995	NON-EXPEDITED			US-APOTEX-2015AP014820			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Auditory Disorder	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2016	12713047	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016411777		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Facial Paralysis; Head Discomfort; Intentional Product Misuse; Pain; Rash Erythematous; Sinusitis	Enbrel			S	Unknown	Unk Unk, Every 3 Weeks		Unknown	
	Zithromax			S	Unknown	Unk		Pfizer	
	Vitamin D3			C	Unknown	2000 Iu, Unk		Not Reported	
	Calcium			C		1200 Mg, Unk		Not Reported	
	Valaciclovir			C	Oral	1 Mg, 3x/Day		Not Reported	
	Prednisone			C		6 Day Taper		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2016	12713393	NON-EXPEDITED			US-AMGEN-USASP2016115013		35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Pruritus; Skin Discolouration; Viral	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen	
	Prednisone			S	Unknown	Unk		Not Reported	

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

Infection	Z-Pak	S	Unknown	Unk	Not Reported
	Tramadol	C		Unk	Not Reported
	Alprazolam	C		Unk	Not Reported
	Omeprazole	C		Unk	Not Reported
	Methocarbamol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2016	12713820	EXPEDITED (15-DAY)		OT	CA-ROCHE-1824332		15 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Mycophenolate Mofetil			S	Oral			Not Reported
	Atorvastatin Calcium			S	Oral			Not Reported
	Lansoprazole			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Prednisone			S	Oral			Not Reported
	Sulfamethoxazole/Trimethoprim			S	Oral			Not Reported
	Tacrolimus			S	Oral			Not Reported
	Voriconazole			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2016	12714302	NON-EXPEDITED			US-PFIZER INC-2016415289		8 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Product Dose Omission; Vomiting	Azithromycin			S	Oral	5ml Once Daily		Pfizer
	Albuterol			C		2.5mg Breathing Treatment X 2 Doses		Not Reported
	Albuterol			C				Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2016	12641181	NON-EXPEDITED			US-PFIZER INC-2016365318		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ampicillin Sodium			S		Unk		Unknown	
	Amoxicillin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2016	12687398	EXPEDITED (15-DAY)		OT	US-AKORN PHARMACEUTICALS-2016AKN00552		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Deafness; Feeling Abnormal; Headache; Nausea	Ethambutol			S	Oral	2 Tablets, 1x/Day		Akorn	
	Zithromax			S	Oral	Unk		Not Reported	
	Mycobutin			S	Oral	2 Capsules, 1x/Day		Not Reported	
	Aspirin			C				Not Reported	
	Ocuvite			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Xalatan			C				Not Reported	
	Magnesium			C				Not Reported	
	Zocor			C				Not Reported	
	Betimol			C				Not Reported	
	Mazide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2016	12717430	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2016JPN125233		30 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Atelectasis; Exposure During Pregnancy; Live Birth; Pneumonia; Pyrexia;	Ventoline			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Methylprednisolone			S	Intravenous drip	320 Mg, 1d		Not Reported	

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

Sputum Purulent; Tachypnoea; Wheezing	Methylprednisolone	S		240 Mg, 1d	Not Reported
	Methylprednisolone	S		160 Mg, 1d	Not Reported
	Methylprednisolone	S		80 Mg, 1d	Not Reported
	Aminophylline Hydrate	S	Unknown	500 Mg, 1d	Not Reported
	Dexamethasone	S	Unknown	32 Mg, 1d	Not Reported
	Azithromycin Hydrate	S	Oral	500 Mg, 1d	Not Reported
	Meropenem Hydrate	S	Intravenous drip	3 G, 1d	Not Reported
	Magnesium Sulfate Hydrate	S	Unknown	2.46 G, 1d	Not Reported
	Prednisolone	S	Oral	20 Mg, 1d	Not Reported
	Prednisolone	S		10 Mg, 1d	Not Reported
	Prednisolone	S		5 Mg, 1d	Not Reported
	Montelukast Sodium	S	Oral	10 Mg, 1d	Not Reported
	D-Chlorpheniramine Maleate	S	Oral	6 Mg, 1d	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2016	12717434	EXPEDITED (15-DAY)		OT	JP- GLAXOSMITHKLINE- JP2016JPN125889			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Maternal Drugs Affecting Foetus; Umbilical Cord Around Neck	Ventoline			S	Transplacental	Unk		Glaxosmithkline
	Methylprednisolone			S		320 Mg, 1d		Not Reported
	Methylprednisolone			S		240 Mg, 1d		Not Reported
	Methylprednisolone			S		160 Mg, 1d		Not Reported
	Methylprednisolone			S		80 Mg, 1d		Not Reported
	Aminophylline Hydrate			S		500 Mg, 1d		Not Reported
	Dexamethasone			S		32 Mg, 1d		Not Reported
	Azithromycin Hydrate			S		500 Mg, 1d		Not Reported
	Meropenem Hydrate			S		3 G, 1d		Not Reported
	Magnesium Sulfate Hydrate			S		2.46 G, 1d		Not Reported
	Prednisolone			S		20 Mg, 1d		Not Reported

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

Prednisolone	S	10 Mg, 1d	Not Reported
Prednisolone	S	5 Mg, 1d	Not Reported
Montelukast Sodium	S	10 G, 1d	Not Reported
D-Chlorpheniramine Maleate	S	6 Mg, 1d	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2016	12718482	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016410209		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholangitis	Zithromax			S	Unknown	Unk		Pfizer
	Doliprane			C		3 G, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2016	12703479	NON-EXPEDITED			US-PFIZER INC-2016411889			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cephalexin			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported
	Keppra			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2016	12719820	EXPEDITED (15-DAY)		OT	CH-LUPIN PHARMACEUTICALS INC.-2016-03975		68 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Labelled Drug-Drug Interaction	Azithromycin			S	Oral			Not Reported
Medication Error	Ciprofloxacin			S	Oral	500 Mg		Not Reported
	Domperidone			S	Oral	30 Mg		Not Reported
	Citalopram			S	Oral	10 Mg		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2016	12720158	NON-EXPEDITED			US-PFIZER INC-2016420595			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Heparin Sodium			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2016	12722096	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2016415232		10 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Rash; Swelling	Azithromycin			S	Oral	1 Tsp By Mouth Once Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2016	12676284	NON-EXPEDITED			US-PFIZER INC-2016392857		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity; Dyspnoea; Headache; Product Use In Unapproved Indication; Pruritus; Urticaria	Zithromax			S	Oral	250 Mg, (2 Tab First Day 1 Tab Daily For 4 More Days)		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
	Albuterol			C		Unk, As Needed (90 Mcg 2 Puffs Q 4prn)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2016	12687763	NON-EXPEDITED			US-PFIZER INC-2016399053		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2016	12723764	NON-EXPEDITED			US-PFIZER INC-2016422334		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Enbrel			C	Unknown	50 Mg, Qwk On Saturday		Not Reported	
	Vicodin			C		Unk		Not Reported	
	Soma			C		Unk		Not Reported	
	Carisoprodol			C		Unk		Not Reported	
	Xanax			C		Unk Unk, Qhs		Not Reported	
	Methotrexate			C		7 Pills, Qwk On Tuesdays		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2016	12672024	NON-EXPEDITED			US-PFIZER INC-2016393434		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Aciphex			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2016	12715600	EXPEDITED (15-DAY)		CA, OT	BR-CIPLA LTD.-2016BR17842			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Hydrocephalus; Low Birth Weight Baby; Meningomyelocele	Zidovudine			S	Transplacental	Unk		Cipla	
	Lopinavir/Ritonavir			S	Transplacental	Unk		Cipla	
	Lamivudine/Tenofovir			S	Transplacental	Unk		Cipla	
	Trimethoprim/Sulfamethoxazole			S	Transplacental	Unk, Trimester 1, 2 And 3		Cipla	
	Azithromycin			S	Transplacental	Unk, Trimester 3		Cipla	
	Ceftriaxone			S	Transplacental	Unk, Trimester 3		Not Reported	

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

	Ferrous Sulphate		S	Transplacental	Unk, Trimester 1, 2 And 3			Not Reported	
	Metronidazole		S	Transplacental	Unk, Trimester 3			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2016	12727147	EXPEDITED (15-DAY)		OT	BR-CIPLA LTD.- 2016BR17840			Unknown	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Flavivirus Infection; Vaginal Infection	Zidovudine			S	Intravenous (not otherwise specified)	1 Mg/Kg/Hr		Cipla	
	Zidovudine			S	Intravenous (not otherwise specified)	2 Mg/Kg/Hr		Cipla	
	Lopinavir/Ritonavir			S	Oral	1000 Mg/Day		Cipla	
	Lamivudine/Tenofovir			S	Oral	600 Mg/Day		Cipla	
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk, Prior Conception		Cipla	
	Trimethoprim/Sulfamethoxazole			S	Unknown	Unk, Trimester 1, 2 And 3		Cipla	
	Azithromycin			S	Unknown	Unk, Trimester 3		Cipla	
	Ceftriaxone			S	Unknown	Unk, Trimester 3		Not Reported	
	Metronidazole			S	Unknown	Unk, Trimester 3		Not Reported	
	Ferrous Sulphate			S	Unknown	Unk, Trimester 1, 2 And 3		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2016	12727476	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2016-11009		20 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	Unk		Aurobindo	
	Bedaquiline			S	Unknown	For 2 Weeks		Not Reported	
	Bedaquiline			S	Unknown	200 Mg Three Times Weekly		Not Reported	
	Clofazimine			S	Unknown	Unk		Not Reported	
	Linezolid			C		Unk		Not Reported	
	Pyrazinamide			C				Not Reported	

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

Cycloserine Para-Aminosalicylic Acid			C C		Not Reported Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2016	12729939	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2016418927			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Gingival Bleeding; Haematochezia	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2016	12512134	NON-EXPEDITED		HO	US-JNJFOC- 20160610298		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenia	Xarelto			S	Oral				Not Reported
	Xarelto			S	Oral				Not Reported
	Xarelto			S	Oral				Not Reported
	Bactrim			S	Unknown				Not Reported
	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12509442	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-090			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Eye; Dry Mouth	Unspecified Mucinex			S	Unknown	Unk, Bid			Not Reported
	Azithromycin			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12668863	EXPEDITED (15-DAY)		HO	JP-TEVA-2016-JP- 001818J		13 YR	Female	JPN

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Blood Lactate Dehydrogenase Increased; Fall; Loss Of Consciousness; Overdose; White Blood Cell Count Increased	Azithromycin Tablet 250mg			S	Oral	1500 Milligram Daily;		Not Reported	
	"Teva" Calonal			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12674843	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-874			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Night Sweats	Unspecified Mucinex			S	Unknown	Unk		Not Reported	
	Zithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12735813	NON-EXPEDITED			US-JNJFOC-20160800063		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Nausea; Vision Blurred; Visual Impairment	Ultram Er			S	Oral			Not Reported	
	Imodium		Y	S	Unknown			Not Reported	
	Imodium			S	Unknown			Not Reported	
	Motrin		Y	S	Unknown			Not Reported	
	Motrin			S	Unknown			Not Reported	
	Tylenol		Y	S	Unknown			Not Reported	
	Tylenol			S	Unknown			Not Reported	
	Wellbutrin			S	Oral			Not Reported	
	Wellbutrin			S	Oral			Not Reported	
	Fiorinal			S	Unknown			Not Reported	

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

	Fluticasone	S	Nasal	Not Reported
	Ativan	S	Unknown	Not Reported
	Inderal	S	Unknown	Not Reported
	Lisinopril	S	Unknown	Not Reported
	Miralax	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Mucinex D	S	Unknown	Not Reported
	Nexium	S	Unknown	Not Reported
	Robaxin	S	Unknown	Not Reported
	Zofran	S	Unknown	Not Reported
	Align	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12738438	NON-EXPEDITED			US-PFIZER INC-2016426614			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12738481	NON-EXPEDITED			US-PFIZER INC-2016424996			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Potassium Chloride			S		Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2016	12739841	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016423508		55 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Depressed Level Of Consciousness; Hyperhidrosis		Zithromax	S	Intravenous drip	0.5 G, 1x/Day			Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2016	12740346	NON-EXPEDITED			US-PFIZER INC-2016429527			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12634371	EXPEDITED (15-DAY)		HO, OT	FR-ABBVIE-16P-056-1693505-00		18 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Drug Interaction; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Immunosuppressant Drug Level Increased; Nausea; Overdose	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S				Not Reported	
	Prograf			S	Oral			Not Reported	
	Prograf			S	Oral	2 Mg Am And 2 Mg Pm		Not Reported	
	Ceftriaxone			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Zithromax			S				Not Reported	
	Truvada			S	Oral			Not Reported	
	Truvada			S				Not Reported	
	Orap			C	Unknown	For Several Years		Not Reported	
	Pravastatin			C	Unknown			Not Reported	
	Desogestrel			C	Unknown			Not Reported	
	Ellaone			C	Unknown			Not Reported	
	Xanax			C	Unknown			Not Reported	
	Ventoline			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2016	12729937	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-		37 YR	Male	JPN

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

2016417805

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Zithromac 500mg			S	Intravenous drip	500 Mg, Daily		Pfizer
	Cefxone			C		Unk		Not Reported
	Calonal			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12740617	EXPEDITED (15-DAY)		OT	CN-ROCHE-1828693		8 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pallor; Rash; Syncope	Rocephin			S	Intravenous drip			Not Reported
	Azithromycin Lactobionate			S	Intravenous drip			Not Reported
	Glucose			C	Unknown			Not Reported
	Sodium Chloride			C	Unknown			Not Reported
	Sodium Chloride			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12741341	NON-EXPEDITED			US-PFIZER INC-2016425627		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Condition Aggravated; Cough; Drug Ineffective; Hyperhidrosis	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12742795	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016425036		28 YR	Female	CHN

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

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

Abdominal Pain; Diarrhoea; Gastrointestinal Pain		Zithromax	S	Oral	500 Mg, 1x/Day	Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12743463	NON-EXPEDITED			US-TELIGENT, INC- IGIL20160159			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Muscular Weakness; Temporal Arteritis; Urinary Tract Infection	Zantac			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Lyrica			S				Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12743710	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2001048585FR		73 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Hallucination, Visual	Medrol			S	Oral	4 Mg, 2x/Day		Pfizer	
	Novatrex			S	Oral	4 Df, Weekly		Pfizer	
	Ogast			S	Oral	15 Mg, 1x/Day		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	2 Df, Single		Not Reported	
	Enbrel			S		Unk		Not Reported	
	Athymil			C				Not Reported	
	Theralene			C				Not Reported	
	Imovane			C				Not Reported	
	Equanil			C				Not Reported	
	Seresta			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12744051	EXPEDITED (15-DAY)		OT	US-TEVA-692107USA		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Balance Disorder; Diarrhoea; Dysphagia; Dyspnoea; Headache; Palpitations; Pharyngeal Swelling; Product Use In Unapproved Indication; Syncope	Azithromycin Azithromycin	S S	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12745293	DIRECT		HO, LT			39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Dyspnoea; Feeling Abnormal; Gait Disturbance; Heart Rate Increased; Hypoaesthesia; Hypoaesthesia; Hypoaesthesia; Hypoaesthesia	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2016	12745995	DIRECT	Y	HO			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Jaundice; Nausea	Simvastatin Azithromycin			S S	Oral			Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2016	10015219	NON-EXPEDITED			US-PFIZER INC- 2014074949			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S	Oral	As Directed Once Per Day		Pfizer

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

Azasite		S		Unk		Not Reported			
Paxil		S		Oral		Unk, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2016	11502855	NON-EXPEDITED			US-ASTELLAS-2015US028919			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Nightmare	Xtandi			S	Unknown			Astellas	
	Z-Pak			S	Unknown	Unk Unk, Once Daily		Not Reported	
	Desidone			C	Unknown	Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2016	12746359	NON-EXPEDITED			US-PFIZER INC-2016430076			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2016	12749965	DIRECT		LT			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Product Formulation Issue; Product Substitution Issue	Azithromycin 250 Mg Pliva			S	Oral			Pliva	
	Benazepril			C				Not Reported	
	Estradiol			C				Not Reported	
	Benadryl			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2016	12679684	NON-EXPEDITED			US-PFIZER INC-2016398350		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Hypersensitivity	Azithromycin			S	Oral	500 Mg, (Day 1)		Pfizer	

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

		Azithromycin	S	Oral	250 Mg, (Days 2 - 5)		Pfizer	
		Doxycycline Hyclate	S	Oral	Unk		Pfizer	
		Etodolac	S		Unk		Pfizer	
		Naproxen Sodium	S		Unk		Pfizer	
		Desipramine	S		Unk		Not Reported	
		Meloxicam	S		Unk		Not Reported	
		Prozac	S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2016	12750796	DIRECT		OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Pneumonia	Nitrofurantoin Mono-Mcr			S	Oral			Mylan
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2016	12753499	NON-EXPEDITED			US-PFIZER INC-2016431844		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Flushing; Hyperhidrosis	Azithromycin			S		Unk (Pm)		Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2016	12753972	EXPEDITED (15-DAY)		HO	JP-LUPIN PHARMACEUTICALS INC.-2016-04183		6 YR	Male	JPN

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2016	12717294	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-123206		19 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Live Birth; Viral Test Positive	Tenofovir & Lamivudine			S	Oral	600 Mg, Daily		Not Reported	
	Azithromycin			S	Unknown	Unk		Sun	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ferrous Sulphate			S	Unknown	Unk		Sun	
	Metronidazole			S	Unknown	Unk		Mutual	
	Sulphamethoxazole/Trimethopri m			S	Unknown	Unk		Sun	
	Retrovir, Zdv			S	Intravenous (not otherwise specified)	2 Mg/Kg/H, Daily		Not Reported	
	Retrovir, Zdv			S	Intravenous (not otherwise specified)	1 Mg/Kg/H, Daily		Not Reported	
	Kaletra, Aluvia, Lpv/R (Lopinavir + Ritonavir)			S	Oral	1000 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2016	12719299	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-123076		< 1 DAY	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arnold-Chiari Malformation; Foetal Exposure During Pregnancy	Tenofovir & Lamivudine			S	Transplacental	600 Mg, Daily		Not Reported	
	Azithromycin			S	Transplacental	Unk		Sun	
	Ceftriaxone			S	Transplacental	Unk		Not Reported	
	Ferrous Sulfate			S	Transplacental	Unk		Sun	
	Metronidazole			S	Transplacental	Unk		Mutual	
	Sulphamethoxazole/Trimethopri m			S	Transplacental	Unk		Sun	

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

		Kaletra, Aluvia, Lpv/R (Lopinavir + Ritonavir)	S	Transplacental	1000 Mg, Daily		Not Reported		
		Retrovir, Zdv	S	Transplacental	Unk Unk, Daily		Not Reported		
		Retrovir, Zdv	S	Transplacental	Unk Unk, Daily		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12758735	EXPEDITED (15-DAY)		HO	PHHY2016JP125117		75 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; Rhabdomyolysis	Azithromycin			S	Unknown	500 Mg, Once/Single		Novartis	
	Pregabalin			S	Unknown	75 Mg, Bid		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12759793	EXPEDITED (15-DAY)		HO	FR-JNJFOC-NSADSS2001006155		73 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Delirium; Depression; Hallucination, Visual	Remicade			S	Intravenous drip			Not Reported	
	Remicade			S	Intravenous drip			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Medrol			S	Oral			Not Reported	
	Ogast			S	Oral			Not Reported	
	Enbrel			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Sep-2016	12759992	NON-EXPEDITED			US-PFIZER INC-2016435934		70 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Diflucan			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Nexium	S	Unk	Unknown
Protonix	S	Unk	Pfizer
Zithromax	S	Unk	Pfizer
Levaquin	S	Unk	Not Reported
Prilosec	S	Unk	Not Reported
Keflex	S	Unk	Not Reported
Codeine	S	Unk	Not Reported
Dexamethasone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2016	12760241	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016430201		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Back Pain; Nephrolithiasis; Pulmonary Mass	Azithromycin			S		Unk		Pfizer
	Ethambutol			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2016	12621088	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2016342002			Male	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Hypoaesthesia; Nerve Injury; Peripheral Swelling; Skin Exfoliation	Azithromycin			S		250 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2016	12763865	EXPEDITED (15-DAY)		HO, LT	JP-MYLANLABS-2016M1039405			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Purpura; Rhabdomyolysis	Azithromycin			S	Unknown	A Single Dose Of 500mg		Not Reported
	Pregabalin			S	Unknown			Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2016	12764460	EXPEDITED (15-DAY)		HO	JP-FRESENIUS KABI-FK201606783		75 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Purpura; Rhabdomyolysis	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Pregabalin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2016	12644696	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2016US030531		18 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Interaction; Immunosuppressant Drug Level Increased	Prograf			S	Oral	2 Mg, Twice Daily (2 Df Twice Daily)		Astellas	
	Prograf			S	Unknown	2 Mg, Twice Daily (Morning And Evening)		Astellas	
	Kaletra			S	Oral	2 Df (Strength: 200 Mg/ 50 Mg), Twice Daily		Not Reported	
	Ceftriaxone			S	Unknown	500 Mg, Total Dose (One Intake)		Not Reported	
	Zithromax			S	Oral	1000 Mg, Total Dose (4 Df In One Intake)		Not Reported	
	Truvada			S	Oral			Not Reported	
	Orap			C	Unknown			Not Reported	
	Pravastatin			C	Unknown			Not Reported	
	Desogestrel			C	Unknown			Not Reported	
	Ellaone			C	Unknown	1 Single Dose, Unknown Frequency		Not Reported	
	Xanax			C	Unknown	0.25 Mg, As Needed		Not Reported	
	Ventoline /00139501/			C	Unknown	Unk Unk, As Needed		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2016	12767353	EXPEDITED (15-DAY)		OT	US-TEVA-685429USA		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Back Pain; Chills; Diarrhoea; Dizziness; Dry Mouth; Feeling Hot; Insomnia; Lip Dry; Malaise; Muscle Tightness; Myalgia; Nasopharyngitis; Paraesthesia	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2016	12767620	NON-EXPEDITED			US-PFIZER INC- 2016440110			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S				Pfizer	
	Penicillin G Benzathine			S				Pfizer	
	Iodine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2016	12770546	DIRECT		OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Heart Rate Increased; Product Prescribing Error	Zithromax Z-Pak			S	Oral			Pfizer	
	Deplin (L Methylfolate)			C				Not Reported	
	Klonopin (Clonazepam)			C				Not Reported	
	Lexapro (Escitalopram)			C				Not Reported	
	Lipitor (Atorvastatin)			C				Not Reported	
	Lithium Carbonate			C				Not Reported	
	Protonix (Pantoprazole Sod Dr)			C				Not Reported	
	Restoril (Temazepam)			C				Not Reported	
	Seroquel Xr (Quetiapine)			C				Not Reported	

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

Fumarate)		
Verapamil Er	C	Not Reported
Zantac (Ranitidine)	C	Not Reported
Pepto Bismol (Bismuth Subsalicylate)	C	Not Reported
Tums (Calcium Carbonate Usp)	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2016	12771189	DIRECT		HO			48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Inflammation;	Azithromycin			S	Oral			Not Reported
Gastroesophageal Reflux Disease; Oesophageal Ulcer	Marshallow Root			C				Not Reported
	Aloe Vera			C				Not Reported
	Probiotic			C				Not Reported
	Colostrum Human			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2016	12694160	NON-EXPEDITED			US-PFIZER INC-2016402501		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		250 Mg, Unk		Pfizer
	Augmentin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2016	12708830	NON-EXPEDITED			US-PFIZER INC-2016409743		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2016	12770115	NON-EXPEDITED			US-PFIZER INC-2016440496		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Keflex /00145501/			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2016	12770422	NON-EXPEDITED			US-PFIZER INC-2016441306		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2016	12773012	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-2016-IPXL-01031		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Electrocardiogram Qt Prolonged; Headache; Malaise; Myalgia; Nausea; Pyrexia; Torsade De Pointes	Methadone Hydrochloride			S	Unknown	Unk		Corepharma	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ondansetron			S	Unknown	Unk		Not Reported	
	Diphenhydramine			S	Unknown	Unk		Not Reported	
	Sertraline			S	Unknown	Unk		Not Reported	
	Fluoxetine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2016	12774200	NON-EXPEDITED			US-PFIZER INC-2016443324			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2016	12780830	EXPEDITED (15-DAY)		OT	AU-SA-2016SA174604		3 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Osteomyelitis Bacterial; Q Fever	Ciprofloxacin Salt Not Specified			S	Unknown			Not Reported	
	Rifampicin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2016	12781049	EXPEDITED (15-DAY)		OT	US-JUBILANT CADISTA PHARMACEUTICALS- 2016JUB00334		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Ineffective; Dyspnoea; Immune System Disorder; Insomnia; Memory Impairment; Sleep Apnoea Syndrome	Prednisone			S	Oral	20 Mg, 1x/Day		Jubilant	
	Prednisone			S		60 Mg, 1x/Day		Jubilant	
	Prednisone			S		Unk		Jubilant	
	Albuterol, Rescue Inhaler			S		6 Times Daily, As Needed		Not Reported	
	Albuterol, Rescue Inhaler			S		3 To 4, As Needed		Not Reported	
	Albuterol			S		Unk Unk, As Needed		Not Reported	
	Albuterol Ipratropium			S		Unk		Not Reported	
	Cromolyn			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Unspecified Antibiotic			S				Not Reported	
	Symbicort			C		Unk, 4x/Day		Not Reported	
	Chlorthalidone			C		25 Mg, Unk		Not Reported	
	Montelukast Sodium			C		10 Mg, Unk		Not Reported	
	Mirtazapine			C		45 Mg, Unk		Not Reported	
	Alprazolam			C		1 Mg, Unk		Not Reported	
	Aleve			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2016	10230121	NON-EXPEDITED			US-PFIZER INC-2014156235		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2016	12742797	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016421610		18 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Zithromax			S	Oral	1000 Mg, Single		Pfizer	
	Ceftriaxone Sodium			S		500 Mg, Single		Not Reported	
	Truvada			S	Oral	1 Df, 1x/Day		Not Reported	
	Kaletra			S	Oral	2 Df, 2x/Day		Not Reported	
	Prograf			S	Oral	2 Mg, 2x/Day (Morning And Evening)		Not Reported	
	Prograf			S		2 Mg, 2x/Day (Morning And Evening)		Not Reported	
	Orap			C		1 Mg, 1x/Day		Not Reported	
	Pravastatin			C		5 Mg, Daily		Not Reported	
	Desogestrel			C		1 Df, Daily		Not Reported	
	Ellaone			C		Unk, Single		Not Reported	
	Xanax			C		0.25 Mg, As Needed		Not Reported	
	Ventoline			C		Unk, As Needed		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2016	12767488	NON-EXPEDITED		OT	US-PFIZER INC-2016437817			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2016	12767603	NON-EXPEDITED			US-PFIZER INC- 2016428017			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ondansetron Hcl			S		Unk		Pfizer	
	Imitrex			S		Unk		Not Reported	
	Zofran			S		Unk		Not Reported	
	Iodinated Contrast			S		Unk		Not Reported	
	Albuterol /00139501/ Zinc Oxide			S S				Not Reported Not Reported	
	<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>
27-Sep-2016	12782260	EXPEDITED (15-DAY)		HO	JP-LUPIN PHARMACEUTICALS INC.-2016-04297		75 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Purpura; Rhabdomyolysis	Azithromycin			S	Unknown			Not Reported	
	Pregabalin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2016	12782959	NON-EXPEDITED			US-PFIZER INC- 2016448952		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Oxycodone Hcl			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2016	12784800	NON-EXPEDITED			US-PFIZER INC-2016449300		53 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2016	12696979	EXPEDITED (15-DAY)		HO, LT, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2016R1-122802		75 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Purpura; Rhabdomyolysis	Azithromycin			S	Unknown	500 Mg, Single		Sun	
	Pregabalin			S	Unknown	75 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2016	12787351	NON-EXPEDITED		HO	US-DRREDDYS-USA/USA/16/0077810		1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema Multiforme	Amoxicillin W/Clavulanate			S	Unknown			Not Reported	
	Potassium Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2016	12788935	EXPEDITED (15-DAY)		HO, OT	FR-GILEAD-2016-0234432		18 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Truvada			S	Oral	1 Df, Qd		Gilead	
	Zithromax			S	Oral	1000 Mg, Qd		Not Reported	
	Prograf			S	Oral	4 Df, Qd		Not Reported	
	Prograf			S	Oral	2 Mg, Qd In The Morning		Not Reported	

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

Kaletra	S	Oral	And Evening	Not Reported
Ceftriaxone	S	Unknown	4 Df, Qd	Not Reported
Orap	C	Unknown	500 Mg, Once	Not Reported
Pravastatin	C	Unknown	1 Mg, Qd	Not Reported
Desogestrel	C	Unknown	5 Mg, Qd	Not Reported
Ellaone	C	Unknown	1 Df, Qd	Not Reported
Xanax	C	Unknown	1 Df, Once	Not Reported
Ventolin /00139501/	C	Unknown	0.25 Mg, Prn	Not Reported
			Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2016	12790056	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016447588		71 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Haematochezia	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer
	Clarith			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2016	12790391	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201609-004867		4 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Off Label Use; Osteomyelitis Bacterial; Q Fever	Hydroxychloroquine			S	Unknown			Concordia
	Doxycycline			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12481028	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2016300354		20 YR	Female	GBR

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

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

Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin	S	Unk	Pfizer
	Bedaquiline	S	400 Mg Once Daily For 2 Weeks	Not Reported
	Bedaquiline	S	200 Mg Three Times Weekly	Not Reported
	Clofazimine	S	Unk	Not Reported
	Linezolid	C	Unk	Not Reported
	Pyrazinamide	C	Unk	Not Reported
	Cycloserine	C	Unk	Not Reported
	Para-Aminosalicylic Acid	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12741389	NON-EXPEDITED			US-PFIZER INC-2016429696		80 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diplopia; Headache; Impaired Driving Ability; Product Use In Unapproved Indication; Strabismus; Vision Blurred; Visual Impairment	Azithromycin			S		250mg Capsules, Took 2 First Day And Then 1 The Rest Od The Day		Pfizer
	Azithromycin			S		Unk		Pfizer
	Xarelto			C		Unk		Not Reported
	Aspirin			C		81 Mg, Unk		Not Reported
	Sotalol Hydrochloride			C		80 Mg, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12749144	EXPEDITED (15-DAY)		HO	JP-ELI_LILLY_AND_COMP ANY-JP201609004138		72 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Cymbalta			S	Oral	Unk		Eli Lilly And Co
	Cymbalta			S	Oral	20 Mg, Qd		Eli Lilly And Co
	Depromel /00615202/			S	Oral	25 Mg, Tid		Not Reported

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

Zithromac	S	Oral	500 Mg, Qd	Not Reported
Tryptanol /00002202/	S	Oral	10 Mg, Bid	Not Reported
Tryptanol /00002202/	S			Not Reported
Neurotropin /06251301/	C	Oral	Unk	Not Reported
Sennoside /00571902/	C	Oral	Unk	Not Reported
Hibon	C	Oral	Unk	Not Reported
Wypax	C	Oral	Unk	Not Reported
Viviant	C	Oral	Unk	Not Reported
Berizym /07475701/	C	Oral	Unk	Not Reported
Magnesium Oxide	C	Oral	Unk	Not Reported
Rebamipide	C	Oral	Unk	Not Reported
Rabeprazole Na	C	Oral	Unk	Not Reported
Acetaminophen	C	Oral	Unk	Not Reported
Pranlukast	C	Oral	Unk	Not Reported
Carbocisteine	C	Oral	Unk	Not Reported
Tulobuterol Hmt	C	Transdermal	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12750371	EXPEDITED (15-DAY)		HO	FR-ASTELLAS-2016US035394		18 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dyspnoea Exertional; Electrocardiogram Qt Prolonged; Nausea; Overdose	Prograf			S	Oral	2 Df (1 Mg), Twice Daily (Since Several Years)		Astellas
	Prograf			S	Unknown	2 Mg, Morning And Night		Astellas
	Zithromax			S	Oral	4 Df, In One Intake		Not Reported
	Kaletra			S	Oral			Not Reported
	Ceftriaxone			S	Unknown	500 Mg, In One Intake.		Not Reported
	Truvada			S	Oral			Not Reported
	Orap			C	Unknown	1 Mg, Once Daily (For The Past Few Years)		Not Reported

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

Pravastatin	C	Unknown		Not Reported
Desogestrel	C	Unknown		Not Reported
Ellaone	C	Unknown	1 Single Dose	Not Reported
Xanax	C	Unknown	0.25 Mg, As Needed	Not Reported
Ventoline /00139501/	C	Unknown	Unk Unk, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12788962	NON-EXPEDITED			US-PFIZER INC-2011171891		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Imitrex			S				Not Reported
	Darvocet			S				Not Reported
	Wellbutrin			S				Not Reported
	Alprazolam			C		0.5 Mg, 3x/Day		Not Reported
	Hydrocodone W/Acetaminophen			C		5/325 Mg, 3 X/Day		Not Reported
	Lexapro			C		10 Mg, 1x/Day		Not Reported
	Lisinopril W/Hydrochlorothiazide			C		10/12.5 Mg, 1x/Day		Not Reported
	Nortriptyline			C		50 Mg, 1x/Day		Not Reported
	Nortriptyline			C		25 Mg, 1x/Day		Not Reported
	Norvasc			C		5 Mg, 1x/Day		Not Reported
	Albuterol Sulfate			C		Unk, 4x/Day (1.25/3 MI)		Not Reported
	Celebrex			C		200 Mg, 1x/Day		Not Reported
	Flonase			C	Nasal	Unk Unk, 2x/Day (50 Mcg/Actuation Spray)		Not Reported
	Klonopin			C		0.5 Mg, 4x/Day		Not Reported
	Propranolol			C		60 Mg, 1x/Day		Not Reported
	Proventil Hfa			C		Unk Unk, Every 4 Hrs (90 Mcg/Actuation) (2 Puffs)		Not Reported
	Prozac			C		80 Mg, 1x/Day		Not Reported

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

Ranitidine	C	150 Mg, 2x/Day	Not Reported
Seroquel	C	300 Mg, 1x/Day (Before Bed)	Not Reported
Seroquel	C	50 Mg, 2x/Day	Not Reported
Spiriva Handihaler	C	18 Ug, 1x/Day (W/Inhalation Device)	Not Reported
Minipress	C	2 Mg, 1x/Day (Before Bed)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12790957	NON-EXPEDITED			US-PFIZER INC-2016446603			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ethambutol			S		Unk		Pfizer	
	Rifabutin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12791137	NON-EXPEDITED			US-PFIZER INC-2016452063		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Terazol			S		Unk		Not Reported	
	Pyridium			S		Unk		Not Reported	
	Histussind			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12794916	EXPEDITED (15-DAY)		OT	PHHY2016ES131831		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Acute Generalised Exanthematous Pustulosis		Azithromycin		S	Unknown	500 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12795257	NON-EXPEDITED			US-PFIZER INC-2016451748		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neosporin			S		Unk		Pfizer	
	Amiodarone Hcl			S		Unk		Pfizer	
	Polycillin			S		Unk		Not Reported	
	Cipro /00697201/			S		Unk		Not Reported	
	Lotrimin /00212501/			S		Unk		Not Reported	
	Keflex /00145501/			S		Unk		Not Reported	
	Darvon /00018802/			S		Unk		Not Reported	
	Ery-Tab			S		Unk		Not Reported	
	Retramycin			S		Unk		Not Reported	
	Imiquimod			S		5 %, Unk		Not Reported	
	Flecainide Acetate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2016	12795824	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2016M1041631			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	500 Mg, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2016	12800300	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2016455053		74 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Zithromax			S	Oral	250 Mg, Every 3 Weeks			Pfizer

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

Ibuprofen	S	Oral	400 Mg, 2x/Day	Pfizer
Alendronic Acid	C	Oral	70 Mg/Weekly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2016	8421340	EXPEDITED (15-DAY)	HO		FR-ROCHE-1039338		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Agranulocytosis; Low Density Lipoprotein Increased; Monocytosis; Pyrexia; Vitamin D Deficiency	Rituximab			S	Intravenous (not otherwise specified)	First Cycle		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Second Cycle		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Third Cycle		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)	Fourth Cycle, First Infusion		Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported
	Novatrex			S	Oral			Not Reported
	Speciafoldine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2016	11219620	NON-EXPEDITED			US-PFIZER INC- 2015208178		38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2016	12723805	EXPEDITED (15-DAY)		OT	IE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-123610		19 YR	Male	IRL

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Tobramycin			S	Unknown	480 Mg, Daily		Not Reported	
	Meropenem			S	Intravenous (not otherwise specified)	2 G, Tid		Not Reported	
	Nebulised Colistin			S	Unknown	Two Mega-Units Twice Daily, On Alternate Months		Not Reported	
	Azithromycin			S	Oral	250 Mg, Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2016	12753510	NON-EXPEDITED			US-PFIZER INC-2016431828		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2016	12803207	NON-EXPEDITED			US-PFIZER INC-2016460777		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S				Pfizer	
	Diazepam			S				Pfizer	
	Ibuprofen			S				Pfizer	
	Morphine Sulfate			S				Pfizer	
	Isoniazid			S				Pfizer	
	Metformin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2016	12804503	NON-EXPEDITED			US-PFIZER INC-2016460762		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2016	12483556	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016R1-118649		20 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	Unk		Sun	
	Bedaquiline			S	Unknown	For 2 Weeks		Not Reported	
	Bedaquiline			S	Unknown	200 Mg Three Times Weekly		Not Reported	
	Clofazimine			S	Unknown	Unk		Not Reported	
	Cycloserine			C	Unknown	Unk		Not Reported	
	Linezolid			C	Unknown	Unk		Not Reported	
	Para-Amino Salicylic Acid			C	Unknown	Unk		Not Reported	
	Pyrazinamide			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2016	12531787	EXPEDITED (15-DAY)		DS, HO, OT	TR-PFIZER INC- 2016326030		55 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adjustment Disorder; Blood Albumin Abnormal; Blood Electrolytes Abnormal; Depressed Mood; Drug Interaction; Loss Of Employment; Muscle Atrophy; Pain; Purpura Fulminans; Thrombocytopenia	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zitromax			S				Pfizer	
	Zitromax			S				Pfizer	
	Zadevital			S	Oral	500 Mg, Daily		Not Reported	
	Beloc-Zok Mite			C		50 Mg, 1x/Day		Not Reported	
	Euthyrox			C	Oral	25 Unk, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2016	12741884	EXPEDITED (15-DAY)		DS, OT	US-DRREDDYS- USA/USA/16/0083079		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Deafness; Hyperacusis; Tinnitus	Augmentin	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Clonazepam	C	Unknown	Took Half Of 0.125mg	Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Cytomel	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2016	12762989	NON-EXPEDITED			US-PFIZER INC- 2016434280		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Zosyn			S		2.25 G, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2016	12492263	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2016304932		16 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2016	12811026	EXPEDITED (15-DAY)		OT	US- GLAXOSMITHKLINE- US2016GSK034897			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Cardiac Disorder; Diarrhoea; Drug Hypersensitivity; Renal Impairment; Respiratory Arrest; Urticaria; Vomiting	Ceftin			S				Glaxosmithkline	
	Morphine			S				Glaxosmithkline	
	Macrobid			S				Glaxosmithkline	
	Neurontin			S				Glaxosmithkline	
	Topamax			S				Glaxosmithkline	
	Relafen			S				Glaxosmithkline	
	Ciprofloxacin			S				Glaxosmithkline	
	Z-Pak			S				Glaxosmithkline	

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

Lovaza			C			Glaxosmithkline			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2016	12811422	NON-EXPEDITED			US-PFIZER INC-2016463411			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Trazodone			S		Unk		Not Reported	
	Haldol			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2016	12811424	NON-EXPEDITED			US-PFIZER INC-2016463398			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ultram			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2016	12815600	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20161001877			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diastolic Dysfunction; Haemoptysis; Hypotension; Oliguria; Respiratory Failure	Levaquin			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Cefepime			S	Unknown			Not Reported	
	Micafungin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Rapamune			S	Unknown			Not Reported	
	Lexapro			C	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2016	12816305	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016455008		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Product Use In Unapproved Indication; Respiratory Disorder; Vision Blurred	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Speciafoldine			C				Not Reported	
	Vitamine A			C				Not Reported	
	Xalatan			C				Not Reported	
	Alphalan			C				Not Reported	
	Azopt			C				Not Reported	
	Naabak /01266803/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2016	9694277	NON-EXPEDITED			US-PFIZER INC-2013322898			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Asa			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Phenergan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2016	12579831	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016326217		35 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pharyngeal Oedema	Zitromax			S	Oral	Unk		Pfizer	
	Medrol			C	Oral			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2016	12820480	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-083362			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Contraindicated Product Administered	Cefepime Dihydrochloride Monohydrate			S	Unknown			Bristol Myers Squibb	
	Aztreonam			S	Unknown			Bristol Myers Squibb	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2016	12821330	EXPEDITED (15-DAY)		OT	US-TEVA-698975USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Peripheral Swelling; Swelling Face; Thrombosis	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2016	12621042	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2016342001		61 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Hypersensitivity; Hypoaesthesia; Nerve Injury; Peripheral Swelling; Skin Exfoliation	Zithromax			S	Oral	500 Mg, Single		Pfizer	
	Zithromax			S		250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2016	12822127	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2016-12386		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Acute Generalised Exanthematous Pustulosis		Azithromycin 500 Mg		S	Oral		500 Mg, Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
07-Oct-2016	12824612	DIRECT	Y				43 YR	Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Headache	Azithromycin 250mg Teva			S				Teva		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
07-Oct-2016	12827593	NON-EXPEDITED			US-PFIZER INC-2016465010			Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer		
	Imitrex			S				Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
07-Oct-2016	12827608	NON-EXPEDITED			US-PFIZER INC-2016468030		51 YR	Female	USA	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Drug Hypersensitivity; Nausea; Vomiting	Doxycycline Hyclate			S		Unk		Pfizer		
	Zithromax			S		Unk		Pfizer		
	Ceftin			S		Unk		Not Reported		
	Pravastatin			S		Unk		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country	
07-Oct-2016	12828441	EXPEDITED (15-DAY)		HO	CH-BAYER-2016-191844		67 YR	Male	CHE	
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr		
Acute Kidney Injury	Aspirin Cardio			S	Oral	100 Mg, Qd		Bayer		
	Torem			S	Oral	5 Mg, Unk		Not Reported		

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

Sandimmun Neoral	S	Oral	10 Mg, Qid	Not Reported
Bactrim	S	Oral	.5 Df, Tiw	Not Reported
Zithromax	S	Oral	250 Mg, Tiw	Not Reported
Valtrex	S	Oral	500 Mg, Bid	Not Reported
Sporanox	S	Oral	100 Mg, Bid	Not Reported
Zestril	S	Oral	2.5 Mg, Qd	Not Reported
Aldactone [Spironolactone]	S	Oral	12.5 Mg, Qd	Not Reported
Fungizone	S	Respiratory (inhalation)	5 Mg, Qd	Not Reported
Prednison Galepharm	C	Oral	7.5 Mg, Tiw	Not Reported
Prednison Galepharm	C	Oral	10 Mg, 4iw	Not Reported
Plavix	C	Oral	75 Mg, Qd	Not Reported
Concor	C	Oral	1.25 Mg, Qd	Not Reported
Metolazone	C	Oral	5 Mg, Qd	Not Reported
Selipran	C	Oral	20 Mg, Qd	Not Reported
Calcimagon	C	Oral	1 Df, Qd	Not Reported
Magnesiocard	C	Oral	10 Mmol, Tid	Not Reported
Movicol	C		1 Df, Bid	Not Reported
Pradif T	C	Oral	.4 Mg, Qd	Not Reported
Ampho-Moronal	C	Buccal	1 Df, Qid	Not Reported
Novorapid	C	Subcutaneous	1 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2016	12482722	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1025529			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea	Azithromycin			S	Oral	500 Mg Daily			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2016	12786714	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016443235		27 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemoptysis; Respiratory Failure	Vancomycin Hcl			S		Unk		Pfizer
	Cefepime Hcl			S		Unk		Unknown
	Azithromycin			S		250 Mg, Unk		Pfizer
	Levaquin			S		Unk		Not Reported
	Micafungin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2016	12831750	NON-EXPEDITED			US-ASTRAZENECA-2016SE90678			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Dyspnoea	Prilosec			S	Oral			Not Reported
	Effexor			S	Unknown			Not Reported
	Effexor			S	Oral			Not Reported
	Zomig			S	Unknown			Zeneca
	Lyrice			S	Oral			Not Reported
	Zithromax			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported
	Skelaxin			S	Unknown			Not Reported
	Synthroid			C		0.75, Daily		Not Reported
	Topomax			C				Not Reported
	Iron			C				Not Reported
	Baby Aspirin			C				Not Reported
	Metformin			C				Not Reported
	Vitamin B Complex			C				Not Reported
	Magnesium Oxide			C				Not Reported
	Temazepam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2016	12831885	EXPEDITED (15-DAY)		OT	US-APOTEX-2016AP012739		27 YR	Male	USA

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

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

Condition Aggravated; Haemoptysis; Respiratory Failure	Azithromycin	S	Unknown	250 Mg, Unk	Apotex
	Cefepime Hcl	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Micafungin	S	Unknown	Unk	Not Reported
	Vancomycin Hcl	S	Unknown	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12832360	EXPEDITED (15-DAY)		OT	ES-LUPIN PHARMACEUTICALS INC.-2016-04532		32 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12834764	NON-EXPEDITED			US-PFIZER INC- 2016469599			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia	Azithromycin			S		10 Mg/Kg, Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Oct-2016	12834799	NON-EXPEDITED			US-PFIZER INC- 2016469537			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chromaturia	Azithromycin			S		10 Mg Per Kg		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Oct-2016	12503748	EXPEDITED (15-DAY)		OT	IT-TEVA-670731ACC		16 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2016	12835657	EXPEDITED (15-DAY)		OT	CH-ARBOR PHARMACEUTICALS, LLC-CH- 2016ARB002116		68 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Ciprofloxacin\Fluocinolone Acetonide			S	Oral	500 Mg, Qd		Arbor	
	Azithromycin			S	Oral	250 Mg/3x Per Week		Not Reported	
	Domperidone			S	Oral	30 Mg, Qd		Not Reported	
	Citalopram			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2016	12835847	EXPEDITED (15-DAY)		OT	CR-PFIZER INC- 2016455855		1 YR	Female	CRI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Sleep Disorder; Soliloquy; Somnambulism	Zithromax			S	Oral	2.5 MI, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2016	12836628	EXPEDITED (15-DAY)		OT	PHHY2016GB137079		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity	Azithromycin			S	Oral	4 Tablets At Once With Half Glass Of Water.		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2016	12836953	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2016464467		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity	Azithromycin			S	Oral	4 Df, Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2016	12839501	DIRECT		OT			5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Musculoskeletal Pain; Product Solubility Abnormal	Azithromycin Multi Vitamin	Y		S C	Oral	Other Daily Oral		Teva Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2016	12467329	NON-EXPEDITED			US-PFIZER INC- 2016289285		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Pyrexia	Zithromax Zithromax			S S	Oral Oral	500 Mg, 1x/Day 250 Mg, 1x/Day		Pfizer Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2016	12699984	NON-EXPEDITED			US-PFIZER INC- 2016402600		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Product Use In Unapproved Indication	Azithromycin L-Thyroxine Betamil			S C C	Oral	250 Mg, Unk (250mg Dose Pack For 5 Days By Mouth) 100 Ug, Unk Eye Drops		Pfizer Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2016	12790390	EXPEDITED (15-DAY)		OT	AU-CONCORDIA PHARMACEUTICALS INC.-GSH201609- 004877		2 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label	Hydroxychloroquine			S	Unknown			Concordia	

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

Use; Osteomyelitis Bacterial; Q Fever	Doxycycline	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Prednisolone	S	Oral	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
	Hydrocortisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2016	12837794	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2015-07718			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Abnormal; Hypersensitivity	Azithromycin			S	Unknown			Aurobindo
	Gabapentin			S	Unknown			Aurobindo
	Sumatriptan			S	Unknown			Aurobindo
	Vancomycin			S	Unknown			Not Reported
	Cipro /00697201/			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Dilantin /00017401/			S	Unknown			Not Reported
	Anaprex			S	Unknown			Not Reported
	Relafin			S	Unknown			Not Reported
	Pyridin			S	Unknown			Not Reported
	Lovastatin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2016	12839745	NON-EXPEDITED			US-PFIZER INC- 2016474615		44 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2016	12333272	NON-EXPEDITED			US-ROCHE-1698545		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Hypersensitivity; Muscle Spasms	Esbriet			S	Oral			Not Reported
	Revatio			S	Oral	90 Day Supply		Not Reported
	Zithromax			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Albuterol			C	Unknown			Not Reported
	Amoxclav			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Benzonatate			C	Unknown			Not Reported
	Cefpodoxime			C	Unknown			Not Reported
	Hydrochlorothiazid			C	Unknown			Not Reported
	Hydrocodone/Apap			C	Unknown	Dose 5-235 Mg		Not Reported
	Toprol XL			C	Unknown			Not Reported
	Nystatin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Proair Hfa			C				Not Reported
	Pulmicort			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported
	Virtussin Ac			C				Not Reported
	Epinephrine Hydrochloride			C				Not Reported
	Morphine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2016	12487992	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2016-08218		45 YR	Male	USA

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

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

Cardiac Arrest; Drug Interaction; Drug Withdrawal Syndrome; Headache; Intentional Product Misuse; Loss Of Consciousness; Malaise; Medication Error; Myalgia; Nausea; Pyrexia; Torsade De Pointes; Ventricular Tachycardia	Azithromycin	S	Unknown	Unk	Aurobindo
	Diphenhydramine	S	Unknown	Unk	Aurobindo
	Fluoxetine	S	Unknown	Unk	Aurobindo
	Methadone	S	Unknown	Unk	Aurobindo
	Ondansetron	S	Unknown	Unk	Aurobindo
	Sertraline	S	Unknown	Unk	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2016	12843506	EXPEDITED (15-DAY)		HO, LT	SK-TEVA-702500ISR		36 YR	Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Oedema; Rash Pruritic	Omeprazol			S	Oral			Actavis	
	Azatriel			S	Oral	500 Milligram Daily;		Not Reported	
	Prednison			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2016	12843683	EXPEDITED (15-DAY)		OT	CN-MYLANLABS-2016M1043838			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Heart Rate Abnormal; Respiratory Distress	Azithromycin			S				Not Reported	
	Indometacin			S				Not Reported	
	Vancomycin			S				Not Reported	
	Cefotiam			S				Mylan	
	Ceftriaxone			S				Mylan	
	Meropenem			S				Mylan	
	Oseltamivir			S				Mylan	
	Thymalfasin			S				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2016	12847636	NON-EXPEDITED			US-PFIZER INC-2016466895			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Tinnitus	Azithromycin		S	Intravenous (not otherwise specified)	500 Mg, 1x/Day (Every 24 Hours)		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2016	12848080	NON-EXPEDITED			US-JNJFOC-20140714903		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ibuprofen			S	Unknown			Not Reported	
	Acetaminophen		Y	S	Unknown			Not Reported	
	Acetaminophen			S	Unknown			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Tramadol Hcl			S	Unknown			Not Reported	
	Chlorpheniramine			S				Not Reported	
	Pristiq			S				Not Reported	
	Zithromax			S				Not Reported	
	Prozac			S				Not Reported	
	Aleve			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2016	12851604	DIRECT		OT			47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Tinnitus	Azithromycin			S	Oral	3 Tablet(S) Day1-2, Day1-2 Oral		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2016	12854861	NON-EXPEDITED			US-PFIZER INC-2016480477		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Azulfidine			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2016	12855361	EXPEDITED (15-DAY)		DE, OT	PHHY2016KR140532		65 YR	Male	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Diarrhoea; Disease Progression; Multiple Organ Dysfunction Syndrome; Pneumonia; Right Ventricular Failure; Shock	Azithromycin			S	Unknown	Unk		Novartis	
	Piperacillin+Tazobactam			S	Unknown			Not Reported	
	Ribavarin			S	Unknown			Not Reported	
	Kaletra			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Teicoplanin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2016	12791269	EXPEDITED (15-DAY)		DE, OT	PHHY2016GB130591		68 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin			S	Oral	500 Mg, Qw3		Novartis	
	Bedaquiline			S	Oral	400mg Daily For 2 Weeks Then 200mg Three Times A Week		Not Reported	
	Ciprofloxacin			C	Unknown			Not Reported	
	Ciprofloxacin			C				Not Reported	
	Clarithromycin			C	Unknown			Not Reported	
	Co-Amilofruse			C	Unknown	2 Df, Qd, 5/40, Morning		Not Reported	
	Co-Amilofruse			C		5/40, Morning		Not Reported	
	Morphine Sulfate			C	Unknown	10mg/5ml		Not Reported	
	Quinine Sulfate			C	Unknown	300 Mg, Qd, At Night		Not Reported	
	Quinine Sulfate			C		At Night		Not Reported	
	Rifampicin			C	Unknown			Not Reported	
	Seretide			C	Unknown	1 Df, Bid, 500 Accuhaler		Not Reported	
	Seretide			C		500 Accuhaler		Not Reported	

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

Tiotropium	C	Unknown	1 Df, Qd, Morning	Not Reported
Tiotropium	C		Morning	Not Reported
Clofazimine	C	Unknown		Not Reported
Salbutamol	C	Unknown	200 Ug, Unk	Not Reported
Sertraline	C	Unknown	100 Mg, Qd, Morning	Not Reported
Sertraline	C		Morning	Not Reported
Trimethoprim	C	Unknown	200 Mg, Bid	Not Reported
Oxygen	C	Unknown	On Long Term Oxygen Therapy	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2016	12845194	EXPEDITED (15-DAY)		DE, OT	AU-PFIZER INC-2016471978		55 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Metronidazole			S		Unk		Pfizer
	Metronidazole			S				Pfizer
	Piperacillin/Tazobactam			S		Unk		Unknown
	Fluconazole			S		Unk		Pfizer
	Fluconazole			S				Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Ciprofloxacin			S				Unknown
	Ceftriaxone Sodium			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Daptomycin			S		Unk		Not Reported
	Daptomycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2016	12856714	DIRECT		DS, OT			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Dysgeusia; Fatigue; Feeling	Valacyclovir Tab 1 Gm			S	Oral	Quantity:.(Ilr'Rmb 8»,		Cadista

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

Abnormal; Gait Disturbance; Hypersomnia; Rash; Tremor	Azithromycin 250mg Pak Tab Gr Asa Centrum Senior Vitamins Cq10 Tart Cherry Valtrex	S C C C C C	Momt 3x11»;	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2016	12858513	NON-EXPEDITED			US-PFIZER INC- 2016482762			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Naproxen Sodium			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2016	10596686	NON-EXPEDITED			US-PFIZER INC- 2014316887		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Skelaxin			S		Unk		Pfizer	
	Medrol			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Azithromycin			S		250 Mg, Unk		Pfizer	
	Amoxicillin			S		250 Mg, Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Prednisolone			S		Unk		Pfizer	
	Avinza			S				Pfizer	
	Benadryl			S		Unk		Not Reported	
	Motrin			S		Unk		Not Reported	

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

Codeine	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Serzone	S	Unk	Not Reported
Ritalin	S	Unk	Not Reported
Albuterol	S	Unk	Not Reported
Imdur Er	S	Unk	Not Reported
Oxycontin	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Naprosyn	S	Unk	Not Reported
Zocor	S	Unk	Not Reported
Foradil	S	Unk	Not Reported
Ecotrin	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Aleve	S	Unk	Not Reported
Mobic	S	Unk	Not Reported
Voltaren	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Savella	S	Unk	Not Reported
Nucynta	S	Unk	Not Reported
Symbicort	S	Unk	Not Reported
Cipro	S	Unk	Not Reported
Keflex	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Decongestant	S		Not Reported
Bisacodyl	S		Not Reported
Prednisone	S		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2016	12861534	NON-EXPEDITED			US-PFIZER INC-2016485982		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Inappropriate Schedule Of Product Administration	Zithromax			S		Unk		Pfizer	
	Enbrel			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2016	12861588	NON-EXPEDITED			US-PFIZER INC-2016483222		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S				Pfizer	
	Naproxen			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2016	12861613	NON-EXPEDITED			US-PFIZER INC-2016483233			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin Hcl			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Septra			S		Unk		Pfizer	
	Singulair			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2016	12861644	NON-EXPEDITED			US-PFIZER INC-2016485525		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Levothyroxine Sodium			S		Unk		Pfizer	
	Indomethacin			S		Unk		Unknown	

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

	Zithromax	S	Unk	Pfizer
	Simvastatin	S	Unk	Not Reported
	Iodine	S	Unk	Not Reported
	Lortab /00607101/	S	Unk	Not Reported
	Synthroid	S	Unk	Not Reported
	Cipro /00697201/	S	Unk	Not Reported
	Uloric	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2016	12863432	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016480551			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12161237	EXPEDITED (15-DAY)		OT	PHJP2016JP004289		20 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatitis Infectious Mononucleosis; Product Use In Unapproved Indication	Voltaren (Diclofenac Sodium)			S	Oral	75 Mg, Qd		Glaxosmithkline	
	Levofloxacin			S	Oral	500 Mg, Qd		Glaxosmithkline	
	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline	
	Zithromac			S	Oral	2 G, Qd		Glaxosmithkline	
	Calonal			S	Oral	400 Mg, Qd		Glaxosmithkline	
	Loxoprofen			S	Oral	180 Mg, Qd		Not Reported	
	Meiact			S	Oral	300 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12630461	NON-EXPEDITED			US-PFIZER INC-2016343066		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity		Azithromycin		S		5 Day Dose Pack		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699236	NON-EXPEDITED			US-009507513-1608USA005861		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singular			S	Oral	Unk		Merck	
	Fluticasone			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Predisone Teva			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699265	NON-EXPEDITED			US-009507513-1608USA014368		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singular			S	Oral	Unk		Merck	
	Fluticasone			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Predisone Teva			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699266	NON-EXPEDITED			US-009507513-1608USA014363		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singular			S	Oral	Unk		Merck	
	Fluticasone			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Predisone Teva			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699274	NON-EXPEDITED			US-009507513-1608USA014362		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singular			S	Oral	Unk		Merck	
	Fluticasone			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Predisone Teva			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699275	NON-EXPEDITED			US-009507513-1608USA014365		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singular			S	Oral	Unk		Merck	
	Fluticasone			S		Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699319	NON-EXPEDITED			US-009507513-1608USA014366		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singular			S	Oral	Unk		Merck	
	Fluticasone			S		Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699330	NON-EXPEDITED			US-009507513-1608USA014364		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Ineffective	Singulair	S	Oral	Unk	Merck
	Fluticasone	S		Unk	Not Reported
	Azithromycin	S		Unk	Not Reported
	Prednisone	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12699332	NON-EXPEDITED			US-009507513-1608USA014367		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Singulair			S	Oral	Unk		Merck
	Fluticasone			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Prednisone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2016	12799123	NON-EXPEDITED			US-ASTRAZENECA-2016SF00089		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Nexium			S	Oral	Unk		Not Reported
	Prilosec			S	Oral	Unk		Not Reported
	Diflucan			S	Unknown	Unk		Not Reported
	Doxycycline Hyclate			S	Unknown	Unk		Not Reported
	Flagyl			S	Unknown	Unk		Not Reported
	Protonix			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Keflex			S	Unknown	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12865367	NON-EXPEDITED			US-AKORN-39766			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Eye Pain	Azasite Ophthalmic Solution 1%			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Oct-2016	12867311	NON-EXPEDITED			US-AKORN-41467			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysgeusia; Lacrimation Increased; Nasal Congestion	Azasite			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12471619	EXPEDITED (15-DAY)		OT	FR-ABBVIE-16K-056-1650634-00		55 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Ineffective; Dry Eye; Visual Acuity Reduced	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
	Novatrex			S	Oral			Not Reported
	Novatrex			S	Oral			Not Reported
	Speciafoldine			C				Not Reported
	Mopral			C	Oral			Not Reported
	Zolpidem			C	Oral			Not Reported
	Ixprim			C		If Pain		Not Reported
	Dafalgan			C		If Pain		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12762172	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016429872		52 YR	Female	JPN

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

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

Abdominal Pain; Diarrhoea; Melaena		Zithromac Sr 2g		S	Oral	2g, Single Before Bedtime		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12797156	NON-EXPEDITED			US-PFIZER INC- 2016457693			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12840658	EXPEDITED (15-DAY)		DE, OT	PHHY2016SI138122		83 YR	Female	SVN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Septic Shock	Azithromycin			S	Unknown			Novartis	
	Cefotaxime			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12868978	NON-EXPEDITED			US-PFIZER INC- 2016489798			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Oct-2016	12874538	NON-EXPEDITED			US-PFIZER INC- 2016491639			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Methylprednisolone			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2016	12877094	DIRECT					20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Headache; Muscle Spasms; Nausea; Urticaria	Zithromax			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2016	12877933	NON-EXPEDITED			US-PFIZER INC- 2016488024		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Methadone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2016	12878493	EXPEDITED (15-DAY)		OT	ALCN2016DE002931		80 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Ciloxan Otic			S		Unk		Not Reported	
	Zithromax			S	Oral	1 Df, Qd		Not Reported	
	Atorvastatin			C	Unknown	1 Df, Qd		Not Reported	
	Metoprolol			C	Unknown	1 Df, Qd		Not Reported	
	Valsartan			C	Unknown	1 Df, Qd		Not Reported	
	Lercanidipine			C	Unknown	1 Df, Qd		Not Reported	
	Opipramol			C	Unknown	0.5 Df, Unk		Not Reported	
	Arcoxia			C	Unknown	1 Df, Prn		Not Reported	
	Marcumar			C	Unknown	1 Df, Prn		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2016	12106141	EXPEDITED (15-DAY)		HO, LT, OT	FR- ELI_LILLY_AND_COMP ANY-FR201602006459		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Acute Respiratory Failure; Bronchospasm; Chronic Obstructive Pulmonary Disease; Enterobacter Infection; Eosinophilia; Pulmonary Eosinophilia	Cymbalta			S	Oral	30 Mg, Each Morning		Eli Lilly And Co	
	Zithromax			S	Unknown	250 Mg, 3/W		Not Reported	
	Spiriva			C	Unknown	Unk, Unknown		Not Reported	
	Spiriva			C		1 Df, Each Morning		Not Reported	
	Innovair			C	Unknown	Unk, Unknown		Not Reported	
	Innovair			C		3 Df, Bid		Not Reported	
	Bricanyl			C	Unknown	Unk, Unknown		Not Reported	
	Atrovent			C	Unknown	Unk, Unknown		Not Reported	
	Bronchodual			C	Unknown	Unk, Unknown		Not Reported	
	Paracetamol			C	Unknown	Unk, Unknown		Not Reported	
	Tramadol			C	Unknown	Unk, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2016	12460851	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2016290248		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Visual Acuity Reduced	Novatrex			S	Oral	20 Mg, Weekly		Pfizer	
	Novatrex			S	Oral	15 Mg, Weekly		Pfizer	
	Humira			S	Subcutaneous	40 Mg Every 2 Weeks		Not Reported	
	Speciafoldine			C		15 Mg, Weekly		Not Reported	
	Mopral /00661201/			C	Oral	20 Mg, Daily		Not Reported	
	Zolpidem			C	Oral	10 Mg, Daily		Not Reported	
	Dafalgan			C		Unk, As Needed		Not Reported	
	Ixprim			C		Unk, As Needed		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2016	12771160	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016439026		50 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Pneumonia; Product Use In Unapproved Indication	Novatrex			S	Oral	Unk		Pfizer	
	Novatrex			S	Oral	12.5 Mg, Weekly		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	450 Mg, Every 6 Weeks		Not Reported	
	Cortancyl			S	Oral	Unk		Not Reported	
	Cortancyl			S	Oral	10 Mg, Daily		Not Reported	
	Risedronate Sodium			C				Not Reported	
	Kardegic			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Mirtazapine			C				Not Reported	
	Escitalopram			C				Not Reported	
	Prazepam			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Oxycodone Hydrochloride			C				Not Reported	
	Diffu K			C				Not Reported	
	Orocal D3			C				Not Reported	
	Spasfon /00765801/			C				Not Reported	
	Perindopril			C				Not Reported	
	Amlor			C				Not Reported	
	Baclofen			C				Not Reported	
	Speciafoldine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2016	12879859	NON-EXPEDITED			US-PFIZER INC-2016491699			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Benzylpenicillin Potassium			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12882672	NON-EXPEDITED			US-PFIZER INC-2016489611			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Insomnia; Nervousness	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12883281	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2016487087			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acoustic Neuroma; Deafness Neurosensory	Zithromax			S		250 Mg, Three Times Weekly		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Oct-2016	12883282	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016491901			Unknown	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cellulitis	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Oct-2016	11814613	EXPEDITED (15-DAY)		HO	US-ABBVIE-15K-163-1512355-00		67 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Asthenia; Blood Potassium Decreased;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
Chronic Kidney Disease;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
Drug Hypersensitivity;	Androgel			S	Topical			Not Reported	
Lethargy; Malaise;	Androgel			S	Topical			Not Reported	
Nephritis; Pneumonia	Azithromycin			S	Oral			Not Reported	
Viral; Poor Peripheral Circulation; Renal Disorder; Restless Legs Syndrome; Weight	Enalapril			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2016	12641272	NON-EXPEDITED			US-PFIZER INC-2016365609			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lotrel			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Orudis			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2016	12779708	NON-EXPEDITED			US-PFIZER INC-2016446621		35 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Fatigue	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Zithromax			S	Oral	1 Tablet Daily For 4 Days		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2016	12883864	NON-EXPEDITED			US-PFIZER INC-2016495578		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Use In Unapproved Indication; Product Use Issue	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer
	Simvastatin			C	Oral	20 Mg, 1x/Day		Not Reported
	Synthroid			C		112mcg Or Mg Not Sure One Tablet, Daily		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2016	12884809	NON-EXPEDITED		OT	US-TEVA-707405USA		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Parkinson'S Disease; Urticaria; Viral Infection; Wheezing	Azilect			S	Unknown			Teva	
	Z-Pack			S				Not Reported	
	Sinemet			C				Not Reported	
	Metoprolol			C				Not Reported	
	Norvasc			C				Not Reported	
	Zinc			C				Not Reported	
	Vitamin D2			C				Not Reported	
	Coenzyme Q10			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2016	12886603	NON-EXPEDITED			US-PFIZER INC-2016496982			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Bicillin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2016	12224863	NON-EXPEDITED			US-PFIZER INC-2016139977		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Cortisone			S		Unk		Pfizer	
	Lorabid			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Doxycycline			S		Unk		Not Reported	
	Cyclosporine			S		Unk		Not Reported	
	Ceclor			S		Unk		Not Reported	
	Provigil			S		Unk		Not Reported	

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

	Sulfamethoxazole	S	Unk	Not Reported
	Pravastatin	S	Unk	Not Reported
	Tropicamide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2016	12890188	NON-EXPEDITED			GXBR2016US002628			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dyspnoea; Hypotension	Azithromycin 250 Mg			S	Unknown	Unk Df, Unk		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2016	12893584	DIRECT					45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crepitations; Deafness Unilateral; Discomfort; Ear Discomfort; Ear Discomfort; Inflammation; Tinnitus	Zithromax, Azithromycin			S	Oral	Quantity:6 Tablet(S);Other Frequency:2x Day 1, Then 1x;		Not Reported	
	Gabapentin			C				Not Reported	
	Bactrim			C				Not Reported	
	Multi Vitamin			C				Not Reported	
	Calcium And Vitamin D			C				Not Reported	
	Fish Oil			C				Not Reported	
	Move Free Ultra			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2016	12853396	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2016-12596		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Pustule; Temperature Regulation Disorder	Azithromycin 500 Mg			S	Unknown	500 Mg, Every 24 Hrs		Aurobindo	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2016	12886963	NON-EXPEDITED			US-PFIZER INC-2016496935			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Tetanus Toxoid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2016	12893527	NON-EXPEDITED			US-AKORN-41101			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eyelid Irritation	Azasisite 1% Ophthalmic Solution			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2016	12894623	NON-EXPEDITED			US-PFIZER INC-2016497549		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Zithromax			S		Unk		Pfizer	
	Vitamin D2			C		Unk Unk, Daily		Not Reported	
	Vitamin A			C		Unk Unk, Daily		Not Reported	
	Irbesartan			C		Unk Unk, Daily		Not Reported	
	Clonidine			C		Unk Unk, Daily		Not Reported	
	Januvia			C		Unk Unk, Daily		Not Reported	
	Prandin			C		Unk Unk, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2016	12895088	DIRECT	Y				40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Dyspnoea; Oropharyngeal Spasm Azithromycin S Oral Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2016	12784480	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2016444213		68 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Azithromycin			S	Oral	500 Mg, Weekly		Pfizer
	Bedaquiline			S	Oral	400mg Daily For 2 Wks Then 200mg 3x/Wk		Not Reported
	Ciprofloxacin			C		Unk		Not Reported
	Clarithromycin			C		Unk		Not Reported
	Co-Amilofruse			C		2 Df [Amiloride 5mg]/[Furosemide 40 Mg], 1x/Day In The Morning		Not Reported
	Morphine Sulfate			C		10mg/5ml, As Needed		Not Reported
	Quinine Sulfate			C		300 Mg, 1x/Day At Night		Not Reported
	Rifampicin			C		Unk		Not Reported
	Seretide			C		1 Df, 2x/Day		Not Reported
	Tiotropium			C		1 Df, 1x/Day In The Morning		Not Reported
	Clofazimine			C		Unk		Not Reported
	Salbutamol			C		200 Ug, As Needed		Not Reported
	Sertraline			C		100 Mg, 1x/Day In The Morning		Not Reported
	Trimethoprim			C		200 Mg, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2016	12803739	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016456967		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Lung	Azithromycin			S	Oral	500 Mg, 1x/Day (First Day)		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Abscess	Azithromycin	S	250 Mg, Daily (Remaining Four Days)	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2016	12899851	DIRECT	Y	LT			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cardio-Respiratory Arrest; Dyspnoea; Hypotension; Mental Status Changes; Nausea; Oxygen Saturation Decreased	Ondansetron			S	Intravenous bolus			Not Reported
	Azithromycin			S	Intravenous drip			Not Reported
	Aspirin			C				Not Reported
	Atorvastatin Calcium			C				Not Reported
	Tamsulosin Hcl			C				Not Reported
	Furosemide			C				Not Reported
	Carvedilol			C				Not Reported
	Gabapentin			C				Not Reported
	Hydrocodone/Acetaminophen			C				Not Reported
	Metolazone			C				Not Reported
	Nitroglycerin			C				Not Reported
	Ranitidine Hcl			C				Not Reported
	Ceftriaxone Sodium			C				Not Reported
	Guaifenesin/Dextromethorphan			C				Not Reported
	Albuterol/Ipratropium			C				Not Reported
	Alprazolam			C				Not Reported
Diphenhydramine Hcl			C				Not Reported	
Hydromorphone Hcl			C				Not Reported	
Oxycodone Hcl			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2016	12784479	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016444290		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Tightness; Seizure; Tremor	Azithromycin			S	Oral	250 Mg (Two Tablets)		Pfizer
	Azithromycin			S	Oral	One 250 Mg Tablet A Day		Pfizer
	Phenergan Vc			S		3 Teaspoons Three Times A Day		Not Reported
	Phenergan Vc			S				Not Reported

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

	Promethazine Vc		C		Unk			Not Reported	
	Promethazine Vc		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2016	12899255	EXPEDITED (15-DAY)		HO	HK-ROCHE-1845612		53 YR	Male	HKG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Factor V Inhibition	Ceftriaxone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Piperacillin Sodium/Tazobactam			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Fluconazole			S	Unknown			Not Reported	
	Linezolid			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2016	12906632	DIRECT		DS			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Tinnitus	Azithromycin 250mg			S	Oral	Quantity:7 Tablet(S);		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2016	12780165	EXPEDITED (15-DAY)			US-PFIZER INC-2016442492			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication	Vfend			S		200 Mg, Unk		Pfizer	
	Azithromycin			S		Unk Unk, 1x/Day (At Lunch)		Pfizer	
	Clindamycin Phosphate			S		Unk Unk, 1x/Day (At Lunch)		Pfizer	
	Flagyl			S		Unk Unk, 1x/Day (At		Pfizer	

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

Rifampin	S	Lunch)	Not Reported
Cipro /00697201/	S	Unk Unk, 1x/Day (At Lunch)	Not Reported
Mepron /00049601/	S	Unk Unk, 1x/Day (At Lunch)	Not Reported
Meloxicam	C	Unk Unk, 1x/Day (At Lunch)	Not Reported
Estradiol	C	Unk Unk, 1x/Day (At Lunch)	Not Reported
Doxycycline	C	Unk Unk, 1x/Day (At Lunch)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2016	12822617	EXPEDITED (15-DAY)		DE	SI-009507513-1609SVN014186		83 YR	Female	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Ertapenem Sodium			S		Unk		Merck
	Ertapenem Sodium			S				Merck
	Ertapenem Sodium			S				Merck
	Cefotaxime Sodium			S		Unk		Not Reported
	Cefotaxime Sodium			S				Not Reported
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S				Not Reported
	Penicillin G			S		Unk		Not Reported
	Penicillin G			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2016	12904954	NON-EXPEDITED			US-PFIZER INC-2016506433			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Codeine Phosphate			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2016	12795699	EXPEDITED (15-DAY)		DE, OT	GB-MYLANLABS-2016M1040813			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin			S	Oral	500 Mg, 3xw		Not Reported	
	Bedaquiline			S	Oral	Unk (400mg Daily For 2 Weeks Then 200mg Three Times A Week)		Mylan	
	Ciprofloxacin			C		Unk		Mylan	
	Clarithromycin			C		Unk		Mylan	
	Co-Amilofruse			C		2 Df, Qd (5/40, Morning)		Mylan	
	Morphine Sulfate			C		Unk (10mg/5ml)		Mylan	
	Quinine Sulfate			C		300 Mg, Qd (At Night)		Mylan	
	Rifampicin			C		Unk		Mylan	
	Seretide			C		1 Df, Bid (500 Accuhaler)		Mylan	
	Tiotropium			C		1 Df, Qd (Morning)		Mylan	
	Clofazimine			C		Unk		Mylan	
	Salbutamol			C		200 Mg, Total		Mylan	
	Sertraline			C		100 Mg, Qd (Morning)		Mylan	
	Trimethoprim			C		200 Mg, Bid		Mylan	
	Oxygen			C		Unk (On Long Term Oxygen Therapy)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2016	12905448	EXPEDITED (15-DAY)		HO	CH-009507513-1610CHE013975		90 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Ventricular	Remeron			S	Oral	15 Mg, Qd		Merck	

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

Tachycardia	Zithromax	S	Oral			Not Reported
	Sintrom Mitis	C	Oral			Not Reported
	Concor	C	Oral	2.5 Mg, Bid		Not Reported
	Enatec	C	Oral	2.5 Mg, Bid		Not Reported
	Torem	C	Oral	20 Mg, Qd		Not Reported
	Pantozol (Pantoprazole Sodium)	C	Oral	40 Mg, Qd		Not Reported
	Zyloric	C	Oral	100 Mg, Qd		Not Reported
	Lyrica	C	Oral	75 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2016	12906258	NON-EXPEDITED			US-PFIZER INC-2016505345			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2016	12906541	NON-EXPEDITED			US-PFIZER INC-2016509103			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2016	12907948	EXPEDITED (15-DAY)		CA, HO, OT	IL-MYLANLABS-2016M1046581			Unknown	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Escherichia Infection;	Azithromycin			S	Transplacental	For 3 Days		Not Reported	
Foetal Exposure During	Ampicillin			C	Intravenous (not			Mylan	
Pregnancy; Neonatal					otherwise specified)				
Respiratory Distress;	Gentamicin			C	Intravenous (not			Mylan	
Pyloric Stenosis					otherwise specified)				

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2016	12162165	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-112647		15 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Atorvastatin			S	Oral	Unk		Sun
	Lansoprazole			S	Oral	Unk		Sun
	Mycophenolate			S	Oral	Unk		Not Reported
	Pantoprazole			S	Oral	Unk		Sun
	Azithromycin			S	Oral	Unk		Sun
	Prednisone			S	Oral	Unk		Mutual
	Sulphamethoxazole/Trimethoprim			S	Oral	Unk		Sun
	Tacrolimus			S	Oral	Unk		Not Reported
	Voriconazole			S	Oral	Unk		Not Reported
	Voriconazole			S	Oral	Unk		Not Reported
	Pms-Azithromycin			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2016	12912544	NON-EXPEDITED			US-PFIZER INC- 2016509000			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Azithromycin			S		500 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2016	12912892	NON-EXPEDITED			US-PFIZER INC- 2016510356		37 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Palpitations	Zithromax			S		Unk		Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2016	12912921	NON-EXPEDITED		DS	GXBR2016US003266			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coma; Communication Disorder; Craniocerebral Injury; Hypersensitivity	Azithromycin 250 Mg			S	Unknown	Unk Df, Unk		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2016	12806012	EXPEDITED (15-DAY)		DE, OT	GB-TEVA-697624ACC		68 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin			S	Oral			Not Reported	
	Bedaquiline			S	Oral	400mg Daily For 2 Weeks Then 200mg Three Times A Week		Not Reported	
	Ciprofloxacin			C				Not Reported	
	Clarithromycin			C				Not Reported	
	Co-Amilofruse			C		2 Dosage Forms Daily; 5/40, Morning		Not Reported	
	Morphine Sulfate			C		10mg/5ml		Not Reported	
	Quinine Sulfate			C		300 Milligram Daily; At Night		Not Reported	
	Rifampicin			C				Not Reported	
	Seretide			C		2 Dosage Forms Daily; 500 Accuhaler		Not Reported	
	Tiotropium			C		1 Dosage Forms Daily; Morning		Not Reported	
	Clofazimine			C				Not Reported	
	Salbutamol			C				Not Reported	
	Sertraline			C		100 Milligram Daily; Morning		Not Reported	
	Trimethoprim			C		400 Milligram Daily;		Not Reported	

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

Oxygen

C

On Long Term Oxygen
Therapy

Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12836892	EXPEDITED (15-DAY)		DS, HO, OT	US-AKORN PHARMACEUTICALS- 2016AKN00686		67 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Abscess;	Ethambutol			S		Unk		Akorn	
Atrial Fibrillation; Back Pain; Bronchopulmonary	Azithromycin			S		Unk		Not Reported	
Aspergillosis;	Flomax			C				Not Reported	
Echocardiogram Abnormal;									
Encephalopathy;									
Hospitalisation; Mobility Decreased;									
Nephrolithiasis;									
Neurogenic Bowel; Off Label Use; Organising									
Pneumonia; Osteomyelitis;									
Urinary Tract Infection									
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12917473	NON-EXPEDITED			US-AKORN-42401			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Photopsia	Azasite 1% Ophthalmic Solution			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Nov-2016	12918355	EXPEDITED (15-DAY)		OT	IL-FRESENIUS KABI- FK201608484		2 DAY	Male	ISR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Maternal Drugs Affecting Foetus; Pyloric Stenosis;	Azithromycin (Manufacturer Unknown)			S	Transplacental			Fresenius Medical Care	
Respiratory Distress	Penicillin G			C	Transplacental			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2016	12920917	EXPEDITED (15-DAY)		HO	PHHY2016NL149336		67 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block; Drug Interaction; Palpitations	Azithromycin Sandoz			S	Oral	500 Mg, Tid, 3 Keer Per Dag 1 Stuk(S)		Novartis	
	Codeinefosfaat			S	Oral	10 Mg, Unk 1-3dd 1t		Not Reported	
	Simvastatin Sandoz			C	Oral	20 Mg, Qd, 1dd1		Not Reported	
	Metoprolol Succinate			C	Oral	100 Mg, Qd 1dd1		Not Reported	
	Pantoprazol Sandoz			C	Oral	40 Mg, Unk		Not Reported	
	Carbasalaatcalcium Sandoz Cardio			C	Oral	100 Mg, Qd		Not Reported	
	Perindopril Tert Butylamine Glenmark			C	Oral	4 Mg, Qd		Not Reported	
	Metformine Sandoz			C	Oral	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2016	12920960	DIRECT	Y	HO			72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Lisinopril			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2016	12921293	NON-EXPEDITED			US-AKORN-40403		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error	Azasite 1% Ophthalmic Solution			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2016	12921311	NON-EXPEDITED			US-AKORN-42643			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite 1% Ophthalmic Solution			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2016	12919586	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2016-04939		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vanishing Bile Duct Syndrome	Dapsone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ethambutol			S	Unknown			Not Reported	
	Ethambutol			S	Unknown			Not Reported	
	Divalproex			S	Unknown			Not Reported	
	Tenofovir			C	Unknown			Not Reported	
	Emtricitabine			C	Unknown			Not Reported	
	Lopinavir/Ritonavir			C	Unknown			Not Reported	
	Cefepime			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2016	12919718	NON-EXPEDITED			US-PFIZER INC- 2016516930			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2016	12921810	EXPEDITED (15-DAY)		DS	PHHY2016FR150434		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Arthralgia; Bone Pain; Ear Pain; Incorrect Product Administration Duration; Pain In Jaw	Azithromycin Sandoz	S	Oral	1 Df, Qd In The Morning	Novartis
	Azithromycin Sandoz	S	Unknown		Novartis
	Dicetel	C	Unknown	100 Mg, Unk	Not Reported
	Pariet	C	Unknown	20 Mg, Unk	Not Reported
	Seretide	C	Unknown		Not Reported
	Calcium	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2016	12921853	EXPEDITED (15-DAY)		HO	US-LUPIN PHARMACEUTICALS INC.-2016-04913		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vanishing Bile Duct Syndrome	Tenofovir			S	Unknown			Not Reported
	Tenofovir			S	Unknown			Not Reported
	Didanosine			S	Unknown			Not Reported
	Didanosine			S	Unknown			Not Reported
	Atazanavir			S	Unknown			Not Reported
	Atazanavir			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2016	11748926	EXPEDITED (15-DAY)		LT, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-15-01		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Labelled Drug-Drug Interaction Medication Error;	Lorazepam			S	Unknown			Eurohealth International
	Suboxone			S	Sublingual			Not Reported

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

Respiratory Failure	Azithromycin	S	Oral	Not Reported
	Cocaine	C	Unknown	Not Reported
	Tramadol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2016	12810281	EXPEDITED (15-DAY)		DE	GB-AUROBINDO-AUR-APL-2016-11985		68 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest	Azithromycin 500 Mg			S	Oral	500 Mg, Unk		Aurobindo
	Bedaquiline			S	Oral	400mg Daily For 2 Weeks Then 200mg Three Times A Week		Not Reported
	Ciprofloxacin			C	Unknown			Not Reported
	Clarithromycin			C	Unknown			Not Reported
	Co-Amilofruse			C	Unknown	5/40, Morning		Not Reported
	Morphine Sulfate			C	Unknown	10mg/5ml		Not Reported
	Quinine Sulfate			C	Unknown	300 Mg, Once A Day At Night		Not Reported
	Rifampicin			C	Unknown			Not Reported
	Seretide			C	Unknown	1 Df, Two Times A Day		Not Reported
	Seretide			C		500 Accuhaler		Not Reported
	Tiotropium			C	Unknown	Morning		Not Reported
	Clofazimine			C	Unknown			Not Reported
	Salbutamol			C	Unknown	200 Mg, Unk		Not Reported
	Sertraline			C	Unknown	100 Mg, Once A Day Morning		Not Reported
	Trimethoprim			C	Unknown	200 Mg, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2016	12927102	NON-EXPEDITED			US-PFIZER INC-2016508171		50 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Product Use In Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2016	11892717	NON-EXPEDITED			US-PFIZER INC-2015436793		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Livalo			S		Unk		Not Reported	
	Tricor			S		Unk		Not Reported	
	Tylenol			S		Unk		Not Reported	
	Vytorin			S		Unk		Not Reported	
	Zetra			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2016	12168487	NON-EXPEDITED			US-PFIZER INC-2016139951		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Xanax			S		Unk		Pfizer	
	Norvasc			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Calcium Carbonate			S		600 Mg, Unk		Pfizer	
	Homatropine Methylbromide/Hydrocodone Bitartrate			S		Unk		Pfizer	

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

Naproxen Sodium	S	Unk	Pfizer
Zoloft	S	Unk	Pfizer
Effexor Xr	S	Unk	Pfizer
Sonata	S	Unk	Pfizer
Zithromax	S	Unk	Pfizer
Furosemide	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Trazodone Hcl	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Cefuroxime Sodium	S	Unk	Not Reported
Diovan	S	Unk	Not Reported
Dyrenium	S	Unk	Not Reported
Ketek	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Proventil	S	Unk	Not Reported
Prozac	S	Unk	Not Reported
Qvar	S	Unk	Not Reported
Rhinocort Aqua	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Triamterene And Hydrochlorothiazide	S	Unk	Not Reported
Ultram	S	Unk	Not Reported
Wellbutrin	S	Unk	Not Reported
Biaxin	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Toprol XL	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2016	12932414	EXPEDITED (15-DAY)	HO		IL-LUPIN PHARMACEUTICALS INC.-2016-04992			Male	ISR

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Foetal Exposure During Pregnancy; Pyloric Stenosis	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12933018	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2016521839		39 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diverticulum; Haemorrhoids; Helicobacter Test Positive; Irritable Bowel Syndrome; Leukocytosis; Liver Function Test Increased; Sinusitis; Syncope; Vitamin D Decreased	Benicar			S		20 Mg, Unk		Not Reported	
	Benicar Hct			S	Oral	20/12.5 Mg, Daily		Not Reported	
	Azithromycin			S		Unk		Pfizer	
	Prilosec /00661201/			C		20 Mg, Unk		Not Reported	
	Aspirin /00002701/			C		81 Mg, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12934088	EXPEDITED (15-DAY)		OT	US-TEVA-711964USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Cardiac Flutter; Chest Pain; Nausea	Azithromycin			S	Oral	Two Tablets First Day, One Every Day Following		Not Reported	
	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Nov-2016	12934305	EXPEDITED (15-DAY)		DE, OT	PHHY2016FR154758			Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Foetal Death; Foetal Growth Restriction; Placental Insufficiency	Tobi			S	Transplacental	Unk (Mother Dose 300 Mg/5 MI)		Novartis	
	Singulair			S	Transplacental	Unk		Not Reported	
	Ventilastin			S	Transplacental			Not Reported	

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

Zithromax	S	Transplacental	Unk (Mother Dose 1 Df Qd)	Not Reported
Creon	S	Transplacental	Unk (Mother Case 7 Df Qd)	Not Reported
Orelox	S	Transplacental	Unk (Mother Dose 2 Df Bid)	Not Reported
Pariet	S	Transplacental	Unk (Mother Dose 1 Df Qd)	Not Reported
Aerius (Desloratadine)	S	Transplacental	Unk (Mother Dose 1 Df Qd)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2016	12934310	EXPEDITED (15-DAY)		DE, OT	PHHY2016FR154757			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Death; Foetal Growth Restriction; Neonatal Disorder; Placental Transfusion Syndrome	Tobi			S	Transplacental	Mother Dose 300mg/ 5 MI		Novartis
	Singulair			S	Transplacental			Not Reported
	Ventilastin			S	Transplacental			Not Reported
	Zithromax			S	Transplacental	Unk (Mother Dose 1 Df Qd)		Not Reported
	Creon			S	Transplacental	Unk (Mother Dose 7 Df Qd)		Not Reported
	Orelox			S	Transplacental	Unk (Mother Dose 2 Df Bid)		Not Reported
	Pariet			S	Transplacental	Unk (Mother Dose 1 Df Qd)		Not Reported
	Aerius (Desloratadine)			S	Transplacental	Unk (Mother Dose 1 Df Qd)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2016	8495865	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2012081546		76 YR	Female	USA

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Acute Generalised Exanthematous Pustulosis		Azithromycin		S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12667480	NON-EXPEDITED			US-PFIZER INC-2016391659		67 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Drug Ineffective	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12753594	NON-EXPEDITED			US-PFIZER INC-2016432695		68 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S		500 Mg, Unk (For 5 Days)		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12935796	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016521461		7 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Chest Discomfort; Pallor	Azithromycin			S	Intravenous drip	0.3 G, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Nov-2016	12937255	NON-EXPEDITED			US-PFIZER INC-2016526329			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Glucotrol			S		Unk		Pfizer	
	Glynase			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	

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

Oxycodone	S	Unk	Not Reported
Ciprofloxacin	S	Unk	Not Reported
Compazine	S	Unk	Not Reported
Keftab	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Phenergan	S	Unk	Not Reported
Glyburide	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Ceftin	S		Not Reported
Lantus	C	Subcutaneous	1 Df, 1x/Day (Inject 1 Dose Subcutaneously At Bedtime)
Lantus	C	Subcutaneous	15 lu, 1x/Day(Inject 15 Unit Subcutaneously At Bedtime)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2016	12937319	NON-EXPEDITED			US-PFIZER INC-2016526258		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Acne; Arthralgia; Condition Aggravated; Malaise	Azithromycin			S	Oral	250 Mg, Daily		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2016	12937574	NON-EXPEDITED			US-PFIZER INC-2016522291		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Pristiq			S		Unk		Pfizer

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

Effexor	S	Unk	Pfizer
Ciprofloxacin	S	Unk	Unknown
Amoxicillin	S	Unk	Pfizer
Meclozine Hcl	S	Unk	Not Reported
Codeine	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Celexa	S	Unk	Not Reported
Cefprozil	S	Unk	Not Reported
Meloxicam	S	Unk	Not Reported
Naprosyn	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2016	12940202	EXPEDITED (15-DAY)		DE, OT	PH-PFIZER INC-2016521370		73 YR	Female	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Silent Myocardial Infarction	Zithromax			S		500 Mg, 1x/Day		Pfizer	
	Insulin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2016	12941085	NON-EXPEDITED			US-PFIZER INC-2016524155		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2016	12938790	NON-EXPEDITED			US-PFIZER INC-2016526491			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2016	12944794	DIRECT		OT			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Chills; Flushing; Treatment Failure; Vomiting	Zithromax			S	Oral	Quantity:6 Tablet(S); Daily; Oral		Teva
	Hydrocodone-Acetaminophen			C				Not Reported
	Atorvastatin			C				Not Reported
	Low-Dose Aspirin			C				Not Reported
	Omeprazole			C				Not Reported
	Losartan Potassium			C				Not Reported
	Temazepam			C				Not Reported
	Duloxetine			C				Not Reported
	B-12			C				Not Reported
	Multi-Vitamin			C				Not Reported
	Ibuprofen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2016	12945695	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2016524082		90 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure	Zithromac			S	Intravenous (not otherwise specified)	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2016	11119225	NON-EXPEDITED			US-PFIZER INC- 2015162199			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2016	12712262	EXPEDITED (15-DAY)		DE, HO	JP-EISAI MEDICAL RESEARCH-EC-2016- 019852		85 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Torsade De Pointes	Aricept			S	Oral			Not Reported
	Sulpiride			S	Oral			Not Reported
	Levofloxacin Hydrate			S	Oral			Not Reported
	Levofloxacin Hydrate			S	Oral	Unknown		Not Reported
	Azithromycin Hydrate			S	Oral			Not Reported
	Zacras			C	Oral	Unknown		Not Reported
	Bi Sifrol			C	Oral	Unknown		Not Reported
	Pitavastatin Ca			C	Oral	Unknown		Not Reported
	Zenaspirin			C	Oral	Unknown		Not Reported
	Equa			C	Oral	Unknown		Not Reported
	Glubes			C	Oral	Unknown		Not Reported
	Toviaz			C	Oral	Unknown		Not Reported
	Omeprazole			C	Oral	Unknown		Not Reported
	Miya			C	Oral	Unknown		Not Reported
	Itopride			C	Oral	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2016	12931379	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2016522395			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lower Limb Fracture	Viagra			S		Unk		Pfizer
	Glucotrol			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Procardia			S		Unk		Pfizer

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

Lincocin	S	Unk	Pfizer
Zoloft	S	Unk	Pfizer
Detrol La	S	Unk	Pfizer
Celebrex	S	Unk	Pfizer
Accupril	S	Unk	Pfizer
Cardura	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	10720869	NON-EXPEDITED			US-PFIZER INC-2015017895		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Skelaxin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Emycin			S		Unk		Not Reported	
	Azasite			S		Unk		Not Reported	
	Tetracycline Hcl Aventis			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Mercury			S		Unk		Not Reported	
	Simvastatin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	11269497	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2015R1-100132		15 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gene Mutation; Pathogen Resistance	Azithromycin			S	Unknown	11 Mg/Kg, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12882716	NON-EXPEDITED			US-PFIZER INC-2016494990		83 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12946756	EXPEDITED (15-DAY)		OT	PHHY2014GB032665			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin Sandoz			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12949084	NON-EXPEDITED			US-PFIZER INC- 2016526059			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12949098	NON-EXPEDITED			US-PFIZER INC- 2016528068			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S		500 Mg, Unk (Took 2 Tablets This Morning)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12949441	EXPEDITED (15-DAY)		DE	GXJP2016JP001685		85 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome; Torsade De Pointes; Ventricular Fibrillation	Levofloxacin Tablet			S	Oral	500 Mg, Unk		Novartis	
	Levofloxacin Tablet			S	Oral	Unk		Novartis	
	Azithromycin Tablets			S	Oral	250 Mg, Unk		Not Reported	

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

Aricept	S	Oral	3 Mg, Qd	Not Reported
Sulpiride	S	Oral		Not Reported
Itopride	C	Oral		Not Reported
Zacras	C	Oral		Not Reported
Bi Sifrol	C	Oral		Not Reported
Pitavastatin Ca	C	Oral		Not Reported
Zenaspirin	C	Oral		Not Reported
Equa	C	Oral		Not Reported
Glubes	C	Oral		Not Reported
Omeprazole	C	Oral		Not Reported
Miya Bm	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12950354	EXPEDITED (15-DAY)		DE, OT	FR-EISAI MEDICAL RESEARCH-EC-2016- 022222		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy; Product Use In Unapproved Indication	Pariet			S	Oral			Not Reported
	Aerius (Desloratadine)			S	Oral			Not Reported
	Orelox			S	Oral			Not Reported
	Creon			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Ventilastin			S	Respiratory (inhalation)	Unknown		Not Reported
	Singulair			S	Oral	Unknown		Not Reported
	Tobi			S	Respiratory (inhalation)	300 Mg/5ml		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12950359	EXPEDITED (15-DAY)		OT	FR-EISAI MEDICAL RESEARCH-EC-2016- 022224			Female	FRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Placental Transfusion Syndrome	Pariet			S	Transplacental			Not Reported	
	Aerius (Desloratadine)			S	Transplacental			Not Reported	
	Orelox			S	Transplacental			Not Reported	
	Creon			S	Transplacental			Not Reported	
	Zithromax			S	Transplacental			Not Reported	
	Ventilastin			S	Transplacental	Unknown		Not Reported	
	Singulair			S	Transplacental	Unknown		Not Reported	
	Tobi			S	Transplacental	300 Mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12950360	EXPEDITED (15-DAY)		OT	FR-EISAI MEDICAL RESEARCH-EC-2016-022225			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Growth Restriction; Intestinal Ischaemia; Placental Transfusion Syndrome	Pariet			S	Transplacental			Not Reported	
	Aerius (Desloratadine)			S	Transplacental			Not Reported	
	Orelox			S	Transplacental			Not Reported	
	Creon			S	Transplacental			Not Reported	
	Zithromax			S	Transplacental			Not Reported	
	Ventilastin			S	Transplacental	Unknown		Not Reported	
	Singulair			S	Transplacental	Unknown		Not Reported	
	Tobi			S	Transplacental	300 Mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12951866	NON-EXPEDITED			US-PFIZER INC-2016528832		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2016	12953384	NON-EXPEDITED			US-PFIZER INC-2016530915			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2016	12888304	EXPEDITED (15-DAY)		OT	IL-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-126697			Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Neonatal Aspiration; Prepyloric Stenosis	Azithromycine			S	Transplacental	500 Mg, Qd		Sun	
	Penicillin G			C	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2016	12955019	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2016M1048566			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cough; Drug Ineffective; Dyspnoea; Pseudomonas Infection	Ciprofloxacin			S		500 Mg, Bid		Not Reported	
	Levofloxacin			S		500 Mg, Qd		Not Reported	
	Azithromycin			S		Unk, 3xw		Not Reported	
	Methylprednisolone			S	Unknown	25 Mg, Qd		Mylan	
	Methylprednisolone			S		8 Mg, Qd		Mylan	
	Methylprednisolone			S		16 Mg, Qd		Mylan	
	Salmeterol/Fluticasone Cascan			S		Unk Unk, Q2d		Mylan	
	Salmeterol/Fluticasone Cascan			S				Mylan	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2016	12955878	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2016532008		76 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Erythema; Erythema	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Nolotil /06276702/			S	Oral	575 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2016	12956008	NON-EXPEDITED			US-AKORN-43574			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liquid Product Physical Issue; Product Dispensing Error	Azasite 1% Ophthalmic Solution			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2016	12844190	EXPEDITED (15-DAY)		HO	CL-BAXTER-2016BAX051609		55 YR	Female	CHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Gastritis; Hypotension; Sinusitis; Tracheobronchitis	Dianeal Solución Para Dialisis Peritoneal Calcio Fisiologica C/Dextros			S	Intraperitoneal			Baxter	
	Dianeal Solución Para Dialisis Peritoneal Calcio Fisiologica C/Dextros			S				Baxter	
	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2016	12961821	EXPEDITED (15-DAY)		DE, HO	JP-PFIZER INC-2016416550		85 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Long Qt Syndrome; Torsade De Pointes	Aricept			S	Oral	3 Mg, 1x/Day		Pfizer	

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

Azithromycin	S	Oral	250 Mg, 1x/Day	Pfizer
Sulpiride	S	Oral	50 Mg, 3x/Day	Not Reported
Levofloxacin Hydrate	S	Oral	500 Mg, 1x/Day	Not Reported
Levofloxacin Hydrate	S	Oral	Unk	Not Reported
Zacras	C	Oral	Unk	Not Reported
Bi Sifrol	C	Oral	Unk	Not Reported
Pitavastatin Ca	C	Oral	Unk	Not Reported
Zenaspirin	C	Oral	Unk	Not Reported
Equa	C	Oral	Unk	Not Reported
Glubes	C	Oral	Unk	Not Reported
Toviaz	C	Oral	Unk	Not Reported
Omeprazole	C	Oral	Unk	Not Reported
Miya	C	Oral	Unk	Not Reported
Itopride	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2016	12506315	EXPEDITED (15-DAY)		DS, HO, OT	BR-ABBVIE-15K-020-1504779-00			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Blood Pressure Increased;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Cataract; Catarrh;	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported
Deafness Unilateral;	Azithromycin			S	Unknown			Not Reported
Erythema Of Eyelid;	Scaflam			C				Not Reported
Immunodeficiency;	Losartan			C	Oral			Not Reported
Micturition Frequency Decreased; Muscular	Prednisone			C	Oral			Not Reported
Weakness; Pneumonia;	Methotrexate			C	Oral			Not Reported
Pneumonia; Pneumonia;	Amlodipine			C	Oral			Not Reported
Pruritus; Sputum	Sustrate			C	Oral			Not Reported
Discoloured; Swelling Of Eyelid; Tinnitus	Dipyron			C	Oral			Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2016	12676597	NON-EXPEDITED			US-PFIZER INC-2016397131		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Clindamycin Hcl			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Amantadine Hcl			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Bactroban /00753901/			S		Unk		Not Reported	
	Macrochantin			S		Unk		Not Reported	
	Opana			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2016	12964301	NON-EXPEDITED			US-PFIZER INC-2016534461			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Gastric Disorder; Wheezing	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2016	12964346	NON-EXPEDITED			US-PFIZER INC-2016535625		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Tetracycline Hcl			S				Pfizer	
	Zithromax			S				Pfizer	
	Pseudoephedrine Hcl			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2016	12964374	NON-EXPEDITED			US-PFIZER INC-2016540264			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Dexamethasone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2016	10923607	EXPEDITED (15-DAY)		OT	US-JNJFOC-20140503105			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Torsade De Pointes	Haloperidol			S	Unknown			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Amiodarone			S	Unknown			Not Reported	
	Ciprofloxacin			S	Unknown			Not Reported	
	Moxifloxacin			S	Unknown			Not Reported	
	Methadone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Cocaine			S	Unknown			Not Reported	
	Furosemide			S	Unknown			Not Reported	
	Verapamil			S	Unknown			Not Reported	
	Moxifloxacin			S	Unknown			Not Reported	
	Hydrochlorothiazide			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2016	12970045	EXPEDITED (15-DAY)		HO, OT	CH-PFIZER INC-2016500877		90 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Cardiac Failure; Chest Pain; Drug Interaction; Electrocardiogram Qt Prolonged; Malaise; Syncope; Ventricular Tachycardia	Zithromax	S	Oral	Unk	Pfizer
	Remeron	S	Oral	15 Mg, 1x/Day	Not Reported
	Sintrom	C	Oral	Unk	Not Reported
	Concor	C	Oral	2.5 Mg, 2x/Day	Not Reported
	Enatec	C	Oral	2.5 Mg, 2x/Day	Not Reported
	Tozem	C	Oral	20 Mg, 1x/Day	Not Reported
	Pantozol	C	Oral	40 Mg, 1x/Day	Not Reported
	Zyloric	C	Oral	100 Mg, 1x/Day	Not Reported
	Lyrica	C	Oral	75 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2016	12970215	NON-EXPEDITED		HO, OT	US-PFIZER INC-2016535974			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2016	12970802	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2016-US-022644			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Decreased; Diabetic Ketoacidosis; Drug Ineffective; Exposure During Pregnancy; Heart Rate Decreased; Infection; Pre-Existing Condition Improved; Premature Delivery; Seizure; Somnolence; Substance Use; Therapeutic Response Unexpected	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustments		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Azithromycin			S		Unk		Not Reported	
	Fluoxetine Hcl			C		Unk		Not Reported	
	Lamictal			C		Unk		Not Reported	
	Novolog			C		Unk		Not Reported	
	Marinol (Allopurinol)			C		Unk		Not Reported	
	Humalog			C		Unk		Not Reported	

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

Maxalt Mlt	C	Unk	Not Reported
Maxalt Mlt	C	Unk	Not Reported
Fiorinal With Codeine	C	Unk	Not Reported
Abilify Maintena Er	C	Unk	Not Reported
Apidra	C	Unk	Not Reported
Atenolol	C	Unk	Not Reported
Atorvastatin	C		Not Reported
Cymbalta	C	Unk	Not Reported
Ibuprofen	C		Not Reported
Klonopin	C		Not Reported
Lexapro	C	Unk	Not Reported
Lortab	C	Unk	Not Reported
Neurontin	C		Not Reported
Promethazine	C		Not Reported
Protonix Dr	C	Unk	Not Reported
Provigil	C		Not Reported
Tylenol Arthritis Er	C		Not Reported
Zovia	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2016	12760824	EXPEDITED (15-DAY)		HO, OT	IT-BAUSCH-BL-2016-022829		74 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Confusional State; Deep Vein Thrombosis; Dehydration; Dermatitis; Dermatitis Exfoliative; Diarrhoea; Drug Reaction With Eosinophilia And Systemic Symptoms; Neutrophilia; Pneumonitis; Rash Pruritic; Skin Lesion	Metronidazole			S	Intravenous (not otherwise specified)			Not Reported
	Phenobarbital			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Ceftriaxone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Furosemide			C				Not Reported
	Lansoprazole			C				Not Reported
	Methylprednisolone			C				Not Reported

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

Folic Acid/Thiamine	C	Not Reported
Dalteparin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2016	12953569	EXPEDITED (15-DAY)		HO, OT	IT-BAUSCH-BL-2016-027960		74 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Confusional State; Deep Vein Thrombosis; Dehydration; Dermatitis Exfoliative; Diarrhoea; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Erythema; Leukocytosis; Lymphadenopathy; Neutrophilia; Oedema Peripheral; Pneumonitis; Pyrexia; Rash Erythematous; Rash Erythematous; Rash Maculo-Papular; Rash Pruritic; Scratch	Metronidazole			S	Unknown	Few Week		Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Phenobarbital			S	Unknown	28 Day		Not Reported
	Ceftriaxone			S	Unknown	Few Week		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Dalteparin			C				Not Reported
	Lansoprazole			C				Not Reported
	Furosemide			C				Not Reported
	Folic Acid			C				Not Reported
	Methylprednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2016	12977647	DIRECT	Y	HO			43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12322649	NON-EXPEDITED			US-PFIZER INC-2016230179		29 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12976987	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-04822			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Food Craving; Inappropriate Schedule Of Product Administration; Irritability	Azithromycin Tablets Usp, 250 Mg			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12976990	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2016-03868		21 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dyspnoea; Headache; Hypersensitivity	Azitromed			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12976992	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-E2B_00006106		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Swelling; Peripheral Swelling; Swelling Face	Azithromycin Tablets Usp, 250 Mg Teva			S	Oral			Not Reported	
	Azithromycin Tablets Usp, 250 Mg Teva			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12976994	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2016-04599			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	Moxifloxacin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S		Intravenous (not otherwise specified)		Not Reported	
	Cefepime			S	Unknown		Not Reported		
	Aztreonam			S	Intravenous (not otherwise specified)		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12976996	NON-EXPEDITED		OT	JP-LUPIN PHARMACEUTICALS INC.-2016-05035		20 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Loxoprofen			S	Oral			Not Reported	
	Loxoprofen			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12978586	NON-EXPEDITED			US-PFIZER INC-2016545304			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12978798	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016474264		12 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tendonitis	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
	Minomycin 100mg			S	Intravenous drip	200 Mg, 1x/Day		Pfizer	

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

Kakkonto /07985901/	C	Oral	6 Df, 3x/Day	Not Reported
Calonal	C	Oral	300 Mg, As Needed	Not Reported
Sp Troches	C	Oral	0.25 Mg, Unk	Not Reported
Mucodyne	C	Oral	500 Mg, 3x/Day	Not Reported
Medicon /00048102/	C	Oral	15 Mg, 3x/Day	Not Reported
Meptin Minitab	C	Oral	25 Ug, 3x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12978981	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intercepted Product Administration Error; Product Dispensing Error; Transcription Medication Error	Azithromycin 250mg			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12979141	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2016GSK175039		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Gene Mutation; Haemolytic Anaemia; Parasite Blood Test Positive; Treatment Failure	Atovaquone			S				Glaxosmithkline
	Azithromycin			S				Glaxosmithkline
	Doxycycline			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12980768	NON-EXPEDITED		HO	US-PFIZER INC-2016549626		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Oral	Unk		Pfizer

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

Azithromycin	S	Oral	Unk	Pfizer
Tremelimumab	C	Intravenous (not otherwise specified)	1 Mg/Kg, Cyclic Every 4 Weeks	Not Reported
Medi4736	C	Intravenous (not otherwise specified)	20 Mg/Kg, Cyclic Every 4 Weeks	Not Reported
Amlodipine	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12980770	NON-EXPEDITED			US-PFIZER INC-2016545688			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Hctz			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2016	12980776	NON-EXPEDITED			US-PFIZER INC-2016545357			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2016	12894620	EXPEDITED (15-DAY)		DE, OT	ET-PFIZER INC-2016500885		3 YR	Male	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspiration; Choking; Product Administered To Patient Of Inappropriate Age	Zithromax			S	Oral	1 Tablet (250mg), Single Dose		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2016	12919703	NON-EXPEDITED			US-PFIZER INC-2016512620			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Donnagel			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2016	12948046	EXPEDITED (15-DAY)		OT	PHHY2016FR154760		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy	Tobi			S	Respiratory (inhalation)	1 Df, Unk (300 Mg/5 MI)		Novartis
	Singulair			S	Oral	Unk		Not Reported
	Ventilastin			S	Respiratory (inhalation)	Unk		Not Reported
	Zithromax			S	Oral	1 Df, Qd		Not Reported
	Creon			S	Oral	7 Df, Qd		Not Reported
	Orelox			S	Oral	2 Df, Bid		Not Reported
	Pariet			S	Oral	1 Df, Qd		Not Reported
	Aerius (Desloratadine)			S	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2016	12984039	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2016543907			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia	Zithromac			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2016	12986866	NON-EXPEDITED			US-PFIZER INC- 2016548102			Female	USA

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

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Nexium	S	Unk	Unknown
	Biaxin	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported
	Macrochantin	S	Unk	Not Reported
	Duricef	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2016	12986885	NON-EXPEDITED			US-PFIZER INC-2016548324			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2016	12986929	NON-EXPEDITED			US-PFIZER INC-2016547879			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2016	12990531	DIRECT		OT			41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dizziness; Fatigue; Headache; Insomnia; Lymphadenopathy; Menorrhagia; Palpitations	Azithromycin Tablets Usp 250 Mg Teva Pharmaceutical Usa, Inc.			S	Oral	Quantity:1 Tablet(S);		Teva	
	Ginger			C				Not Reported	
	Lemon Grass			C				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2016	12990994	DIRECT					22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Azithromycin 250 Mg			S	Oral	Quantity:6 Tablet(S); Daily; Oral		Teva	
	Propranolol			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Maxalt			C				Not Reported	
	B-12			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2016	12970022	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2016523029		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous	Orelox			S	Oral	2 Df, 2x/Day		Pfizer	
	Zithromax			S	Oral	1 Df, 1x/Day		Pfizer	
	Aerius (Desloratadine)			S	Oral	1 Df, 1x/Day		Not Reported	
	Pariet			S	Oral	1 Df, 1x/Day		Not Reported	
	Creon			S	Oral	7 Df, 1x/Day		Not Reported	
	Ventilastin Novolizer			S	Respiratory (inhalation)	Unk		Not Reported	
	Singulair			S	Oral	Unk		Not Reported	
	Tobi			S	Respiratory (inhalation)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2016	12985858	EXPEDITED (15-DAY)		OT	IT-009507513- 1611ITA011619		54 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Hepatitis	Raltegravir Potassium			S	Oral	Unk		Merck	

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

Cholestatic	Indomethacin	S	50 Mg, Tid	Not Reported
	Lamivudine	S	Unk	Not Reported
	Emtricitabine (+) Tenofovir	S	Unk	Not Reported
	Disoproxil Fumarate			
	Darunavir (+) Ritonavir	S	800/100 Mg, Qd	Not Reported
	Sulfamethoxazole (+) Trimethoprim	S	Unk	Not Reported
	Azithromycin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2016	12990580	DIRECT	Y					Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Packaging Quantity Issue	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2016	12991316	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2016M1052264			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lower Respiratory Tract Infection	Azithromycin			S	Unknown	120 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	2.5 Mg, Unk		Mylan
	Levothyroxine			S	Unknown	50 Mg, Unk		Mylan
	Renvela			S	Unknown	Powder		Mylan
	Salbutamol			S	Unknown			Mylan
	Warfarin			S	Unknown	0.5 Mg, Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2016	12991928	NON-EXPEDITED			US-PFIZER INC-2016550114			Unknown	USA

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

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

Drug Hypersensitivity	Amoxicillin	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2016	12760719	EXPEDITED (15-DAY)	HO		GB-009507513-1609GBR008979		64 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Lower Respiratory Tract Infection; Nausea; Vomiting	Dexamethasone			S	Oral	2.8571 Mg (20 Mg, 1 In 1 Wk)		Merck
	Revlimid			S	Oral	25 Mg, Days 1-21		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Monthly (Unknown)		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, 3 In 1 Wk		Not Reported
	Acyclovir			C	Oral	Unk		Not Reported
	Morphine			C	Oral	Unk		Not Reported
	Omeprazole			C	Oral	40 Mg, Qod (40 Mg,1 In 2 D)		Not Reported
	Ondansetron			C	Oral	8 Mg, Qod (8 Mg, 1 In 2 D)		Not Reported
	Acetaminophen			C	Oral	1 G, Qid (1 Gm, 4 In 1 D)		Not Reported
	Pregabalin			C	Oral	200 Mg, Qod (200 Mg,1 In 2 D)		Not Reported
	Clodronic Acid			C	Oral	800 Mg, Bid (1600 Mg,1 In 2 D)		Not Reported
	Clodronic Acid			C	Oral	50 Mg, Bid (100mg,1 In 2 D)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2016	12992595	NON-EXPEDITED	HO		JP-LUPIN PHARMACEUTICALS INC.-2016-05023		365 DAY	Female	JPN

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

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

Drug Reaction With Eosinophilia And Systemic Symptoms		Azithromycin		S	Unknown		Not Reported		
		Pranlukast		S	Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2016	12992596	NON-EXPEDITED		OT	MY-LUPIN PHARMACEUTICALS INC.-2016-04826		60 YR	Female	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2016	12994055	NON-EXPEDITED			US-PFIZER INC-2016552398			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2016	12995144	EXPEDITED (15-DAY)		HO	IT-FRESENIUS KABI-FK201609408		52 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cough; Drug Ineffective; Dyspnoea; Pseudomonas Infection	Levofloxacin (Manufacturer Unknown)			S	Unknown				Not Reported
	Ciprofloxacin (Manufacturer Unknown)			S	Unknown				Not Reported
	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2016	12995335	NON-EXPEDITED			US-ASTRAZENECA-2016SF27265			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Nexium			S	Oral	Unk			Astrazeneca

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

	Biacin	S	Unknown	Unk	Not Reported
	Zithromax	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Macrochantin	S	Unknown	Unk	Not Reported
	Duricef	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2016	12945155	NON-EXPEDITED			US- ELI_LILLY_AND_COMP ANY-US201611000256			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Interaction; Inappropriate Schedule Of Product Administration; Infection; Nasopharyngitis; Pyrexia; Wrong Technique In Product Usage Process	Cialis			S	Unknown	5 Mg, Qd		Not Reported	
	Lotrel /01388302/			S	Unknown			Not Reported	
	Betapace			S	Unknown			Not Reported	
	Metformin			S	Unknown	1 Df, Qd		Not Reported	
	Metformin			S	Unknown	1 Df, Bid		Not Reported	
	Zithromax			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2016	12983646	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2016544547		52 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cough; Dyspnoea; Product Measured Potency Issue; Pseudomonas Infection	Ciprofloxacin			S		500 Mg, Unk		Unknown	
	Levofloxacin			S		500 Mg, Unk		Unknown	
	Azithromycin			S				Pfizer	
	Methylprednisolone			S		25 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2016	12998433	EXPEDITED (15-DAY)		HO	IT-JNJFOC- 20161125316		54 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Acute Kidney Injury; Drug Interaction; Hepatitis Cholestatic	Darunavir	S	Oral	Not Reported
	Raltegravir Potassium	S	Oral	Not Reported
	Indomethacin	S	Unknown	Not Reported
	Lamivudine	S	Unknown	Not Reported
	Emtricitabine W/Tenofovir	S	Unknown	Not Reported
	Disoproxil Fumarate	S	Unknown	Not Reported
	Ritonavir	S	Unknown	Not Reported
	Sulfamethoxazole/Trimethoprim	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2016	12998941	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2016M1052249			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Confusional State; Diarrhoea; Drug Reaction With Eosinophilia And Systemic Symptoms; Leukocytosis; Rash Maculo-Papular	Levofloxacin			S				Not Reported
	Ceftriaxone			S				Not Reported
	Azithromycin Mylan			S				Mylan
	Piperacillin/Tazobactam			S				Not Reported
	Metronidazole			S	Intravenous drip	500 Mg, Tid		Mylan
	Phenobarbital			S				Mylan
	Dalteparin Sodium			C				Mylan
	Furosemide			C				Mylan
	Lansoprazole			C				Mylan
	Methylprednisolone			C				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2016	12999855	NON-EXPEDITED			US-AKORN-43971			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pain; Overdose	Azasite 1% Ophthalmic Solution			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2016	12999905	NON-EXPEDITED			US-JUBILANT CADISTA PHARMACEUTICALS-2016JUB00336			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Disturbance In Attention; Feeling Abnormal; General Physical Condition Abnormal; Headache; Malaise; Pain; Psychotic Disorder; Quality Of Life Decreased; Sensory Disturbance	Methylprednisolone Z-Pak Gabapentin			S S C				Jubilant Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2016	13002783	EXPEDITED (15-DAY)		OT	AU-APOTEX- 2016AP015191		62 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium Febrile; Eosinophilia; Neutrophilia; Oxygen Saturation Decreased; Tachycardia; Tachypnoea; White Blood Cell Count Increased	Azithromycin Ceftriaxone Clozapine Quetiapine Quetiapine Duloxetine Metoprolol Multivitamin /00097801/ Paracetamol Gliclazide Aspirin /00002701/ Lorazepam Sodium Valproate Sodium Valproate Budesonide W/Formoterol Esomeprazole			S S S C C C C C C C C C C C C C C	Unknown Intravenous (not otherwise specified) Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk 300 Mg, Qd 100 Mg, Q.Am 150 Mg, Q.H.S. 120 Mg, Q.Am 12.5 Mg, Q.Am Unk 1 G, Bid 60 Mg, Unk 100 Mg, Q.Am 1 Mg, Bid 200 Mg, Q.Am 400 Mg, Q.H.S. 200/6 Mcg, Bid 20 Mg, Q.Am		Apotex Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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

Thyroxine	C	Unknown	50 Mg, Q.Am	Not Reported
Linagliptin	C	Unknown	5 Mg, Q.Am	Not Reported
Metformin	C	Unknown	2 G, Q.Am	Not Reported
Rosuvastatin	C	Unknown	20 Mg, Q.H.S.	Not Reported
Risperidone	C	Unknown	2 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	12987114	EXPEDITED (15-DAY)		HO	IT-ABBVIE-16P-083-1794289-00		54 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Diarrhoea; Drug Interaction; Hepatitis Cholestatic	Norvir			S	Oral			Not Reported
	Azithromicin			S	Unknown			Not Reported
	Trimetoprim/Sulfametoxazolo			S	Unknown			Not Reported
	Darunavir			S	Unknown			Not Reported
	Lamivudine			S	Unknown			Not Reported
	Indometacina			S	Unknown			Not Reported
	Raltegravir			S	Unknown			Not Reported
	Emtricitabine / Tenofovir Disoproxil Fumarate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	13004991	NON-EXPEDITED			US-PFIZER INC-2016564685		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	13005014	NON-EXPEDITED			US-PFIZER INC-2016567840		64 YR	Female	USA

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

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

Drug Ineffective	Zithromax	S	Unk	Pfizer
	Enbrel	C	Unk Unk, Weekly	Not Reported
	Apple Cider Vinegar	C	Unknown	Unk
				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	13005033	NON-EXPEDITED			US-PFIZER INC-2016558956			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Iodine			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	13007141	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016557642		44 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oculomucocutaneous Syndrome; Stevens-Johnson Syndrome	Zithromac 250mg			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2016	13007224	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1053610			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Haemorrhagic; Rectal Haemorrhage	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2016	13008625	NON-EXPEDITED			US-PFIZER INC-2016559491			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective		Azithromycin		S		250 Mg, (6) Pills		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2016	13008646	NON-EXPEDITED			US-PFIZER INC-2016564210		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Betadine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2016	13008654	NON-EXPEDITED			US-PFIZER INC-2016570284		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrooesophageal Reflux Disease	Zithromax			S		Unk		Pfizer	
	Albuterol /00139501/			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2016	13009732	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016561429			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Pneumonia	Zithromac			S				Pfizer	
	Minomycin			S				Pfizer	
	Ceftriaxone Sodium			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2016	13010367	NON-EXPEDITED			US-PFIZER INC-2016557108			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

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

Aleve	S	Unk	Not Reported
Avelox	S	Unk	Not Reported
Cipro	S	Unk	Not Reported
Clarithromycin	S	Unk	Not Reported
Darvocet-N 100	S	Unk	Not Reported
Ethambutol Hcl	S	Unk	Not Reported
Imitrex	S	Unk	Not Reported
L-Lysine	S	Unk	Not Reported
Lysine	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Rifampin	S	Unk	Not Reported
Tobi	S	Unk	Not Reported
Xopenex	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	11574837	NON-EXPEDITED			US-PFIZER INC-2015316288		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Azithromax			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	12919898	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-702876ACC		74 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Confusional State; Deep Vein Thrombosis; Diarrhoea; Drug Reaction With	Ceftriaxone Disodico			S	Unknown			Teva	
	Levofloxacin			S	Unknown			Teva	
	Azithromycin			S				Not Reported	
	Piperacillina/Tazobactam			S				Not Reported	

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

Eosinophilia And Systemic Symptoms; Leukocytosis; Rash Maculo-Papular	Fenobarbital	S						Not Reported
	Metronidazolo	S	Intravenous drip					Not Reported
	Fenobarbital	C	Unknown					Not Reported
	Dalteparin	C	Unknown					Not Reported
	Furosemide	C						Not Reported
	Lansoprazolo	C						Not Reported
	Metilprednisolone	C						Not Reported
	Thiamine/Folic Acid	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	13011270	EXPEDITED (15-DAY)		OT	FR-ROCHE-1865229			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Inappropriate Schedule Of Product Administration; Product Use In Unapproved Indication; Tendon Disorder; Tendon Pain; Urticaria	Xolair			S	Unknown			Not Reported
	Xolair			S	Unknown			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Novatrex			S	Oral			Not Reported
	Novatrex			S				Not Reported
	Bilastine			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	13012233	NON-EXPEDITED			US-PFIZER INC-2016559356			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	13012344	NON-EXPEDITED			US-PFIZER INC-2016570168			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Zmax			S		Unk		Pfizer

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

Zithromax	S	Unk	Pfizer
Azithromycin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2016	13014497	EXPEDITED (15-DAY)		OT	JP-SUNOVION-2016SUN003037			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Fluctuation; Dyspnoea; Feeling Abnormal; Presyncope; Rash Pruritic; Stomatitis; Swelling Face; Wheezing	Omnaris			S	Respiratory (inhalation)	400 Mg, Qd		Sunovion
	Azithromycin			S	Unknown	250 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2016	13017631	NON-EXPEDITED			US-PFIZER INC-2016573165			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2016	13019102	NON-EXPEDITED			US-ROCHE-1771862			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash	Valium			S	Unknown			Not Reported
	Celebrex			S	Oral	90 Capsules, One Capsule By Mouth Daily, 1 Refill.		Not Reported
	Lipitor			S	Unknown			Not Reported
	Zithromax			S	Oral	2 Tablets For The First Day And One Tablet Daily Afterwards For A Total Of 5 Days As Directed In The		Not Reported

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

Cholecalciferol	C	Oral	Over The Counter Product, 1000 Unit, 3 Refills	Not Reported
Celexa (Canada)	C	Oral	Half A Day, Over The Counter Product, 30 Tablets, 0 Refills	Not Reported
Vitamin B-12	C	Unknown	1 Cubic Centimeter Twice A Month, 3 Refills, 1000 Mcg/ML	Not Reported
Flexeril (Canada)	C	Oral	30 Tablets, 2 Refills, 1 Tablet By Mouth 3 Times A Day As Needed	Not Reported
Hydrodiuril	C	Oral	Once A Day As Needed, 1 Refill, 90 Tablets	Not Reported
Combivent RespiMat	C	Unknown	20 To 100 Mcg Or Actuation Inhaler, 3 Puffs 4 Times A Day As Needed, 2 Refills	Not Reported
Lancets	C	Unknown	1 Each By Other Route Daily Use As Instructed, 1 Box, 3 Refills	Not Reported
Synthroid	C	Oral		Not Reported
Ampicillin	C			Not Reported
Bactrim	C	Unknown		Not Reported
Percocet	C			Not Reported
Augmentin	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2016	13023583	DIRECT	Y	DS			44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Potassium Decreased; Cardiac Arrest; Craniocerebral Injury; Face Injury; Fall; Hypernatraemia; Hypoxia;	Z-Pak			S	Oral	Other Frequency:500 Mgx1 Then 250;		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Seizure; Syncope;
Troponin Increased;
Wound

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	11587195	NON-EXPEDITED			US-PFIZER INC-2015314780			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Benadryl			S		Unk		Not Reported
	Betadine			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	11772262	NON-EXPEDITED			US-TEVA-565300USA		63 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pain; Product Substitution Issue; Swelling; Throat Irritation	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	12935066	EXPEDITED (15-DAY)		OT	FR-009507513-1611FRA005805		27 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous	Singulair			S	Oral	Unk		Merck
	Aerius (Desloratadine)			S	Oral	1 Df, Qd		Merck
	Pariet			S	Oral	1 Df, Qd		Not Reported
	Orelox			S	Oral	2 Df, Bid		Not Reported
	Creon (Pancreatin)			S	Oral	7 Df, Qd		Not Reported

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

Zithromax	S	Oral	1 Df, Qd	Not Reported
Ventilastin Novolizer	S	Respiratory (inhalation)		Not Reported
Tobi	S	Respiratory (inhalation)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13022158	NON-EXPEDITED			US-PFIZER INC-2016566211		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		250 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13022180	NON-EXPEDITED			US-PFIZER INC-2016566359			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Cefalexin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Levoquin			S		Unk		Not Reported	
	Suprax			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13022202	NON-EXPEDITED			US-PFIZER INC-2016567039		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Septra			S		Unk		Pfizer	
	Zitromax			S		Unk		Pfizer	

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

Lisinopril	S	Unk	Not Reported
Aspirin /00002701/	S	Unk	Not Reported
Biaxin	S	Unk	Not Reported
Bactimed (Ampicillin Trihydrate)	S	Unk	Not Reported
Tmp-Smx	S	Unk	Not Reported
Bleph	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13022616	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016567064		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Injury; Pancytopenia	Novatrex			S	Oral	2.5 Mg, 2x/Week		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023023	NON-EXPEDITED			US-TEVA-620442USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dysphonia	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023024	NON-EXPEDITED			US-TEVA-610720USA		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Feeling Abnormal; Headache	Azithromycin			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023025	NON-EXPEDITED			US-TEVA-612897USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Aggression; Dysgeusia; Product Taste Abnormal; Vomiting		Azithromycin		S	Oral	200mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023026	NON-EXPEDITED			US-TEVA-615473USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023027	NON-EXPEDITED			US-TEVA-609282USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysgeusia	Azithromycin			S	Oral	200 Mg / 5ml			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023030	NON-EXPEDITED			US-TEVA-623689USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Drug Hypersensitivity; Nausea; Pruritus; Rash; Urticaria	Azithromycin			S	Unknown				Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown				Teva
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023031	NON-EXPEDITED			US-TEVA-621599USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Feeling Abnormal; Headache; Hypoaesthesia	Azithromycin			S	Unknown				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023032	NON-EXPEDITED			US-TEVA-625445USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023033	NON-EXPEDITED			US-TEVA-620972USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Back Pain; Diarrhoea; Hyperhidrosis; Insomnia; Irritable Bowel Syndrome; Product Use In Unapproved Indication	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Xanax			C	Unknown			Not Reported	
	Tramadol			C	Unknown			Not Reported	
	Bentyl			C	Unknown			Not Reported	
	Dayquil			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023034	NON-EXPEDITED			US-TEVA-616707USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tooth Discolouration	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023035	NON-EXPEDITED			US-TEVA-620541USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S	Unknown			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023036	NON-EXPEDITED		OT	US-TEVA-626375USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Azithromycin			S	Oral	2 Tabs First Day And 1 Tab Following 4 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023037	NON-EXPEDITED			US-TEVA-621937USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023038	NON-EXPEDITED			US-TEVA-620443USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
	Pantoprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023039	NON-EXPEDITED			US-TEVA-629280USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response	Azithromycin			S	Unknown			Not Reported	
Unexpected	Levofloxacin			S	Unknown			Not Reported	
	Methlpredmisson			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023040	NON-EXPEDITED			US-TEVA-624068USA		66 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023041	NON-EXPEDITED			US-TEVA-622214	USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Therapeutic Product Effect Decreased	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023042	NON-EXPEDITED			US-TEVA-641353	USA	39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Chest Discomfort; Extrasystoles; Gastrooesophageal Reflux Disease; Heart Rate Irregular	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023043	NON-EXPEDITED			US-TEVA-618661	USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Medication Error; Product Packaging Issue	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023044	NON-EXPEDITED			US-TEVA-615313	USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023045	NON-EXPEDITED			US-TEVA-610066USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Balanoposthitis; Diarrhoea; Drug Ineffective; Dry Skin; Proctalgia; Product Coating Issue; Product Formulation Issue; Skin Fissures; Urinary Incontinence	Azithromycin			S	Unknown	2000 Milligram Daily;		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023046	NON-EXPEDITED			US-TEVA-621600USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Headache; Migraine	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023047	NON-EXPEDITED			US-TEVA-639215USA		8 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pain In Extremity; Serum Sickness	Azithromycin			S	Oral	200mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023048	NON-EXPEDITED			US-TEVA-632743USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Intentional Product Misuse	Azithromycin			S	Oral	200mg/5ml		Not Reported	

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023049	NON-EXPEDITED			US-TEVA-629969USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin			S		100 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023050	NON-EXPEDITED			US-TEVA-621808USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tinnitus	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023051	NON-EXPEDITED			US-TEVA-637400USA		60 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pain In Extremity	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023052	NON-EXPEDITED			US-TEVA-629165USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Intolerance; Irritability	Azithromycin			S	Oral	200mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023053	NON-EXPEDITED			US-TEVA-627070USA		80 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Glucose Increased	Azithromycin			S	Oral			Not Reported	

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023054	NON-EXPEDITED			US-TEVA-632744USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypoaesthesia Oral; Intentional Product Misuse	Azithromycin			S	Oral	200mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023055	NON-EXPEDITED			US-TEVA-626230USA		55 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eyelid Margin Crusting; Ocular Hyperaemia	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023056	NON-EXPEDITED		OT	US-TEVA-637648USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blister; Respiratory Tract Infection; Sinusitis	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023057	NON-EXPEDITED			US-TEVA-627104USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Heart Rate Increased	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023058	NON-EXPEDITED			US-TEVA-630612USA		74 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Chest Discomfort; Chest Pain; Dyspnoea; Feeling Abnormal; Heart Rate Increased; Hyperhidrosis; Pharyngeal Swelling	Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023059	NON-EXPEDITED			US-TEVA-639164USA		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Headache; Lacrimation Increased; Product Use In Unapproved Indication; Rhinorrhoea; Sinus Headache; Therapeutic Product Effect Decreased	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023060	NON-EXPEDITED			US-TEVA-628915USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Malaise	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023061	NON-EXPEDITED			US-TEVA-630356USA			Female	USA

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023062	NON-EXPEDITED			US-TEVA-633664USA			Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Dysgeusia; Product Reconstitution Quality Issue; Product Taste Abnormal; Retching	Azithromycin			S	Unknown	200mg In 5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023063	NON-EXPEDITED			US-TEVA-630667	USA	1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Taste Abnormal; Vomiting	Azithromycin			S		200mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023064	NON-EXPEDITED			US-TEVA-635120	USA	7 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia	Azithromycin			S		200 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023065	NON-EXPEDITED			US-TEVA-639391	USA	8 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S		200mg-5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023069	NON-EXPEDITED			US-TEVA-688096	USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023070	NON-EXPEDITED			US-TEVA-694160USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Nausea; Pain	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023071	NON-EXPEDITED			US-TEVA-691901USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urine Calcium Increased	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023072	NON-EXPEDITED		HO, OT	US-TEVA-683684USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Haemorrhagic; Product Use In Unapproved Indication; Vomiting	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported	
	Azithromycin			S				Not Reported	
	Levothyroxine			C				Not Reported	
	Norvasc			C				Not Reported	
	Evista			C				Not Reported	
	Paxil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023076	NON-EXPEDITED			US-TEVA-642404USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Dysphagia; Product Use Complaint	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023079	NON-EXPEDITED			US-TEVA-667993USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Pruritus	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023080	NON-EXPEDITED			US-TEVA-697857USA		8 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gastrointestinal Disorder; Gluten Sensitivity	Azithromycin			S		200 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023082	NON-EXPEDITED			US-TEVA-641418USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Product Storage Error	Azithromycin			S	Oral	Daily X 5 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023083	NON-EXPEDITED			US-TEVA-693923USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Product Taste Abnormal; Taste Disorder; Wrong Technique In Product Usage Process	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023085	NON-EXPEDITED			US-TEVA-694028USA		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Oral Disorder; Throat Irritation; Tongue Discolouration	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023087	NON-EXPEDITED			US-TEVA-642900USA		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Nausea	Azithromycin			S		500 Milligram Daily; For 3 Days		Not Reported	
	Potassium			C				Not Reported	
	Calcium			C				Not Reported	
	Vitamin C			C				Not Reported	
	Glucosamine			C				Not Reported	
	Chondroitin			C				Not Reported	
	Imdur			C				Not Reported	
	Aspirin			C				Not Reported	
	Lasix			C				Not Reported	
	Eliquis			C				Not Reported	
	Iron			C				Not Reported	
	Cozaar			C				Not Reported	
	Toprol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023088	NON-EXPEDITED			US-TEVA-700088USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S				Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023089	NON-EXPEDITED			US-TEVA-694393USA		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Use Issue; Nausea	Azithromycin			S	Oral	200mg/5ml, 2 Teaspoons Once Daily, But Only Taking One Teaspoon		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023091	NON-EXPEDITED			US-TEVA-700083USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Azithromycin			S	Oral			Not Reported	
	Warfarin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023092	NON-EXPEDITED			US-TEVA-646868USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dizziness; Vomiting	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023093	NON-EXPEDITED			US-TEVA-646068USA		16 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Burning Sensation; Diarrhoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023094	NON-EXPEDITED			US-TEVA-648602USA		66 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Pain	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023095	NON-EXPEDITED			US-TEVA-646866	USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023096	NON-EXPEDITED			US-TEVA-646864	USA	83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Pain Upper	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023097	NON-EXPEDITED			US-TEVA-648155	USA		Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Taste Abnormal; Tongue Discomfort	Azithromycin			S	Oral	200mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023098	NON-EXPEDITED			US-TEVA-646771	USA		Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Fatigue; Myalgia; Pain In Extremity; Sleep Disorder; Somnolence	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023099	NON-EXPEDITED			US-TEVA-650250USA		2 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Liquid Product Physical Issue; Product Storage Error	Azithromycin			S	Oral	100mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023100	NON-EXPEDITED			US-TEVA-648941USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Urticaria	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023101	NON-EXPEDITED			US-TEVA-668765USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Deposit; Product Preparation Error; Product Reconstitution Quality Issue; Product Taste Abnormal; Product Use Complaint; Screaming; Taste Disorder; Throat Irritation	Azithromycin			S	Oral	200 Mg / 5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023102	NON-EXPEDITED			US-TEVA-641433USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Event; Bedridden	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023103	NON-EXPEDITED		OT	US-TEVA-672497USA		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Drug Ineffective; Ear Disorder; Hyperacusis; Hyperacusis; Tinnitus	Azithromycin			S		500 Milligram Daily;		Not Reported	
	Azithromycin			S		250 Milligram Daily;		Not Reported	
	Augmentin			S		500 Milligram Daily;		Not Reported	
	Prednisone			S				Not Reported	
	Prednisone			S				Not Reported	
	Clonazepam			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Cytomel			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023104	NON-EXPEDITED			US-TEVA-697668USA		7 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Vomiting	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023105	NON-EXPEDITED			US-TEVA-706978USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Behaviour Disorder	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023106	NON-EXPEDITED			US-TEVA-643299USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrasystoles; Reaction To Excipient	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023107	NON-EXPEDITED			US-TEVA-648603USA		65 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dry Mouth; Dysgeusia; Taste Disorder; Tongue Rough	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023108	NON-EXPEDITED			US-TEVA-652740USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Wrong Technique In Product Usage Process	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023109	NON-EXPEDITED			US-TEVA-660447USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Diarrhoea	Azithromycin			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023110	NON-EXPEDITED			US-TEVA-670165USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysgeusia; Product Taste Abnormal; Throat Irritation	Azithromycin			S	Oral	200mg/5ml 22.5 MI			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023111	NON-EXPEDITED			US-TEVA-653647USA		51 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Vomiting	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023112	NON-EXPEDITED			US-TEVA-650112USA		6 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Pallor; Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023113	NON-EXPEDITED			US-TEVA-648555USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Oral Discomfort; Product Taste Abnormal	Azithromycin			S	Oral	200mg / 5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023114	NON-EXPEDITED			US-TEVA-656690USA		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Headache; Pain; Paraesthesia	Azithromycin			S	Oral			Not Reported	
	Insulin			C				Not Reported	
	Metformin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023115	NON-EXPEDITED			US-TEVA-650688USA		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Paraesthesia; Secretion	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	

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

Discharge

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023116	NON-EXPEDITED			US-TEVA-655489USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Discomfort; Feeling Abnormal; Insomnia; Product Substitution Issue	Azithromycin			S	Oral	8 Loose Tablets		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023117	NON-EXPEDITED			US-TEVA-659890USA		66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Vomiting	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023118	NON-EXPEDITED			US-TEVA-673329USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diplopia	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023119	NON-EXPEDITED			US-TEVA-678210USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023120	NON-EXPEDITED			US-TEVA-662989USA		16 YR	Female	USA

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

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

Drug Ineffective; Fatigue; Laziness; Sleep Paralysis	Azithromycin	S	Unknown					Not Reported
	Azithromycin	S						Not Reported
	Mucinex	C						Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023121	NON-EXPEDITED			US-TEVA-666115USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Skin Discolouration	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023122	NON-EXPEDITED			US-TEVA-665708USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain Upper; Vomiting	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023123	NON-EXPEDITED			US-TEVA-666419USA			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event; Drug Ineffective For Unapproved Indication; Dysphagia; Ear Pain; Oropharyngeal Pain	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2016	13023124	NON-EXPEDITED		OT	US-TEVA-677509USA			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cough; Dysphonia; Throat Tightness; Wrong	Azithromycin			S				Not Reported

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

Technique In Product
Usage Process

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023125	NON-EXPEDITED			US-TEVA-667916USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023126	NON-EXPEDITED			US-TEVA-677505USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure To Allergen	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023127	NON-EXPEDITED			US-TEVA-667992USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response	Azithromycin			S	Unknown				Not Reported
Unexpected	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023128	NON-EXPEDITED			US-TEVA-682749USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Mouth; Hyperaesthesia; Product Solubility Abnormal; Tongue Discomfort	Azithromycin			S		500 Milligram Daily;			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023137	NON-EXPEDITED			US-TEVA-676620USA		1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Diarrhoea	Azithromycin			S	Oral	15 MI Daily; 100mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13023940	NON-EXPEDITED			US-TEVA-676104USA		7 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Product Physical Consistency Issue; Product Preparation Issue; Therapeutic Product Ineffective	Azithromycin			S		200mg/5ml		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13024004	EXPEDITED (15-DAY)		LT, OT	IT-PFIZER INC- 2016532570		54 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Hepatitis Cholestatic	Azithromycin			S		Unk		Pfizer	
	Indomethacin			S		50 Mg, 3x/Day		Not Reported	
	Co Trimoxazole			S		Unk		Not Reported	
	Emtricitabine W/Tenofovir			S		Unk		Not Reported	
	Darunavir/Ritonavir			C		[Darunavir 800mg]/[Ritonavir 100 Mg], 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13024135	EXPEDITED (15-DAY)		OT	IT-GLAXOSMITHKLINE- IT2016GSK179375		54 YR	Male	ITA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Hepatitis Cholestatic	Lamivudine			S	Oral	Unk		Viiv	
	Raltegravir			S		Unk		Glaxosmithkline	
	Indomethacine 50mg 3/Day			S		50 Mg, Tid		Glaxosmithkline	
	Co-Trimoxazole			S		Unk		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Darunavir + Ritonavir			S		800/100 Mg Qd		Not Reported	
	Emtricitabine/Tenofovir Disoproxil Fumarate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13024235	EXPEDITED (15-DAY)		OT	US-TEVA-695655USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Lip Swelling; Stomatitis	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13024402	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2016571713		27 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tic	Zithromax			S	Oral	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13024890	EXPEDITED (15-DAY)		OT	CN-ASTRAZENECA-2016SF31120		54 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dyspnoea; Palpitations; Tremor	Budesonide			S	Respiratory (inhalation)	2 Vial Two Times A Day		Not Reported	
	Azithromycin			S	Intravenous drip			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2016	13026027	DIRECT		HO, LT			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Long Qt Syndrome	Azithromycin			S	Oral	Quantity:6 Tablet(S);		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	10529168	EXPEDITED (15-DAY)		HO, OT	IT-GILEAD-2014-0118638		54 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Hepatitis Cholestatic	Truvada			S	Unknown	1000 Mg, Unk		Gilead	
	Indomethacin /00003801/			S	Unknown	50 Mg, Tid		Not Reported	
	Darunavir W/Ritonavir			S	Oral	800/100mg		Not Reported	
	Co Trimoxazole			S	Unknown	Unk		Not Reported	
	Azitromycin			S	Unknown	Unk		Not Reported	
	Raltegravir			S	Unknown	100 Mg, Qd		Not Reported	
	Lamivudine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	10706249	EXPEDITED (15-DAY)		HO, OT	HR-RANBAXY-2014R1-91336		13 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tubulointerstitial Nephritis	Acetaminophen		Y	S	Unknown	Unk		Ranbaxy	
	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	10708147	NON-EXPEDITED			US-PFIZER INC-2015010829		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Sulfamide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	11383624	NON-EXPEDITED			US-PFIZER INC-2015271115		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Feeling Abnormal; Malaise	Azithromycin			S		Unk		Pfizer
	Azithromycin			S		250 Mg, Unk		Pfizer
	Azithromycin			S		Unk (2-6 Pill)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	12306184	NON-EXPEDITED			US-PFIZER INC-2016220522		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer
	Cefuroxime			S		Unk		Unknown
	Ceclor			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported
	Amoxicillin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	12952020	NON-EXPEDITED			US-PFIZER INC-2016533317			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Benzylpenicillin Potassium			S		Unk		Pfizer
	Bactrim			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	12982570	EXPEDITED (15-DAY)		OT	PHHY2016AU160025			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium; Eosinophilia; Leukocytosis; Neutrophilia; Oxygen Saturation; Polychromasia; Pyrexia; Tachycardia; Tachypnoea	Clozapine			S	Unknown	300 Mg, Qd		Not Reported
	Ceftriaxone			S	Unknown			Novartis
	Azithromycin			S	Unknown			Not Reported
	Quetiapine			C	Unknown			Not Reported
	Duloxetine Hydrochloride			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Multi Vit			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Gliclazide			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Sodium Valproate			C	Unknown			Not Reported
	Budesonide			C	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Thyroxine			C	Unknown			Not Reported
	Linagliptin			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	13026364	EXPEDITED (15-DAY)		OT	IT-VIIV HEALTHCARE LIMITED- IT2016GSK179375		54 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Acute Kidney Injury; Drug Interaction; Hepatitis Cholestatic	Lamivudine	S	Oral	Unk	Viiv
	Raltegravir	S		Unk	Glaxosmithkline
	Indomethacine 50mg 3/Day	S		50 Mg, Tid	Glaxosmithkline
	Co-Trimoxazole	S		Unk	Glaxosmithkline
	Azithromycin	S		Unk	Glaxosmithkline
	Darunavir + Ritonavir	S		800/100 Mg Qd	Not Reported
	Emtricitabine/Tenofovir Disoproxil Fumarate	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	13027898	NON-EXPEDITED			US-PFIZER INC-2016575208			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Mucinex			S		Unk		Not Reported	
	Enbrel			C	Unknown	50 Mg, Qwk		Not Reported	
	Methotrexate			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	13027911	NON-EXPEDITED			US-PFIZER INC-2016574818		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles	Azithromycin			S		500 Mg, Daily		Pfizer	
	Losartan			C		10 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	13028180	NON-EXPEDITED			US-PFIZER INC-2016570632		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	13028626	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2016571890		15 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiotoxicity	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2016	13028631	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2015039304		62 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Benign Neoplasm Of Thyroid Gland; Contusion; Gingival Bleeding; Liver Disorder; Myalgia; Product Dose Omission; Pruritus; Pruritus; Rash Macular; Rheumatoid Arthritis; Ulcer	Novatrex			S		2.5 Mg, Unk		Pfizer	
	Novatrex			S		2.5 Mg, Weekly (Every Wednesday In The Morning)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2016	13031809	NON-EXPEDITED			US-PFIZER INC-2016571414		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S				Pfizer	
	Benzympenicillin Potassium			S				Pfizer	
	Tetracycline Hcl			S				Pfizer	
	Azithromycin			S				Pfizer	
	Meperidine Hcl			S				Unknown	
	Propoxyphene			S				Not Reported	
	Acetaminophen			S				Not Reported	
	Codeine			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2016	13031829	NON-EXPEDITED			US-PFIZER INC-2016567038		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2016	13031999	NON-EXPEDITED			US-PFIZER INC-2016573233		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Hypersensitivity; Nausea; Rash; Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2016	13032038	NON-EXPEDITED			US-PFIZER INC-2016573109		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Tramadol			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Aleve			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2016	13034130	DIRECT		OT			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Headache; Nausea; Product Substitution Issue; Vision	Clonazepam			S				Unknown	
	Unknown			S				Not Reported	
	Z-Pak			S				Not Reported	
	Bupropion			S				Not Reported	

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

Blurred	B Complex	C	Not Reported
	Fish Oil	C	Not Reported
	Multivitamin	C	Not Reported
	Citrus Pectin	C	Not Reported
	Magnesium	C	Not Reported
	Garlic	C	Not Reported
	Vitamin D3	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2016	12592397	NON-EXPEDITED			US-PFIZER INC-2016352840		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Aminophylline			S		Unk		Unknown
	Atorvastatin Calcium			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Rythmol			S		Unk		Not Reported
	Ativan			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported
	Brilinta			S		Unk		Not Reported
	Cerivastatin			S		Unk		Not Reported
	Foradil			S		Unk		Not Reported
	Letrozole			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Metrozole			S		Unk		Not Reported
	Pravastatin			S		Unk		Not Reported
	Tagamet			S		Unk		Not Reported
	Theophylline			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Xopenex			S		Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2016	13035918	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP015467		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoglycaemia	Apo-Cefuroxime			S	Oral	5 Mg, Bid		Apotex	
	Apo-Azithromycin			S	Oral	5 Mg, Bid		Apotex	
	Glyburide			C	Unknown	Unk		Not Reported	
	Metformin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2016	13036996	NON-EXPEDITED			US-PFIZER INC-2016572764			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2016	13037005	EXPEDITED (15-DAY)		DE	GH-PFIZER INC-2016579613		78 YR	Female	GHA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Incorrect Route Of Product Administration	Zithromax			S	Intravenous bolus	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2016	13037285	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2016186149		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Productive Cough	Advair Diskus Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline	
	Proair			S	Respiratory (inhalation)	2 Puff(S), Prn		Not Reported	

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

Azithromycin	S	Unk	Not Reported
Cialis	C		Not Reported
Lyrica	C		Not Reported
Finasteride	C		Not Reported
Ibuprofen	C		Not Reported
Lovastatin	C		Not Reported
Omeprazole	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2016	13038089	NON-EXPEDITED			US-ASTRAZENECA-2016SF29080		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Eye Disorder; Migraine	Omeprazole			S	Oral			Not Reported
	Premarin			S	Oral			Not Reported
	Cleocin			S	Unknown			Not Reported
	Tessalon Perles			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported
	Citracal/Vitamin D			C				Not Reported
	Excedrin			C				Not Reported
	Flonase			C				Not Reported
	Folic Acid			C				Not Reported
	Latanoprost			C				Not Reported
	Levothyroxine			C				Not Reported
	Maxalt-Mlt			C				Not Reported
	Prednisone			C				Not Reported
	Premarin			C				Not Reported
	Propafenone-Hcl			C				Not Reported
	Propranolol-Hcl			C				Not Reported
	Reclast			C				Not Reported
	Sertraline Hcl			C				Not Reported
	Sumatriptan Succinate			C				Not Reported
	Tylenol			C				Not Reported
	Vitamin D3			C				Not Reported
	Avelox			C				Not Reported
	Darvocet-N			C				Not Reported
	Demerol			C				Not Reported
	Morphine			C				Not Reported
	Quinine Sulfate			C				Not Reported

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

		Reglan		C					Not Reported
		Tussionex Pennkinetic Er Lqcr		C					Not Reported
		Zithromax Z-Pak		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2016	13039715	DIRECT		DS			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Pain; Dyspnoea; Jaw Disorder; Vision Blurred; Vision Blurred	Azithromycin Teva			S	Oral	Quantity:7 Tablet(S);Other Frequency:2 Tabs, Then 1 Qd; Oral		Teva	
	Atenolol			C				Not Reported	
	Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2016	11405612	NON-EXPEDITED			US-PFIZER INC- 2015279503		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S	Oral	Unk		Pfizer	
	Aleve			S	Oral	Unk		Not Reported	
	Amoxil			S	Oral	Unk		Not Reported	
	Keflex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2016	12978255	NON-EXPEDITED			US-PFIZER INC- 2016540999		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Multaq			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2016	13018977	EXPEDITED (15-DAY)		OT	PT-PFIZER INC- 2016569902		68 YR	Male	PRT

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Head Injury; Loss Of Consciousness; Nausea; Syncope; Vomiting	Azithromycina Generis			S	Oral	500 Mg, 1x/Day		Not Reported	
	Azithromycina Generis			S				Not Reported	
	Alprazolam Mylan			C	Oral	0.5 Mg, Unk		Not Reported	
	Aspirina Gr			C	Oral	100 Mg, 1x/Day		Not Reported	
	Plavix			C	Oral	25 Mg, 1x/Day		Not Reported	
	Carvedilol			C	Oral	12.5 Mg (Half 25mg Tablet), 2x/Day		Not Reported	
	Triatec (Ramipril)			C	Oral	5 Mg, Daily		Not Reported	
	Atozec			C	Oral	[Atorvastatin 20mg]/[Ezetimibe 10mg], Daily		Not Reported	
	Serenal (Oxazolam)			C		15 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2016	13042099	NON-EXPEDITED			US-PFIZER INC-2016575301			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhoidal Haemorrhage	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2016	13024307	EXPEDITED (15-DAY)			JP-PFIZER INC-2016568505			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromac Sr 2g			S		2000 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2016	13046169	NON-EXPEDITED			US-PFIZER INC-2016577998			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Hypersensitivity	Morphine Sulfate	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Lisinopril	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2016	13047080	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2016AP016032		89 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Acute Generalised	Azithromycin			S	Unknown	Unk		Apotex
Exanthematous	Metronidazole			S	Unknown	Unk		Not Reported
Pustulosis; Angioedema;	Piperacilin/Tazobactam			S	Unknown	Unk		Not Reported
Biliary Tract Disorder; Blister; Blood Bilirubin Increased; Cardiac Failure; Cholelithiasis; Gastrointestinal Inflammation; Haemodynamic Test Abnormal; Hypersensitivity; Leukocytosis; Liver Disorder; Neutrophilia; Oedema; Oedema Peripheral; Pancreatitis Acute; Rash Morbilliform; Rash Pustular; Retroperitoneal Fibrosis; Wound Treatment	Vancomycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2016	13047425	NON-EXPEDITED			US-AKORN-40194			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Discharge; Eye Irritation; Eye Irritation; Eye Pain; Skin Irritation;	Azasite (Azithromycin Ophthalmic Solution) 1%			S				Not Reported

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

Swelling Of Eyelid; Vision
Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2016	13047653	NON-EXPEDITED			US-WOCKHARDT USA, LLC-1061062		82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Transitory	Azithromycin			S	Oral			Wockhardt
	Clopidogrel			C	Oral			Not Reported
	Carvedilol			C	Oral			Not Reported
	Losartan			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2016	13050054	NON-EXPEDITED			US-AKORN-45760		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation; Eye Pain	Azasite 1%			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2016	12594517	EXPEDITED (15-DAY)		HO	US-LPDUSPRD- 20160630		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Cardiac Arrest; Electrocardiogram Qt Prolonged; Torsade De Pointes	Ondansetron Injection (4420-01)			S	Unknown	Dose Not Provided		Luitpold
	Azithromycin			S	Unknown	Dose Not Provided		Not Reported
	Diphenhydramine			S	Unknown	Dose Not Provided		Not Reported
	Fluoxetine			S	Unknown	Dose Not Provided		Not Reported
	Methadone			S	Unknown	Dose Not Provided		Not Reported
	Sertraline			C	Unknown	Dose Not Provided		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2016	13007140	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2016562065		23 YR	Female	ITA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Haemorrhagic; Rectal Haemorrhage	Azithromycin			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2016	13056682	EXPEDITED (15-DAY)		DE, OT	IE-PFIZER INC- 2016593358			Unknown	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	12630780	NON-EXPEDITED			US-PFIZER INC- 2016357696			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Chlorhexidine			S		Unk		Not Reported	
	Tamiflu			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	12994841	EXPEDITED (15-DAY)		OT	DE-IPSEN BIOPHARMACEUTICAL S, INC.-2016-10320		58 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous	Dysport			S	Intramuscular	Not Reported		Not Reported	
	Cefuroxime			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	13029343	EXPEDITED (15-DAY)		OT	BR-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-106804		32 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Candida Infection; Live Birth; Maternal Exposure During Pregnancy	Atazanavir Sulfate	S	Oral	300 Mg, Qd	Bristol Myers Squibb
	Lamivudine W/Tenofovir	S	Oral	600 Mg, Qd	Not Reported
	Disoproxil Fumarate	S	Oral	100 Mg, Qd	Not Reported
	Ritonavir	S	Intravenous (not otherwise specified)	2 Mg/Kg, Qh	Not Reported
	Retrovir	S	Intravenous (not otherwise specified)	1 Mg/Kg, Qh	Not Reported
	Trimethoprim Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Fluconazole	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Folate	C	Unknown	Unk	Not Reported
	Ferrous Sulfate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	13057292	NON-EXPEDITED			US-ACORDA- ACO_120472_2016			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Zanaflex			S	Unknown	Unk		Acorda
	Lyrica			S	Oral	75 Mg, Q 8 Hrs		Not Reported
	Zithromax			S	Oral	600 Mg, 2x/Wk		Not Reported
	Diovan Hct			C	Oral	Unk Unk, Qd		Not Reported
	Lorazepam			C	Oral	Unk, Tid		Not Reported
	Acetaminophen W/Oxycodone			C	Oral	Unk, Q 6 Hrs		Not Reported
	Tylenol			C	Oral	325 Mg, Prn		Not Reported
	Voltaren			C	Topical	2 G, Q 6 Hrs		Not Reported
	Maxalt			C	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	13057621	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD-			Male	BRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2016US-129160

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Naevus; Foetal Exposure During Pregnancy	Tenofovir & Lamivudine			S	Transplacental	600 Mg, Daily		Not Reported
	Azithromycin			S	Transplacental	Unk		Sun
	Ferrous Sulfate			S	Transplacental	Unk		Sun
	Folic Acid			S	Transplacental	Unk		Sun
	Fluconazole			S	Transplacental	Unk		Ranbaxy
	Sulphamethoxazole/Trimethoprim			S	Transplacental	Unk		Sun
	Atazanavir Sulfate (Reyataz, Atv)			S	Transplacental	300 Mg, Daily		Not Reported
	Ritonavir			S	Transplacental	100 Mg, Daily		Not Reported
	Zidovudine (Retrovir, Zdv)			S	Transplacental	2 Mg/Kg/H, Daily		Not Reported
	Zidovudine (Retrovir, Zdv)			S	Transplacental	1 Mg/Kg/H, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	13057628	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-129159		32 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Live Birth	Tenofovir & Lamivudine			S	Oral	600 Mg, Daily		Not Reported
	Azithromycin			S	Unknown			Sun
	Ferrous Sulfate			S	Unknown			Sun
	Folic Acid			S	Unknown			Sun
	Fluconazole			S	Unknown			Ranbaxy
	Sulphamethoxazole/Trimethoprim			S	Unknown			Sun
	Atazanavir Sulfate			S	Oral	300 Mg, Daily		Not Reported
	Ritonavir			S	Oral	100 Mg, Daily		Not Reported

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

Zidovudine (Retrovir, Zdv)	S	Intravenous (not otherwise specified)	2 Mg/Kg/H, Daily	Not Reported
Zidovudine (Retrovir, Zdv)	S	Intravenous (not otherwise specified)	1 Mg/Kg/H, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	13058354	NON-EXPEDITED			US-PFIZER INC-2016583527			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer
	Mucinex			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2016	13060003	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2016190693			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Condition Aggravated; Drug Ineffective; Life Support; Malaise; Nasopharyngitis; Pneumonia; Underdose	Advair Diskus			S	Respiratory (inhalation)	1 Puff(S), Qd		Glaxosmithkline
	Advair Diskus			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline
	Breo Ellipta			S	Respiratory (inhalation)	1 Puff(S), Qd		Glaxosmithkline
	Zithromycin			S		Unk		Not Reported
	Buspar			C				Not Reported
	Oxygen			C				Not Reported
	Pro-Air (Albuterol Sulfate)			C				Not Reported
	Spiriva			C				Not Reported
	Wellbutrin			C				Not Reported
	Xanax			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2016	13061085	EXPEDITED (15-DAY)		OT	CH-ROCHE-1871472		13 YR	Male	CHE

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Sodium Decreased; Nephropathy Toxic	Cellcept			S	Oral	(750 Mg/M2)		Not Reported	
	Advagraf			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Nexium			S	Oral			Not Reported	
	Creon			C	Oral	Capsule Meal 150000u, Snack 75,000 U, On Average 11000 U/Kg/D		Not Reported	
	Ventolin			C	Respiratory (inhalation)			Not Reported	
	Pulmozyme			C	Respiratory (inhalation)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2016	13061236	NON-EXPEDITED			US-ALEXION PHARMACEUTICALS INC.-A201610047			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blister; Catheter Site Erythema; Chest Pain; Drug Hypersensitivity; Facial Pain; Fall; Sinusitis	Soliris 300mg			S	Intravenous (not otherwise specified)			Alexion	
	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	12552363	EXPEDITED (15-DAY)		DE, LT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-120098		26 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Imipenem/Cilastatin			S	Intravenous (not otherwise specified)			Not Reported	
	Sulphamethoxazole/Trimethopri m			S	Intravenous (not otherwise specified)	320mg/1600 Mg		Sun	

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

Vancomycin Hydrochloride	S	Unknown		Not Reported
Tobramycin	S	Intravenous (not otherwise specified)	560 Mg, Qd	Not Reported
Caspofungin	S	Unknown		Not Reported
Caspofungin	S	Unknown	50 Mg, Unk	Not Reported
Azithromycin	S	Oral		Sun
Piperacillin/Tazobactam	S	Intravenous drip	12 G, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	12949959	EXPEDITED (15-DAY)		HO, OT	IT-TEVA-712067ACC		52 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Cough; Drug Resistance; Dyspnoea Exertional; Eosinophilic Granulomatosis With Polyangiitis; Pathogen Resistance; Product Measured Potency Issue; Pseudomonas Infection	Levofloxacin			S		500 Milligram Daily;		Teva
	Levofloxacin			S				Teva
	Ciprofloxacin			S		1000 Milligram Daily; 2 Dosages 500 Mg Daily		Not Reported
	Ciprofloxacin			S		500 Milligram Daily;		Not Reported
	Azithromycin			S		3 Times Per Week(S)		Not Reported
	Azithromycin			S				Not Reported
	Methylprednisolone			S		25 Milligram Daily;		Not Reported
	Methylprednisolone			S		8 Milligram Daily;		Not Reported
	Methylprednisolone			S		16 Milligram Daily;		Not Reported
	Methylprednisolone			S				Not Reported
	Salmeterol + Fluticasone			S		2 Times Per Day(S)		Not Reported
	Salmeterol + Fluticasone			S				Not Reported
	Montelukast			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	12990993	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2016M1052074			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium; Eosinophilia;	Ceftriaxone			S	Unknown			Not Reported

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

Leukocytosis; Neutrophilia; Oxygen Saturation; Polychromasia; Pyrexia; Tachycardia; Tachypnoea	Azithromycin	S	Unknown	Unk	Not Reported
	Clozapine	S	Unknown	300 Mg, Qd	Not Reported
	Quetiapine	C	Unknown	Unk	Mylan
	Duloxetine	C	Unknown	120 Mg, Qd	Mylan
	Metoprolol	C	Unknown	12.5 Mg, Qd	Mylan
	Multi Vit	C	Unknown		Mylan
	Paracetamol	C	Unknown	1 G, Bid	Mylan
	Gliclazide	C	Unknown	60 Mg, Unk	Mylan
	Aspirin /00002701/	C	Unknown	100 Mg, Qd	Mylan
	Lorazepam	C	Unknown	1 Mg, Bid	Mylan
	Sodium Valproate	C	Unknown		Mylan
	Budesonide	C	Unknown		Mylan
	Esomeprazole	C	Unknown	20 Mg, Qd	Mylan
	Thyroxine	C	Unknown	50 Ug, Qd	Mylan
	Linagliptin	C	Unknown	5 Mg, Qd	Mylan
	Metformin	C	Unknown	2 G, Qd	Mylan
	Rosuvastatin	C	Unknown	20 Mg, Qd	Mylan
	Risperidone	C	Unknown	2 Mg, Bid	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	12991901	NON-EXPEDITED			US-PFIZER INC- 2016548321			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13018963	EXPEDITED (15-DAY)		HO, OT	DK-PFIZER INC- 2016567182		9 YR	Male	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Life Support; Torsade De Pointes		Zitromax	S	Oral	40 Mg, Daily		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13024992	EXPEDITED (15-DAY)		OT	PHHY2016IT166673		23 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rectal Haemorrhage	Azithromycin			S	Oral			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13063668	NON-EXPEDITED			US-PFIZER INC-2016583379			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Imitrex			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Tequin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13063879	NON-EXPEDITED			US-PFIZER INC-2016587744		73 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Tuberculin			S		Unk		Not Reported	
	Salmeterol			S		Unk		Not Reported	
	Thiopental			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13063964	NON-EXPEDITED			US-PFIZER INC-			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2016596279

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Levofloxacin			S	Unknown	Unk		Pfizer	
	Zithromax			S	Unknown	Unk		Pfizer	
	Nitrofurantoin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13064008	NON-EXPEDITED			US-PFIZER INC-2016598614			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13065197	DIRECT	Y	HO, LT, RI			60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Respiratory Depression; Wheezing	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13065781	EXPEDITED (15-DAY)		HO	BE-PFIZER INC-2016590668		90 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Fall; General Physical Health Deterioration; Inappropriate Antidiuretic Hormone Secretion	Zitromax			S	Oral	Unk Unk, 2x/Day		Pfizer	
	Remergon			S	Oral	15 Mg, 1x/Day		Not Reported	
	Tiapridal			S	Oral	Unk Unk, As Needed		Not Reported	
	Diovane			C	Oral	80 Mg, 1x/Day		Not Reported	
	Nobiten /01339101/			C	Oral	2.5 Mg, 1x/Day		Not Reported	

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

	Folavit	C	Oral	4 Mg, 1x/Day	Not Reported
	Pantoprazole	C	Oral	20 Mg, 1x/Day	Not Reported
	D-Cure	C		Unk	Not Reported
	Dafalgan	C		500 Mg, 4x/Day	Not Reported
	Novalgine	C		Unk Unk, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13065789	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016594192			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematemesis; Hyperhidrosis; Nausea; Urine Output Decreased; Vertigo	Zithromac Sr 2g			S	Oral	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13066345	EXPEDITED (15-DAY)		DE, OT	PHHY2016US174817		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Clostridium Difficile Infection; Drug Ineffective; Leukaemoid Reaction; Megacolon; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Septic Shock	Piperacillin, Tazobactam			S	Unknown			Novartis	
	Vancomycin			S	Unknown	500 Mg, Q6h		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Metronidazole			S	Oral	500 Mg, Unk		Not Reported	
	Metronidazole			S	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
	Diltiazem			C	Unknown			Not Reported	
	Losartan			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Aspirin			C	Unknown			Not Reported	

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

Sertraline	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Budesonide	C	Unknown	Not Reported
Formoterol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2016	13066928	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-723016USA		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Leukaemoid Reaction; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Septic Shock	Vancomycin			S	Unknown			Actavis
	Ceftriaxone			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Teva
	Levothyroxine Sodium			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Donepezil			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported
	Formoterol, Budesonide			C	Other			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2016	13017498	EXPEDITED (15-DAY)		OT	NL-APOTEX-2016AP015451		48 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Slow Response To Stimuli	Prednison Apotex Tabletten			S	Oral	Unk		Apotex
	Azithromycin Apotex Filmomhulde Tabletten			S	Oral	500 Mg, Unk		Apotex
	Nitrofurantoin Apotex, Capsules			S	Oral	50 Mg, Qid		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2016	13063389	EXPEDITED (15-DAY)		OT	IT-TEVA-718865ACC		23 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Haemorrhagic; Rectal Haemorrhage	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2016	13067654	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.- 2016US23768			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Concomitant Disease Aggravated; Drug-Induced Liver Injury; Hypersensitivity	Tenofovir			S	Unknown	300 Mg, Qd		Cipla	
	Tenofovir			S	Unknown	Unk,One Year Later		Cipla	
	Emtricitabine			S	Unknown	200 Mg, Qd		Cipla	
	Emtricitabine			S	Unknown	Unk,One Year Later		Cipla	
	Efavirenz			S	Unknown	600 Mg, Qd		Cipla	
	Hydroxyzine			S	Unknown	Unk		Invagen	
	Azithromycin			S	Unknown	Unk		Cipla	
	Fluconazole			S	Unknown	Unk		Cipla	
	Pyrimethamine			S	Unknown	75 Mg, Daily		Not Reported	
	Sulfadiazine			S	Unknown	2 G, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2016	13068595	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS- 2016M1056877			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Leukaemoid Reaction; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome;	Vancomycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Mylan	

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

Septic Shock	Levothyroxine Sodium	C	Unknown	Mylan
	Diltiazem	C	Unknown	Mylan
	Losartan	C	Unknown	Mylan
	Atorvastatin	C	Unknown	Mylan
	Aspirin /00002701/	C	Unknown	Mylan
	Donepezil	C	Unknown	Mylan
	Sertraline	C	Unknown	Mylan
	Budesonide W/Formoterol	C	Other	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	10618844	EXPEDITED (15-DAY)		OT	IT-TEVA-525921ISR		54 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Drug Interaction; Hepatitis Cholestatic	Azithromycin			S	Unknown			Not Reported
	Lamivudine			S				Not Reported
	Indometacin			S	Unknown	150 Milligram Daily;		Not Reported
	Darunavir, Ritonavir			S	Oral	Darunavir-800mg/Ritonavir-100mg Once A Day		Not Reported
	Emtricitabine, Tenofovir			S	Unknown			Not Reported
	Co Trimoxazole			S	Unknown			Not Reported
	Raltegravir			S	Oral	100 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	12933784	NON-EXPEDITED			US-PFIZER INC-2016518661		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Contact; Drug Ineffective; Erythema; Pruritus; Rash	Zithromax			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	13071758	NON-EXPEDITED			US-PFIZER INC-2016590185			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Urticaria	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	13072475	EXPEDITED (15-DAY)		OT	IE-MYLANLABS-2016M1058023			Unknown	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Maternal Exposure During Delivery; Maternal Exposure During Pregnancy; Premature Delivery	Allopurinol			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Calcium			S	Unknown			Not Reported	
	Lansoprazole			S	Unknown			Not Reported	
	Prednisolone			S	Unknown	Maintenance Dose 10mg		Not Reported	
	Tacrolimus			S	Unknown	Later Increased During Pregnancy		Not Reported	
	Tacrolimus			S	Unknown	Dose Just Prior To Delivery		Not Reported	
	Ursodeoxycholic Acid			S	Unknown			Not Reported	
	Pancreatin			S	Unknown			Not Reported	
	Simvastatin			S	Unknown			Not Reported	
	Co Trimoxazole			S	Unknown			Mylan	
	Folinic Acid			S	Unknown			Mylan	
	Hydrocortisone			S	Unknown	100mg Intraoperatively		Mylan	
	Colistimethate Sodium			S	Unknown			Mylan	
	Darbepoetin Alfa			S	Unknown			Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	13073999	EXPEDITED (15-DAY)		HO, OT	CH-ASTRAZENECA-		14 YR	Male	CHE

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2016SF35251

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Sodium Decreased; Influenza; Nephropathy Toxic; Petechiae	Nexium			S	Oral	20 Mg 2 Per Day		Not Reported
	Cellcept			S	Oral			Not Reported
	Advagraf			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Creon			C	Oral	11000.0iu/Kg Unknown		Not Reported
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Pulmozyme			C	Respiratory (inhalation)	2500.0iu Unknown		Not Reported
	Antibiotic Therapy			C				Not Reported
	Salt Supplementation			C				Not Reported
	Insulin Pump			C		Schematic According To Meal And Schedule		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	13075549	DIRECT		OT			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mass; Pain; Swelling; Swelling Face	Azithromycin			S	Oral	Quantity:6 Tablet(S);		Teva
	Gemfibrozil			C				Not Reported
	Metoprolol Tartrate			C				Not Reported
	Crestor			C				Not Reported
	Amlodipine Besylate			C				Not Reported
	Fish Oil			C				Not Reported
	Vitamin D Nos			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2016	13075698	DIRECT		OT			13 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Hypersensitivity; Joint Swelling	Azithromycin Tab, 250 Mg			S	Oral	Quantity:2 Tablet(S);		Pliva	
	Advil			C				Not Reported	
	B Vitamin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	8531325	NON-EXPEDITED			US-PFIZER INC-2012098287		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Chantix			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Benzylopenicillin Potassium			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Vioxx			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	9586035	NON-EXPEDITED			US-PFIZER INC-2013282030		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Effexor			S		10 Mg, 2x/Day		Pfizer	
	Effexor Xr			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Oxycontin			S		10 Mg, 2x/Day		Not Reported	
	Demerol			S		Unk		Not Reported	
	Ultram			S		10 Mg, 2x/Day		Not Reported	
	Quinine			S		20 Mg, 1x/Day		Not Reported	
	Zithromycin			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	11274415	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2015231051		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Exposure During Pregnancy	Azithromycin			S		Unk		Pfizer	
	Cefazolin			S		Unk		Pfizer	
	Cefepime Hcl			S		Unk		Unknown	
	Ceftriaxone Sodium			S		Unk		Pfizer	
	Magnesium Sulfate			S		Unk		Unknown	
	Metronidazole			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Vancomycin Hcl			S		Unk		Pfizer	
	Acetaminophen			S		Unk		Not Reported	
	Albendazole			S		Unk		Not Reported	
	Betamethasone			S		12 Mg (Two Doses 24 Hours Apart)		Not Reported	
	Ivermectin			S		Unk		Not Reported	
	Oseltamivir			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	12353152	NON-EXPEDITED		OT	US-ASTRAZENECA-2016SE28132		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Borderline Personality Disorder; Drug Hypersensitivity; Essential Hypertension; Fibromyalgia; Glucose Tolerance Impaired; Obesity; Post-Traumatic Stress Disorder; Suicidal	Seroquel			S	Oral			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Flagyl			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Medrol			S	Unknown			Not Reported	
	Norvasc			S	Unknown			Not Reported	

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

Ideation; Urinary Tract Infection	Lipitor	S	Unknown		Not Reported
	Topamax	C	Oral	Take 50 Mg By Mouth Two (2) Times A Day	Not Reported
	Kenalog	C	Topical		Not Reported
	Flonase	C	Nasal		Not Reported
	Proair Hfa	C	Respiratory (inhalation)	Take 2 Puffs By Mouth ~Very 6 Hours	Not Reported
	Potassium Chloride	C	Oral		Not Reported
	Lopressor	C	Oral		Not Reported
	Lisinopril	C	Oral		Not Reported
	Aspirin	C	Oral		Not Reported
	Cymbalta	C	Oral		Not Reported
	Desyrel	C	Oral	100.0mg Unknown	Not Reported
	Hydrochlorothiazide	C	Oral	Take 1 Tablet By Mouth Once Daily	Not Reported
	Valium	C	Oral	Take 1 Tab By Mouth Every Eight	Not Reported
	Mycostatin	C		Apply To Affected Area Two {2} TImee A Day	Not Reported
	Multivitamin	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	12652397	NON-EXPEDITED			US-PFIZER INC-2016372358		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	12911056	NON-EXPEDITED			US-PFIZER INC-2016506521		304 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective; Product Preparation Issue	Zithromax			S	Oral	(100/5, 4 MI Day 1, 2 MI Day 2-5)			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	13010361	NON-EXPEDITED			US-PFIZER INC-2016558877			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S	Oral	500 Mg Once The First Day And Then 250 Mg Daily Days 2-5			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	13028627	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016573931		73 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Prostate Cancer	Zitromax			S	Oral	500 Mg For 5 Days Monthly			Pfizer
	Imbruvica			S	Oral	140 Mg, 3x/Day			Not Reported
	Bactrim			C	Oral	1 Tablet Every 12 Hours Only On Saturday And Sunday			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	13074870	NON-EXPEDITED			US-PFIZER INC-2016592157			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	13074939	EXPEDITED (15-DAY)		DE, HO, LT	US-LUPIN PHARMACEUTICALS INC.-2016-05790		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Clostridium Difficile Infection; Leukaemoid Reaction; Metabolic Acidosis; Septic Shock	Azithromycin	S	Unknown		Not Reported
	Ceftriaxone	S	Unknown		Not Reported
	Vancomycin	S	Unknown		Not Reported
	Vancomycin	S	Unknown	By Nasogastric Tube 500 Mg Every 6 Hour	Not Reported
	Vancomycin	S	Unknown	Retention Enema 500 Mg Every 6 Hour	Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Levothyroxine	C	Unknown		Not Reported
	Diltiazem	C	Unknown		Not Reported
	Losartan	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Aspirin	C	Unknown		Not Reported
	Donepezil	C	Unknown		Not Reported
	Sertraline	C	Unknown		Not Reported
	Budesonide-Formoterol Inhaler	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	13075938	DIRECT		DS, OT			82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Disorder; Ear Haemorrhage; Eye Irritation; Herpes Zoster; Ocular Hyperaemia; Thrombosis	Azithromycin			S	Oral	Frequency - 1 First Day, 1 Pill Next 4 Days		Greenstone
	Tylenol			S				Not Reported
	Acetaminophen			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2016	13076967	NON-EXPEDITED			US-PFIZER INC-2016594288			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer

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

Zithromax			S		Oral		250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Dec-2016	13076977	NON-EXPEDITED			US-PFIZER INC-2016595055			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S				Pfizer	
	Aspirin				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-Jan-2017	13078064	NON-EXPEDITED			US-TEVA-697510USA			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Product Dose Omission	Salbutamol W/Ipratropium				S	Unknown			Teva	
	Depo Medrol				S	Intramuscular			Not Reported	
	Prednisone				S	Oral			Not Reported	
	Cromolyn				S	Unknown			Not Reported	
	Generic Of Zpac				S	Unknown			Not Reported	
	Albuterol				S	Unknown			Not Reported	
	Albuterol				S	Unknown			Not Reported	
	Symbicort				C				Not Reported	
	Chlorthalidone				C				Not Reported	
	Montelukast Sodium				C				Not Reported	
Mirtazapine				C				Not Reported		
Alprazolam				C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Jan-2017	13081444	NON-EXPEDITED			US-PFIZER INC-2016597893		55 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Doxycycline Hyclate				S		Unk		Pfizer	
	Erythromycin				S		Unk		Pfizer	

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

	Vibramycin		S		Unk		Pfizer		
	Zithromax		S		Unk		Pfizer		
	Flexeril /00428402/		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2017	13081868	NON-EXPEDITED			US-PFIZER INC-2017000123			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2017	13088750	DIRECT		LT			15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2017	13083400	EXPEDITED (15-DAY)		DE, HO	US-STRIDES ARCOLAB LIMITED-2016SP020468			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Azithromycin			S		Unk			Not Reported
Asthenia; Clostridium	Vancomycin			S		Unk			Strides
Difficile Infection;	Vancomycin			S		Unk			Strides
Diarrhoea; Gastrointestinal	Vancomycin			S		Unk			Strides
Sounds Abnormal;	Vancomycin			S	Rectal	Unk			Strides
Hyporesponsive To	Pantoprazole			S		Unk			Not Reported
Stimuli; Lethargy;	Ceftriaxone			S		Unk			Not Reported
Leukaemoid Reaction;									
Megacolon; Metabolic									
Acidosis; Multiple Organ									
Dysfunction Syndrome;									
Septic Shock; Urinary									
Tract Infection									

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2017	13083506	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2016-01483			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S	Unknown			Aurobindo	
	Hydrochlorothiazide			S	Unknown			Aurobindo	
	Lisinopril			S	Unknown			Aurobindo	
	Metoprolol			S	Unknown			Aurobindo	
	Naproxen			S	Unknown			Aurobindo	
	Advair			S	Unknown			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Cipro /00697201/			S	Unknown			Not Reported	
	Darvocet /00220901/			S	Unknown			Not Reported	
	Lortab /00607101/			S	Unknown			Not Reported	
	Percocet /00446701/			S	Unknown			Not Reported	
	Morphine			S	Unknown			Not Reported	
	Keflex			S	Unknown			Not Reported	
	Z-Pak			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Diovan			S	Unknown			Not Reported	
	Flovent			S	Unknown			Not Reported	
	Asa			S	Unknown			Not Reported	
	Benadryl /00000402/			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Singular			S	Unknown			Not Reported	
	Osa			S	Unknown			Not Reported	
	Hydralazine Hydrochloride/Hydrochlorothiazide			S	Unknown			Not Reported	

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

Dolobid	S	Unknown	Not Reported
Compazine /00013302/	S	Unknown	Not Reported
Percolone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	12970033	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016539503		25 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Intentional Self-Injury; Psychomotor Skills Impaired	Azithromycin			S	Oral	Unk		Pfizer
	Levofloxacin			S	Oral	1000 Mg, Total		Not Reported
	Levothyroxine			S	Oral	750 Ug, Total		Not Reported
	Ibuprofen			S	Oral	2400 Mg, Total		Not Reported
	Klaira			S	Oral	Unk		Not Reported
	Plasil /00041901/			S	Oral	24 Df, Total		Not Reported
	Mylicongas			S	Oral	25 Df, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	13087082	EXPEDITED (15-DAY)		DE, HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-130756		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Clostridium Difficile Infection; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Septic Shock; Urinary Tract Infection	Azithromycin			S	Unknown			Sun
	Ceftriaxone			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Sun
	Levothyroxine			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported
	Losartan			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Donepezil			C	Unknown			Not Reported

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

Sertraline			C	Unknown					Not Reported
Budesonide-Formoterol			C	Unknown					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	13088406	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2016605197		29 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	1 Df, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	13089385	NON-EXPEDITED			US-PFIZER INC-2016581155			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Wrong Technique In Product Usage Process	Zithromax			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	13090512	NON-EXPEDITED			US-PFIZER INC-2016603102			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2017	13092979	DIRECT	Y	LT			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2017	13034976	EXPEDITED (15-DAY)		HO	DE-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2016- BI-08		70 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Blood Immunoglobulin E Increased; Skin Reaction	Micardis			S	Unknown			Boehringer Ingelheim	
	Zithromax			S	Unknown			Not Reported	
	L-Thyroxin			C	Unknown			Not Reported	
	Nexium			C	Unknown			Not Reported	
	Presomen			C	Unknown			Not Reported	
	Crestor			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2017	13091710	EXPEDITED (15-DAY)		LT	PHHY2016HR180007		46 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Loss Of Consciousness; Palatal Oedema	Azithromicin Sandoz			S	Oral	500 Mg, Unk		Novartis	
	Velafax			C	Oral	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2017	13093578	EXPEDITED (15-DAY)		DE, OT	US-JNJFOC- 20170100749			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Cardiac Disorder; Death; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Domperidone			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	
	Domperidone			S	Unknown			Not Reported	

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

Domperidone		S	Unknown	Not Reported
Domperidone		S	Unknown	Not Reported
Domperidone		S	Unknown	Not Reported
Levofloxacin		S	Unknown	Not Reported
Risperidone		S	Unknown	Not Reported
Droperidol		S	Unknown	Not Reported
Itraconazole		S	Unknown	Not Reported
Ketoconazole		S	Unknown	Not Reported
Miconazole	Y	S	Unknown	Not Reported
Miconazole	Y	S	Unknown	Not Reported
Tetracycline		S	Unknown	Not Reported
Fluconazole	Y	S	Unknown	Not Reported
Haloperidol		S	Unknown	Not Reported
Lapatinib		S	Unknown	Not Reported
Diltiazem		S	Unknown	Not Reported
Metronidazole		S	Unknown	Not Reported
Aprepitant		S	Unknown	Not Reported
Nicardipine		S	Unknown	Not Reported
Norfloxacin		S	Unknown	Not Reported
Sertraline		S	Unknown	Not Reported
Verapamil		S	Unknown	Not Reported
Voriconazole		S	Unknown	Not Reported
Clarithromycin		S	Unknown	Not Reported
Amiodarone		S	Unknown	Not Reported
Isoniazid		S	Unknown	Not Reported
Cyclosporine		S	Unknown	Not Reported
Erythromycin		S	Unknown	Not Reported
Desipramine		S	Unknown	Not Reported
Clotrimazole		S	Unknown	Not Reported

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

Lidocaine	S	Unknown	Not Reported
Escitalopram	S	Unknown	Not Reported
Ibutilide	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Imipramine	S	Unknown	Not Reported
Azithromycin	S	Unknown	Not Reported
Methadone	S	Unknown	Not Reported
Moxifloxacin	S	Unknown	Not Reported
Nortriptyline	S	Unknown	Not Reported
Octreotide	S	Unknown	Not Reported
Ondansetron	S	Unknown	Not Reported
Perflutren	S	Unknown	Not Reported
Propafenone	S	Unknown	Not Reported
Quetiapine	S	Unknown	Not Reported
Ranolazine	S	Unknown	Not Reported
Citalopram	S	Unknown	Not Reported
Sotalol	S	Unknown	Not Reported
Clindamycin	S	Unknown	Not Reported
Desipramine	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Doxepin	S	Unknown	Not Reported
Dronedarone	S	Unknown	Not Reported
Tacrolimus	S	Unknown	Not Reported
Flecainide	S	Unknown	Not Reported
Amitriptyline	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2017	13093676	NON-EXPEDITED			US-AKORN-35064			Female	USA

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

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

Drug Ineffective; Incorrect Dose Administered; Liquid Product Physical Issue; Product Packaging Confusion	Azasite 1% 2.5ml	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2017	13094068	NON-EXPEDITED			US-PFIZER INC-2017002520		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
	Zithromax			S		Double Dose		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Double Dose		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2017	13094290	EXPEDITED (15-DAY)		HO	BE-009507513-1612BEL015174		90 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Remergon Soltab			S	Oral	15 Mg, Daily		Merck	
	Zitromax			S		Unk, Bid		Not Reported	
	Diovan			C	Oral	Tablet 160 Mg/80 Mg, Daily		Not Reported	
	Nobiten			C		2.5 Mg, Daily		Not Reported	
	Folavit			C		4 Mg, Daily		Not Reported	
	Pantoprazole			C		20 Mg, Daily		Not Reported	
	D-Cure			C		Unk		Not Reported	
	Dafalgan			C		500 Mg, 4x/ Day		Not Reported	
	Novalgine			C		Unk, Prn		Not Reported	
	Tiaproidal			C		Unk, Prn		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2017	12983195	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2016M1051017			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Psychomotor Skills Impaired	Ibuprofen			S	Oral	2400 Mg, Total		Not Reported	
	Levofloxacin			S	Oral	1000 Mg, Total		Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Klaira			S	Oral			Mylan	
	Plasil /00041902/			S	Oral	24 Df, Total		Mylan	
	Mylicongas			S	Oral	25 Df, Total		Mylan	
	Levothyroxine			S	Oral	750 Mg, Total		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2017	12968097	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2016-14566		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Psychomotor Skills Impaired	Ibuprofen			S	Oral	2.4 Mg, Unk		Aurobindo	
	Levofloxacin Filmcoated Tablet			S	Oral	1000 Mg, Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Klaira			S	Oral	Unk		Not Reported	
	Plasil /00041901/			S	Oral	24 Df, Unk		Not Reported	
	Mylicongas			S	Oral	25 Df, Unk		Not Reported	
	Levothyroxine			S	Oral	750 Mcg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2017	13046909	NON-EXPEDITED			US-PFIZER INC-2016580529			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13098302	NON-EXPEDITED			US-PFIZER INC-2016605004			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Malaise	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13098510	EXPEDITED (15-DAY)		HO	SI-TEVA-724995ISR			Female	SVN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; International Normalised Ratio Increased	Sumamed 500 Mg			S	Oral	1tbl./Day		Not Reported	
	Sintrom 4mg			S	Oral	Sheme		Not Reported	
	Diuver 10 Mg			C	Oral	In The Mornings		Not Reported	
	Coryol 12,5 Mg			C	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Jan-2017	13098657	EXPEDITED (15-DAY)		OT	US-TEVA-726995USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blindness Transient; Body Height Decreased; International Normalised Ratio Decreased	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Jan-2017	12982441	EXPEDITED (15-DAY)		OT	PHHY2016IT159586		25 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Abuse; Intentional Self-Injury; Psychomotor Skills Impaired	Levofloxacin			S	Oral	1000 Mg, Once/Single		Novartis	
	Azithromycin			S	Oral			Not Reported	

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

Ibuprofen	S	Oral	2400 Mg, Once/Single	Not Reported
Mylicongas	S	Oral	1000 Mg, Once/Single	Not Reported
Plasil	S	Oral	240 Mg, Once/Single	Not Reported
Klaira	S	Oral		Not Reported
Levothyroxine	S	Oral	750 Ug, Once/Single	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2017	13022343	NON-EXPEDITED			US-PFIZER INC-2016574374		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Distension	Azithromycin			S	Oral	2 Tablets Of 250 Mg On Day 1 Then 1 Tablet Of 250 Mg Daily For 4 More Days		Pfizer	
	Synthroid			C		150 Mg, 1x/Day		Not Reported	
	Plaquenil			C		200 Mg, Daily		Not Reported	
	Ventolin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2017	13102817	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017007091			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Flutter; Chest Discomfort	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2017	13103022	NON-EXPEDITED			US-PFIZER INC-2017006194			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Azithromycin			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2017	10388164	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-A1084210A		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Device Use Error; Dyspnoea; Feeling Abnormal; Gastric Disorder; Headache; Heart Rate Increased; Laryngitis; Malaise; Myocardial Infarction; Nausea; Nervousness; Palpitations; Product Cleaning Inadequate	Advair Diskus			S		2 Puff(S), Bid		Glaxosmithkline	
	Advair Diskus			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline	
	Flovent			S	Respiratory (inhalation)	1 Puff(S), Unk		Glaxosmithkline	
	Ventolin			S	Respiratory (inhalation)	1 Puff(S), Prn		Glaxosmithkline	
	Ventolin			S		Unk		Glaxosmithkline	
	Erythromycin			S	Unknown	Unk, U		Glaxosmithkline	
	Nasonex			S	Unknown	Unk, U		Glaxosmithkline	
	Symbicort			S	Unknown	Unk, U		Not Reported	
	Zetia			C				Not Reported	
	Lipitor			C				Not Reported	
	Calcium			C				Not Reported	
	Glucosamine			C				Not Reported	
	Azithromycin			S				Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2017	13104187	EXPEDITED (15-DAY)		HO	US-CLINIGEN GROUP PLC/ CLINIGEN HEALTHCARE LTD-E2B		58 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Bilirubin Increased; Cytomegalovirus Test Positive; Drug Eruption; Glaucoma; Hypokalaemia; Hyponatraemia; Renal Impairment; Uveitis	Foscavir			S	Intravenous (not otherwise specified)			Clinigen	
	Foscavir			S	Intravenous (not otherwise specified)			Clinigen	
	Foscavir			S	Intravenous (not otherwise specified)			Clinigen	

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

Foscavir	S	Intravenous (not otherwise specified)	Clinigen
Zithromac	S	Oral	Not Reported
Zithromac	S	Oral	Not Reported
Norvir	S	Oral	Frequency Unknown
Reyataz	S	Oral	Frequency Unknown
Truvada	S	Oral	Frequency Unknown
Stocrin	C	Oral	Frequency Unknown
Epzicom	C	Oral	Frequency Unknown
Micafungin Sodium	C	Intravenous drip	Frequency Unknown
Itraconazole	C	Oral	Frequency Unknown
Polaramine	C	Unknown	Frequency Unknown
Predonine	C	Unknown	Frequency Unknown
Predonine	C	Unknown	Frequency Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2017	13104861	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017008085		74 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Sinus	Vfend			S		0.2 G, 2x/Day		Pfizer	
Bradycardia; Therapeutic Product Effect Incomplete	Zithromax			S		100 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2017	13105071	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017003391		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cytomegalovirus Hepatitis; Cytomegalovirus Infection; Product Use In Unapproved Indication	Novatrex			S	Oral	Unk		Pfizer	
	Acupan			C		Unk		Not Reported	
	Speciafoldine			C		Unk		Not Reported	
	Coumadine			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Plaquenil	C	Unk	Not Reported
Augmentin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2017	12879905	NON-EXPEDITED			US-PFIZER INC-2016492448			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Esomeprazole Magnesium			S		Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Bethanechol			S		Unk		Not Reported
	Losartan Potassium/Hctz			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2017	12995582	EXPEDITED (15-DAY)		OT	BR-GLAXOSMITHKLINE-BR2016GSK175328		6 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Fatigue; Inappropriate Schedule Of Product Administration; Overdose; Pharyngitis; Pneumonia; Product Complaint; Product Use In Unapproved Indication; Pulmonary Fibrosis; Therapeutic Response Unexpected; Wheezing	Aerolin			S		Unk		Glaxosmithkline
	Aerolin			S		4 Puff(S), Unk, Used 4 Puffs Each 4 Hours		Glaxosmithkline
	Aerolin			S		4 Puff(S), Unk, 4 Puffs Every 6 Hours		Glaxosmithkline
	Aerolin			S		4 Puff(S), Unk, 4 Puffs Each 8 Hours		Glaxosmithkline
	Aerolin			S		4 Puff(S), Unk, 4 Puffs Each 12 Hours		Glaxosmithkline
	Azithromycin			S		7 MI, Qd		Glaxosmithkline
	Azithromycin			S				Glaxosmithkline
	Salbutamol			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline

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

	Ranitidine Loratadine		C C		Oral		Unk, 3 Days And A Half		Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2017	13108066	NON-EXPEDITED			US-PFIZER INC- 2017007787			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Oxycodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2017	13109709	NON-EXPEDITED			US-PFIZER INC- 2017007946			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Elavil			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2017	13110420	NON-EXPEDITED		HO	US-ROCHE-1180286		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Alteplase			S	Unknown	Inhal		Not Reported	
	Alteplase			S				Not Reported	
	Alteplase			S				Not Reported	
	Dornase Alfa			S	Unknown	Inhal		Not Reported	
	Dornase Alfa			S				Not Reported	
	Dornase Alfa			S				Not Reported	
	Acetylcysteine			S	Unknown	Inhal		Not Reported	
	Acetylcysteine			S				Not Reported	
	Acetylcysteine			S				Not Reported	
	Sodium Chloride			S	Unknown	Inhal		Not Reported	
	Sodium Chloride			S				Not Reported	
	Sodium Chloride			S				Not Reported	

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

	Azithromycin	S	Unknown	Not Reported
	Azithromycin	S		Not Reported
	Azithromycin	S		Not Reported
	Bosentan	S	Unknown	Not Reported
	Bosentan	S		Not Reported
	Bosentan	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2017	13063988	NON-EXPEDITED			US-PFIZER INC-2016596869			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2017	13113338	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017008414		78 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Bronchospasm; Hypersensitivity	Zithromax			S	Oral	0.5 G, 1x/Day		Pfizer	
	Erdosteine			C	Oral	0.3 G, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2017	13120986	DIRECT					5 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Headache; Vomiting	Azithromycin			S	Oral	Quantity:5.5 Teaspoon(S);		Teva	
	Humalog Insulin			C				Not Reported	
	Erythromycin			C				Not Reported	
	Tylenol			C				Not Reported	
	Ibuprofen			C				Not Reported	
	Benadryl			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2017	13121537	DIRECT		OT			67 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Pruritus; Rash	Azithromycin			S	Oral	Quantity:2 Tablet(S);		Greenstone	
	Synthroid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2017	12896850	NON-EXPEDITED			US-ASTRAZENECA- 2016SF12653			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Esomeprazole Magnesium			S	Oral	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Erythromycin			S	Unknown	Unk		Not Reported	
	Bethanechol			S	Unknown	Unk		Not Reported	
	Losartan Potassium/Hctz			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown	Dosing Unknown		Not Reported	
	Penicillin			S	Unknown	Dosing Unknown		Not Reported	
	Sulfa			S	Unknown	Dosing Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2017	10869966	NON-EXPEDITED			US-PFIZER INC- 2015071250		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Daypro			S		Unk		Pfizer	
	Oxaprozin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Relafen			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Nortriptyline			S		Unk		Not Reported	
	Nabumetone			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2017	13100944	EXPEDITED (15-DAY)		OT	US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-803		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Blood Pressure Increased	Delsym Suspension Adult Orange Z-Pak			S	Unknown	10 MI, Single		Not Reported	
				S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2017	13125423	DIRECT		DS			48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Heart Rate Increased	Zithromax			S	Oral			Not Reported	
	Plegridy			C				Not Reported	
	Toprol XL			C				Not Reported	
	Baby Aspirin			C				Not Reported	
	Levemir			C				Not Reported	
	Novolog			C				Not Reported	
	Singulair			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2017	12870499	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2016492030		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Lower Respiratory Tract Infection; Mobility Decreased; Pain In Extremity; Sinusitis	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown	
	Azithromycin			S		Unk		Pfizer	
	Methotrexate			C		Unk		Not Reported	
	Eltroxin			C		100 Ug, Daily		Not Reported	
	Dexilant			C		600 Mg, Daily		Not Reported	
	Domperidone			C		1 Tab, 2x/Day		Not Reported	

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

Bisoprolol			C			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jan-2017	13124454	NON-EXPEDITED			US-PFIZER INC-2017013788		79 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jan-2017	13124460	NON-EXPEDITED			US-PFIZER INC-2017016322			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jan-2017	13125711	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20170110980			Female	CAN	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cheilitis; Dyspnoea; Oropharyngeal Pain; Pneumonia	Simponi				S	Subcutaneous			Not Reported	
	Azithromycin				S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jan-2017	13127684	NON-EXPEDITED			US-PFIZER INC-2017016334			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax				S		Unk		Pfizer	
	Zithromax				S				Pfizer	
	Xeljanz				C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2017	12653086	NON-EXPEDITED			US-EGALET US INC- US-2015EGA000152			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Function Test Increased; Weight Increased	Oxycodone Hydrochloride			S		Unk		Egalet
	Enbrel			S		Unk		Not Reported
	Reglan /00041902/			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Xeljanz			S		Unk		Not Reported
	Xeljanz			S		1 Df, Daily		Not Reported
	Azithromycin			S		Unk		Not Reported
	Actemra			S		162 Mg, Qwk		Not Reported
	Codeine Sulfate			S		Unk		Not Reported
	Chloroquine			S		Unk		Not Reported
	Keflex /00145501/			S		Unk		Not Reported
	Metamucil /00091301/			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported
	Bayer Aspirin			C		81 Mg, Unk		Not Reported
	Multivitamin /00097801/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2017	13017557	NON-EXPEDITED			US-PFIZER INC- 2016561408			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2017	13129172	EXPEDITED (15-DAY)		OT	IE-SUN PHARMACEUTICAL INDUSTRIES LTD-		33 YR	Female	IRL

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2016R1-131496

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Exposure During Pregnancy; Treatment Noncompliance	Hydrocortisone			S	Unknown			Ranbaxy
	Prednisolone			S	Unknown	Unk		Taro
	Tacrolimus			S	Unknown	1.5 Mg, Bid		Not Reported
	Sulphamethoxazole + Trimethoprim			S	Unknown	Unk		Mutual
	Calcium			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Sun
	Simvastatin			S	Unknown	Unk		Sun
	Ursodeoxycholic Acid			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Sun
	Lansoprazole			S	Unknown	Unk		Sun
	Darbopoetin Alpha			S	Unknown	Unk		Not Reported
	Colistin Sulphomethate Sodium			S	Unknown			Not Reported
	Pancrelipase Capsules			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2017	13130504	EXPEDITED (15-DAY)		HO	IE-ASTRAZENECA-2017SE03754		73 YR	Female	IRL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Malaise; Vertigo	Symbicort Turbohaler			S	Respiratory (inhalation)			Astrazeneca
	Theophylline			S	Unknown	Dosing Unknown		Not Reported
	Zemaira			S	Intravenous (not otherwise specified)			Not Reported
	Salbutamol			S	Unknown	Generic, Dosing Unknown		Not Reported
	Terbinafine			S	Unknown	Dosing Unknown		Not Reported

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

Montelukast Sodium	S	Unknown	Dosing Unknown	Not Reported
Losartan	S	Unknown	Dosing Unknown	Not Reported
Azithromycin	S	Unknown	Generic, Dosing Unknown	Not Reported
Paracetamol	S	Unknown	Dosing Unknown	Not Reported
Lansoprazole	S	Unknown	Generic, Dosing Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2017	13131737	NON-EXPEDITED			US-PFIZER INC-2017014636		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Dizziness; Upper Respiratory Tract Infection	Azithromycin			S		Unk		Pfizer	
	Orenitram			S	Oral	1 Mg, 2x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2017	12775444	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20160922712		50 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Chlamydia Test Positive; Lung Disorder	Remicade			S	Intravenous (not otherwise specified)	55th Infusion		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	56th Infusion		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Cortancyl			S	Oral			Not Reported	
	Risedronate			C	Unknown			Not Reported	
	Kardegic			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Mirtazapine			C	Unknown			Not Reported	
	Escitalopram			C	Unknown			Not Reported	

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

Prazepam	C	Unknown	Not Reported
Pantoprazole	C	Unknown	Not Reported
Oxycodone	C	Unknown	Not Reported
Diffu K	C	Unknown	Not Reported
Orocal D3	C	Unknown	Not Reported
Spasfon (Phloroglucinol, Trimethylphloroglucinol)	C	Unknown	Not Reported
Perindopril	C	Unknown	Not Reported
Amlor	C	Unknown	Not Reported
Baclofene	C	Unknown	Not Reported
Speciafoldine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2017	13132792	EXPEDITED (15-DAY)		OT	CA-TEVA-731436ACC		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia	Cefuroxime			S	Oral	10 Milligram Daily;		Not Reported
	Azithromycin			S	Oral	10 Milligram Daily;		Pliva
	Glyburide			C				Not Reported
	Metformin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2017	13135401	EXPEDITED (15-DAY)		OT	DK-MYLANLABS- 2017M1002663			Unknown	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Neutropenia	Azathioprine			S	Unknown			Not Reported
	Zoledronic Acid			S	Intravenous (not otherwise specified)	5 Mg		Not Reported
	Zoledronic Acid			S	Intravenous (not otherwise specified)	5 Mg		Not Reported
	Azithromycin			S	Unknown	At Constant Dose		Not Reported

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

	Tacrolimus	S	Unknown				Not Reported
	Prednisolone	S	Unknown				Not Reported
	Cellcept /01275102/	S	Unknown	Total Daily Dose 1500 Mg			Mylan
	Co Trimoxazole	S	Unknown	At Constant Dose			Mylan
	Ciclosporin	S	Unknown				Mylan
	Methylprednisolone	S	Unknown				Mylan
	Antithymocyte Immunoglobulin	S	Unknown				Mylan
	Estradiol	C	Unknown				Mylan
	Progesterone	C	Unknown				Mylan
	Sumatriptan	C	Unknown	2 Dosage			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2017	13135484	EXPEDITED (15-DAY)		OT	US-TEVA-730831USA		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Dizziness; Feeling Drunk; Memory Impairment; Metamorphopsia; Movement Disorder	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2017	13135906	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2017022264		2 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Infection	Zithromax			S	Oral	0.13 G, 1x/Day		Pfizer
	Qi Hong			S	Intravenous drip	0.13 G, 1x/Day		Not Reported
	Piperacillin Sodium/Sulbactam Sodium			S	Intravenous drip	0.9 G, 2x/Day		Not Reported
	Sodium Chloride			C	Intravenous drip	50 MI, 2x/Day		Not Reported
	Glucose			C	Intravenous drip	150 MI, 1x/Day		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2017	13148118	DIRECT		OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Nausea; Vomiting	Azithromycin 250 Mg			S	Oral	Quantity:2 Tablet(S);		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2017	13153533	DIRECT					12 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Dizziness; Feeling Abnormal; Headache; Nausea; Pruritus; Tinnitus	Azitromycin 250 Mg Tablet			S	Oral	Quantity:1 Tablet(S);		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2017	13060736	NON-EXPEDITED			US-ASTRAZENECA- 2016SF31459		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Bronchitis; Cough; Drug Hypersensitivity; Incorrect Dose Administered; Injection Site Pain; Product Dose Omission; Product Quality Issue; Urticaria	Bydureon			S	Subcutaneous			Not Reported	
	Lisinopril			S	Oral	Daily		Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2017	13076935	EXPEDITED (15-DAY)		DE	JP-PFIZER INC- 2016602625		82 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective	Zithromac 500mg		S	Intravenous drip		500 Mg, 1x/Day		Pfizer	
	Tazopip		C	Intravenous drip		4.5 G, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2017	13094684	NON-EXPEDITED			US-PFIZER INC-2016601904			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oropharyngeal Pain; Rash	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2017	13137484	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR-APL-2017-11400		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Ibuprofen 800mg			S	Oral	800 Mg, Unk		Aurobindo	
	Azithromycin			S	Oral	500 Mg, Unk		Not Reported	
	Salbutamol			C	Respiratory (inhalation)	As Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2017	13139180	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2017019647		4 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Hypoxia; Tachypnoea	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Ceftriaxone Sodium			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2017	13139380	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017007944			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Blood Urine Present; Product Dose Omission; Protein Urine Present; Upper Respiratory Tract Infection; Urinary Tract Infection	Benlysta Powder For Infusion	S	Intravenous (not otherwise specified)	Unk	Glaxosmithkline
	Z-Pak Tablet	S		2 Df, Single	Glaxosmithkline
	Z-Pak Tablet	S		1 Df, Qd	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2017	12550444	EXPEDITED (15-DAY)		HO, LT, OT	BR-ABBVIE-16P-020- 1673974-00		20 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Jaundice; Lymphadenopathy; Oedema Peripheral; Off Label Use; Rash Macular; Skin Exfoliation	Valproic Acid			S	Unknown			Not Reported
	Diazepam			S	Unknown			Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Haloperidol			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2017	13083219	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	ZA-CIPLA LTD.- 2016ZA23299			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anaphylactic Reaction; Atrial Fibrillation; Brain Injury; Cardiac Failure Congestive; Chronic Obstructive Pulmonary Disease; Circulatory Collapse; Condition Aggravated; Death; Pneumonia; Seizure	Warfarin			S	Unknown	Unk		Invagen
	Cipla Azithromycin			S	Intravenous (not otherwise specified)	500 Mg (10 MI Vial), Stat		Not Reported
	Augmentin (Co-Amoxiclav)			S	Intravenous (not otherwise specified)	1.2 G, Stat		Not Reported
	Solu-Cortef			S	Intravenous (not otherwise specified)	200 Mg, Stat		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2017	13141368	NON-EXPEDITED			US-MYLANLABS- 2016M1047844		60 YR	Female	USA

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Abdominal Distension; Fatigue; Feeling Abnormal; Flatulence; Gallbladder Disorder; Insomnia; Reaction To Excipient	Prednisone Tablets Usp			S	Oral	10 Mg, Qid For 4 Days		Mylan	
	Prednisone Tablets Usp			S	Oral	10 Mg, Tid For 4 Days		Mylan	
	Z-Pak			S	Oral	500 Mg, Qd		Mylan	
	Z-Pak			S	Oral	250 Mg, Qd		Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13144642	EXPEDITED (15-DAY)		HO	US-APOTEX- 2017AP005982			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ventricular Extrasystoles	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13144644	EXPEDITED (15-DAY)		HO	US-APOTEX- 2017AP005984			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Supraventricular Tachycardia	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jan-2017	13144991	EXPEDITED (15-DAY)		HO	US-APOTEX- 2017AP005983			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bundle Branch Block	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2017	12375749	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2016254975		53 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Asthenia; Erythema; Exfoliative Rash; Photosensitivity Reaction; Product Use In Unapproved Indication; Somnolence	Novatrex Amlor Cortancyl Plaquenil /00072603/ Coumadine Discotrine Questran Uvedose Simvastatin Cacit D3 Loperamide Hydrochloride	S C C C C C C C C C C	Oral	15 Mg, Weekly 10 Mg, Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk	Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2017	13146772	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2017-16206		4 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypoxia; Tachypnoea	Azithromycin Azithromycin Ceftriaxone			S S S	Unknown Unknown			Aurobindo Aurobindo Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2017	13146782	EXPEDITED (15-DAY)		HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-131474		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Ibuprofen Azithromycin Salbutamol		Y	S S C	Oral Oral Respiratory (inhalation)	800 Mg, Unk 500 Mg, Daily As Needed		Ranbaxy Sun Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2017	13148819	NON-EXPEDITED			US-PFIZER INC-2017031813		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S				Pfizer	
	Advil			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2017	12965678	EXPEDITED (15-DAY)		OT	IT-BAYER-2016-221471		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Psychomotor Skills Impaired	Klaira			S	Oral	Unk		Bayer	
	Plasil			S	Oral	240 Mg, Once		Not Reported	
	Ibuprofene			S	Oral	2400 Mg, Once		Not Reported	
	Levotiroxina (Levothyroxine Sodium)			S	Oral	750 Mg, Once		Not Reported	
	Levofloxacin			S	Oral	1000 Mg, Once		Not Reported	
	Azitromicina Gi Se			S	Oral	Unk		Not Reported	
	Mylicon			S	Oral	Daily Dose 1000 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2017	13066839	EXPEDITED (15-DAY)		HO, OT	IE-BEH-2016076555		73 YR	Female	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Malaise; Vertigo	Zemaira			S	Intravenous (not otherwise specified)	60 Mg/Kg, Qw		Csl Behring	
	Symbicort			S	Unknown			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Wafine			S	Unknown			Not Reported	
	Montelukast			S	Unknown			Not Reported	

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

	Theophylline	S	Unknown	Not Reported
	Losartan	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Paracetamol	S	Unknown	Not Reported
	Lansoprazole	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2017	13152825	EXPEDITED (15-DAY)		HO	DE-JNJFOC-20170109713		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Ibuprofen		Y	S	Oral			Not Reported	
	Ibuprofen			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Salbutamol			C	Respiratory (inhalation)	As Needed		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2017	13155085	NON-EXPEDITED			US-PFIZER INC-2017031819			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Levofloxacin			S		Unk		Pfizer	
	Niaspan			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2017	13155299	NON-EXPEDITED			US-PFIZER INC-2016603160		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Urticaria	Zithromax			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2017	12922501	EXPEDITED (15-DAY)		OT	IT-JNJFOC-20161101577		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Overdose; Intentional Self-Injury; Psychomotor Skills Impaired; Sluggishness	Mylicongas		Y	S	Oral	25 Tablets		Not Reported	
	Ibuprofen		Y	S	Oral			Not Reported	
	Ibuprofen			S	Oral	6 Tablets		Not Reported	
	Plasil			S	Oral	24 Tablets		Not Reported	
	Levothyroxine Teva			S	Oral	15 Tablets		Not Reported	
	Azithromycin			S	Oral	Unspecified Number Of Tablet		Not Reported	
	Dexmine			S	Oral			Not Reported	
	Klaira			S	Oral			Not Reported	
	Levofloxacin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2017	13110832	EXPEDITED (15-DAY)		OT	GB-TEVA-728199ACC		4 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypoxia; Tachypnoea	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2017	13151092	EXPEDITED (15-DAY)		HO	US-JNJFOC-20170121979			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Unevaluable Event	Methylphenidate			S	Unknown			Not Reported	
	Risperidone			S	Unknown			Not Reported	
	Tetracycline Hydrochloride			S	Unknown			Not Reported	

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

Diphenhydramine	Y	S			Not Reported
Erythromycin		S	Unknown		Not Reported
Warfarin		S	Unknown		Not Reported
Insulin		S	Unknown		Not Reported
Clopidogrel		S	Unknown		Not Reported
Lisinopril		S	Unknown		Not Reported
Metformin		S	Unknown		Not Reported
Acetaminophen W/Hydrocodone		S	Unknown		Not Reported
Cefalexin		S	Unknown		Not Reported
Amoxicillin		S	Unknown		Not Reported
Azithromycin		S	Unknown		Not Reported
Cefdinir		S	Unknown		Not Reported
Clindamycin		S	Unknown		Not Reported
Penicillin Nos		S	Unknown		Not Reported
Glipizide		S	Unknown		Not Reported
Dabigatran		S	Unknown		Not Reported
Metoprolol		S	Unknown		Not Reported
Enoxaparin		S	Unknown		Not Reported
Glyburide		S	Unknown		Not Reported
Glimepiride		S	Unknown		Not Reported
Acetaminophen W/Oxycodone		S	Unknown		Not Reported
Sulfamethoxazole W/Trimethoprim		S	Unknown		Not Reported
Aspirin		S	Unknown		Not Reported
Riveroxaban		C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2017	13157161	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US01189			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Bronchitis; Migraine; Nausea	Bupropion Hydrochloride	S	Oral	150 Mg, Qd	Invagen
	Z Pack	S	Unknown	500 Mg, Unk	Not Reported
	Z Pack	S	Unknown	250 Mg, Unk	Not Reported
	Z Pack	S	Unknown	250 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2017	13158197	EXPEDITED (15-DAY)		OT	GB-ROCHE-1884653		4 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hypoxia; Tachypnoea	Ceftriaxone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2017	13158306	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC- 2017031667		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Gastrointestinal Sounds Abnormal; Hypoaesthesia; Loss Of Consciousness	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Levothyroxine			C		100 Ug, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2017	13162754	DIRECT		HO			51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hiccups	Azithromycin Tablets Usp			S	Oral	Other Frequency:Z-Pack Daily;		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	12782946	NON-EXPEDITED			US-PFIZER INC- 2016449391		38 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swelling	Azithromycin			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	12991066	EXPEDITED (15-DAY)		OT	IT-TEVA-715434ISR		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Psychomotor Skills Impaired	Ibuprofen			S	Oral			Barr	
	Levofloxacin			S	Oral	1000 Milligram Daily; 1000 Total		Teva	
	Azithromycin			S	Oral			Not Reported	
	Levothyroxine			S	Oral	750 Microgram Daily;		Not Reported	
	Klaira - Bayer S.P.A.			S	Oral			Not Reported	
	Plasil 10 Mg Compresse-Sanofi S.P.A			S	Oral	24 Dosage Forms Daily; 10 Mg Tablets At A Dose Of 24 Df Total		Not Reported	
	Mylcongas 40 Mg Compresse Masticabili- Johnson And Johnson			S	Oral	25 Dosage Forms Daily; 40 Milligram Chewable Tablets, 25 Df Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	13162213	NON-EXPEDITED			US-PFIZER INC-2017038997		69 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Tetracycline Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Metformin			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	
	Plaquenil /00072602/			S		Unk		Not Reported	

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

Lovenox	S	Unk	Not Reported
Advair	S	Unk	Not Reported
Dulera	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	13163227	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170122546			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Subcutaneous			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Asacol			S	Unknown			Not Reported	
	Azithromycin Dihydrate			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	13163875	NON-EXPEDITED		OT	US-STI PHARMA LLC-1062514			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Fatigue; Immunodeficiency	Ethambutol Hydrochloride			S				Sti Pharma	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2017	13167000	DIRECT	Y	OT			48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Related Reaction; Rash Erythematous	Azithromycin	Y		S	Intravenous drip			Fresenius Kabi	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2017	13167405	DIRECT	Y	OT			52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Prednisone 10mg Cadista			S	Oral	Dose - 4 X 3d, 3x2d, 2 X 2d, 1 X 2d		Cadista	
	Azithromycin 250g Teva			S	Oral	Dose - 2 Day 1, 1 Daily For 4 Days		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2017	13168740	NON-EXPEDITED		HO, OT	US-PFIZER INC-2017040453		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pain; Respiratory Tract Infection	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown	
	Azithromycin			S	Oral	Unk		Pfizer	
	Amoxicillin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2017	13169757	NON-EXPEDITED			US-ABBVIE-16K-163-1619027-00			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Ulcerative	Humira			S	Subcutaneous			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Aza (Azithromycin Dihydrate)			S	Unknown			Not Reported	
	Entyvio			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2017	13063117	EXPEDITED (15-DAY)		DE, HO	US-APOTEX-2016AP016120		30 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Drug Ineffective; Escherichia Infection; Exposure During Pregnancy; Pneumonia; Septic Shock; Stillbirth; Strongyloidiasis; Systemic Inflammatory Response Syndrome	Azithromycin			S	Unknown	Unk		Apotex
	Cefazolin			S	Unknown	Unk		Not Reported
	Cefepime			S	Unknown	Unk		Not Reported
	Ceftriaxone Sodium			S	Unknown	Unk		Not Reported
	Magnesium Sulfate			S	Unknown	Unk		Not Reported
	Metronidazole			S	Unknown	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Vancomycin Hcl			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Albendazole			S	Unknown	Unk		Not Reported
	Betamethasone			S	Unknown	12 Mg, 2 Doses 24 Hours Apart		Not Reported
	Ivermectin			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2017	13175513	EXPEDITED (15-DAY)		HO, OT	US-TEVA-734894USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Haemoglobin Decreased; Hepatic Enzyme Increased; Hepatic Failure; Jaundice	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2017	13177859	EXPEDITED (15-DAY)		HO	PHHY2017CA011320		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Eye Swelling; Impaired Healing; Lip	Supeudol			S	Unknown	Unk		Not Reported

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

Swelling; Urticaria	Supeudol	S	Unknown	5 Mg, Unk	Not Reported
	Tamsulosin	S	Oral	0.4 Mg,	Novartis
	Tobramycin	S	Unknown	0.3 %,	Not Reported
	Rabeprazole	S	Oral	20 Mg,	Not Reported
	Azithromycin	S	Oral	250 Mg,	Not Reported
	Metformin	S	Unknown	500 Mg, Bid	Not Reported
	Aerius (Desloratadine)	C	Unknown		Not Reported
	Amlodipine	C	Unknown		Not Reported
	Camphor	C	Unknown		Not Reported
	Cozaar	C	Unknown		Not Reported
	Hydroxyzine Hydrochloride	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Zantac	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2017	13179555	DIRECT					21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Asthenia; Diarrhoea; Dysphagia; Feeling Abnormal; Headache; Vomiting	Zithromax			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2017	13181444	NON-EXPEDITED			US-PFIZER INC- 2017044869		10 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2017	12559413	EXPEDITED (15-DAY)		HO, LT, OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-120183		20 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Haloperidol			S	Unknown			Sun	
	Valproic Acid			S	Unknown			Sun	
	Amoxicillin/Clavulanic Acid			S	Unknown			Ranbaxy	
	Azithromycin			S	Unknown			Sun	
	Diazepam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2017	13184538	EXPEDITED (15-DAY)		HO, OT	PL-APOTEX- 2017AP006067		51 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Uterine Haemorrhage	Canbiox, Tabletki Powlekane			S	Oral	500 Mg, Qd		Apotex	
	Coldrex Maxgrip C			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2017	13168613	EXPEDITED (15-DAY)		HO, OT	PHEH2017US002706			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Back Injury; Drug Hypersensitivity; Malaise; Movement Disorder; Neoplasm Malignant; Rectal Haemorrhage; Visual Impairment	Voltaren			S	Unknown	1 Df, Unk		Novartis	
	Premarin			S	Unknown	0.05 Mg, Unk		Not Reported	
	Propoxyphene			S	Unknown	Unk		Not Reported	
	Codeine			S	Unknown	Unk		Not Reported	
	Z-Pak			S	Unknown	Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2017	13184390	EXPEDITED (15-DAY)		DE, HO	ES-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2017- BI-00		84 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Intestinal Haemorrhage; Renal Failure	Pradaxa			S	Oral			Boehringer Ingelheim	
	Azithromycin			S	Oral			Not Reported	
	Lercanidipine			C	Unknown			Not Reported	
	Irbesartan Plus Hydrochlorothiazide			C	Unknown	Form Strength: 300/12.5 Mg		Not Reported	
	Seguril			C	Unknown			Not Reported	
	Risperidone			C	Unknown			Not Reported	
	Seretide Accuhaler			C	Unknown	Form Strength And Unit Dose: 50/250 Mcg		Not Reported	
	Spiriva			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2017	13187540	NON-EXPEDITED			US-PFIZER INC- 2017045613		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zyvox			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Avelox			S		Unk		Not Reported	
	Omnicef			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2017	13187565	NON-EXPEDITED			US-PFIZER INC- 2017047354		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Vistaril			S		Unk		Pfizer	

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

	Ultram			S			Unk		Not Reported
	Z-Pak			S			Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13191574	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2017-29367			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13191576	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2017-29429			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bundle Branch Block	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13191579	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2017-29430			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Supraventricular Tachycardia	Azithromycin			S	Unknown			Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13191962	NON-EXPEDITED			US-PFIZER INC- 2017044494			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; Therapeutic Product Effect Incomplete	Azithromycin			S		500 Mg On The First Day Then 250 Mg Once A Day For 6 Days		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13192168	EXPEDITED (15-DAY)		HO	ES-JNJFOC-20160108872		24 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Abnormal; Neutropenia; Platelet Count Decreased	Motilium			S	Unknown	1 Mg/MI		Not Reported	
	Paracetamol		Y	S	Unknown			Not Reported	
	Paracetamol			S	Unknown			Not Reported	
	Zitromax			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13192560	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017041614		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Iridocyclitis	Zithromax			S	Oral	Unk, As Long-Standing Treatment		Pfizer	
	Monoprost			S	Ophthalmic	Unk		Not Reported	
	Azopt			S	Ophthalmic	Unk		Not Reported	
	Simbrinza			S	Ophthalmic	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13192907	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-16K-163-1811476-00		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Blood Potassium Decreased; Clostridium Difficile Infection; Diarrhoea; Diverticulitis; Dyspnoea; Nausea; Papilloma Viral Infection; Respiratory Tract Infection; Respiratory	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Simvastatin			C				Not Reported	
	Fenofibrate			C				Not Reported	
	Hydrochlorothiazide			C				Not Reported	
	Protonix			C				Not Reported	
	Prozac			C				Not Reported	

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

Tract Infection Viral;	Prempro	C	Not Reported
Vomiting; White Blood Cell	Xyzal	C	Not Reported
Count Increased	Albuterol	C	Not Reported
	Imitrex	C	Not Reported
	Tramadol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2017	13194729	EXPEDITED (15-DAY)	LT		CN-PFIZER INC-2017051616		20 DAY	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cyanosis; Pallor	Zithromax			S	Intravenous drip	37 Mg, 1x/Day		Pfizer
	Glucose			C	Intravenous drip	10 MI, 1x/Day		Not Reported
	Piperacillin Sodium W/Sulbactam Sodium			C	Intravenous drip	0.19 G, 2x/Day		Not Reported
	Sodium Chloride			C	Intravenous drip	5 MI, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2017	13153767	EXPEDITED (15-DAY)	OT		DK-TEVA-733598ISR		28 YR	Female	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Neutropenia	Ciclosporin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azithromycin			S	Unknown	At Constant Dose		Not Reported
	Prednisolone			S	Unknown			Teva
	Zoledronic Acid			S	Intravenous (not otherwise specified)	5 Mg		Not Reported
	Zoledronic Acid			S				Not Reported
	Cellcept			S	Unknown	Total Daily Dose 1500 Mg		Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Antithymocyte Globulin			S	Unknown			Not Reported
	Co Trimoxazole			S	Unknown	At Constant Dose		Not Reported

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

Estradiol	C	Unknown	Not Reported
Progesterone	C	Unknown	Not Reported
Sumatriptan	C	Unknown	2 Dosage Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2017	13196139	EXPEDITED (15-DAY)		OT	US-TEVA-719294USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Bladder Pain; Diarrhoea; Gastrointestinal Disorder; Urinary Retention	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2017	13198939	EXPEDITED (15-DAY)		OT	ALCN2017FR001070		64 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Iridocyclitis	Simbrinza			S	Ophthalmic	Unk		Novartis
	Azopt			S	Ophthalmic	Unk		Not Reported
	Monoprost			S	Ophthalmic	Unk		Not Reported
	Zithromax			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2017	9837324	NON-EXPEDITED			US-PFIZER INC- 2014017575		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Augmentin			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Tramadol Hydrochloride			S		Unk		Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2017	13189821	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2017GSK014230			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Back Injury; Drug Hypersensitivity; Malaise; Movement Disorder; Neoplasm Malignant; Rectal Haemorrhage; Visual Acuity Reduced	Voltaren (Diclofenac Sodium)			S	Unknown	1 Df, Unk		Glaxosmithkline	
	Z-Pak			S	Unknown	Unk		Glaxosmithkline	
	Premarin			S	Unknown	0.05 Mg, Unk		Not Reported	
	Propoxyphene			S	Unknown	Unk		Not Reported	
	Codeine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2017	13205228	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017055243		4 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Upper Gastrointestinal Haemorrhage; Vomiting	Zithromax			S	Intravenous drip	0.15 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2017	13209306	NON-EXPEDITED			US-PFIZER INC-2017049684		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Escitalopram			S		Unk		Not Reported	
	Lamictal			S		Unk		Not Reported	
	Keppra			S		Unk		Not Reported	
	Montelukast			S		Unk		Not Reported	
	Penicillin G			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2017	13211216	EXPEDITED (15-DAY)		HO	GR-PFIZER INC-2017052567		8 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia	Azithromycin			S	Oral	Unk		Pfizer	
	Clindamycin Phosphate			S		Unk		Pfizer	
	Cefotaxime			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Pneumococcal Vaccine			S		Single Dose		Not Reported	
	Alteplase			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	10618500	NON-EXPEDITED			US-TEVA-497094USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	12316547	EXPEDITED (15-DAY)		HO	FR-BEH-2016061673		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Exfoliative Generalised; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Function Abnormal; Oedema; Papule; Rash; Rash Erythematous; Skin Exfoliation	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring	
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring	
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring	
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring	
	Zithromax Monodose			S	Oral	Start Date: ??-Oct 2015; 250 Mg; 0.4286 Df (1 Df, 3		Not Reported	

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

				In 1 Week)					
Neo-Codion Adults (Codeine Camsilate\Ethylmorphine Camsilate\Sulfogaiacol) Zydelig				S	Oral	Not Reported			
				S	Oral	100 Mg; Started In ??-Dec 2014 In Combination With Rituximab; Then On Its Own Since Jun 2015			
Nutritional Supplement				S	Oral	Start Date: ??-Sep-2015			
Loperamide Base				S	Oral	Start Date: ??-???-2014			
Desloratadine				S	Oral	Start Date: ??-???-2014			
Josir Lp				S	Oral	Start Date: ??-???-2013; 0.4 Mg, Prolonged Release Microgranules In Capsule			
Avodart				S	Oral	Start Date: ??-???-2013; 0.5 Mg			
Spasfon (Phloroglucinol, Trimethylphloroglucinol) Ergyphilus Confort				S	Oral	Start Date: ??-???-2013			
				C	Unknown	Start Date: ??-Sep-2015; 2-0-2			
Rituximab				S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13179547	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017041059		47 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Fracture; Syncope	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13211111	NON-EXPEDITED			US-PFIZER INC-2017052746			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

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

Robitussin			Y	S	Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13211264	NON-EXPEDITED			US-PFIZER INC-2017055258		1 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infantile Spitting Up	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13214901	EXPEDITED (15-DAY)		OT	PHHY2017GB020837		4 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypoxia; Tachypnoea	Azithromycin			S	Unknown			Novartis	
	Azithromycin			S				Novartis	
	Ceftriaxone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13215590	EXPEDITED (15-DAY)		OT	GXBR2017US000744		92 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dementia; Tremor	Azithromycin 250 Mg			S	Oral	250 Mg, Qd		Novartis	
	Propranolol			C	Unknown	Unk Df, Unk		Not Reported	
	Antihypertensives			C	Unknown	Unk Df, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13225958	DIRECT		HO, LT, OT			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Eye Disorder; Gingival Pain; Liver Injury; Nerve Injury; Oral Disorder; Scar; Skin	Zithromax			S	Oral	Quantity:12 Capsule(S);		Pfizer	
	Men'S One A Day Vitamin			C				Not Reported	

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

Discolouration; Tongue
Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2017	13225970	DIRECT					21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Urticaria	Azithromycin			S	Oral	Quantity:1 Capsule(S);		Not Reported	
	Benadryl			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2017	13220194	NON-EXPEDITED			US-ACORDA- ACO_128565_2016			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Oral Candidiasis	Ampyra			S	Oral	10 Mg, Q 12 Hrs		Acorda	
	Ampyra			S				Acorda	
	Azithromycin			S	Oral	Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Copaxone			C		Unk		Not Reported	
	Lisinopril			C		Unk		Not Reported	
	Levothyroxine Sodium			C		Unk		Not Reported	
	Simvastatin			C		20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2017	13122974	NON-EXPEDITED			US-PFIZER INC- 2017015519		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash; Swelling	Azithromycin			S		Unk		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2017	13182942	EXPEDITED (15-DAY)		OT	RS-ROCHE-1527870			Female	SRB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia; Pancytopenia; Pneumonia	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Longacef			S	Unknown			Not Reported	
	Hemomycin			S	Unknown			Not Reported	
	Methotrexate			C	Oral			Not Reported	
	Methotrexate			C	Oral			Not Reported	
	Sulfasalazine			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2017	13227838	EXPEDITED (15-DAY)		HO	GR-MYLANLABS-2017M1008256			Unknown	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	Unk		Not Reported	
	Cefotaxime			C	Intravenous (not otherwise specified)	Unk		Mylan	
	Clindamycin			C	Intravenous (not otherwise specified)	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2017	13230222	DIRECT		HO, LT, OT			39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Zithromax			S	Oral	Quantity:6 Tablet(S);Other Frequency:2 First Dayqd Afte;		Not Reported	
	Bisoprolol			C				Not Reported	
	Atorvastatin			C				Not Reported	

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

Asa			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229498	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2017-003396			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Osteomyelitis Bacterial; Q Fever	Prednisolone			S	Unknown			Bausch And Lomb	
	Doxycycline			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Hydroxychloroquine Sulphate			S	Unknown			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229716	EXPEDITED (15-DAY)		HO, OT	PHHY2017GR019136		8 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Empyema; Otorrhoea; Pleural Effusion; Pneumonia Pneumococcal; Respiratory Distress	Azithromycin Sandoz			S	Oral			Novartis	
	Cefotaxime			S	Unknown			Not Reported	
	Clindamycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229773	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-133403			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S				Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229776	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL			Unknown	ESP

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

INDUSTRIES LTD-
2017R1-133404

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S			Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229782	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-133402			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S			Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229788	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-133401			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S			Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2017	13229790	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-133388			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S			Sun		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2017	12293542	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016214907		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Exfoliative Generalised; Eosinophilia; Hepatic Function Abnormal; Oedema; Skin Exfoliation	Zithromax			S	Oral	250 Mg, 3 X/Week		Pfizer	
	Privigen			S	Intravenous (not otherwise specified)	40 G, Cyclic		Not Reported	
	Privigen			S	Intravenous (not otherwise specified)	40 G, Cyclic		Not Reported	
	Neo-Codion /00012606/			S	Oral	15 ML, 1x/Day		Not Reported	
	Zydelig			S	Oral	300 Mg, 1x/Day		Not Reported	
	Zydelig			S	Oral	150 Mg, 1x/Day		Not Reported	
	Ergyphilus Confort			S	Oral	2 Df, 2x/Day		Not Reported	
	Loperamide			S	Oral	1 Df, 1x/Day		Not Reported	
	Desloratadine			S	Oral	1 Df, 1x/Day		Not Reported	
	Josir			S	Oral	0.4 Mg, 1x/Day		Not Reported	
	Avodart			S	Oral	0.5 Mg, 1x/Day		Not Reported	
	Spasfon /00765801/			S	Oral	2 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2017	13235113	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017057738		34 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Laryngeal Discomfort; Oropharyngeal Discomfort	Novatrex			S	Oral	7.5 Mg, Weekly		Pfizer	
	Novatrex			S	Oral	15 Mg, Weekly		Pfizer	
	Speciafoldine			C		15 Mg, Weekly Administered 48h Following Methotrexate Intakes		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2017	13237179	NON-EXPEDITED			GXBR2017US000472			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Contusion; Dizziness; Headache; Impaired Quality Of Life; Insomnia; Loss Of Personal Independence In Daily Activities; Nail Discolouration; Nervousness; Ocular Icterus; Rash Pruritic; Skin Exfoliation; Skin Fissures; Skin Haemorrhage; Skin Hypertrophy	Azithromycin 500 Mg			S	Oral	500 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2017	13237194	NON-EXPEDITED			GXBR2017US000816			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2017	13237941	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Colour Issue; Product Label Confusion; Product Packaging Confusion	Pantoprazole Sodium Azithromycin			S S				Auromedics Auromedics	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017	13238314	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-			Unknown	USA

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

2017SP000868

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Toxicity To Various Agents	Tacrolimus			S		Unk		Strides
	Azithromycin			S		Unk		Not Reported
	Fluconazole			S		400 Mg, Qd		Not Reported
	Clarithromycin			S		1000 Mg, Qd		Not Reported
	Miltefosine			S		Unk		Not Reported
	Albendazole			S		Unk		Not Reported
	Methylprednisolone			C		Unk		Not Reported
	Mycophenolate			C		Unk		Not Reported
	Alemtuzumab			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2017	13239217	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017060170		57 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ejection Fraction Decreased	Novatrex			S	Oral	15 Mg, Weekly		Pfizer
	Cortancyl			S	Oral	5 Mg, 1x/Day		Not Reported
	Bisoprolol			C		7.5 Mg, 1x/Day		Not Reported
	Furosemide			C		40 Mg, 1x/Day		Not Reported
	Pantoprazole			C		40 Mg, 2x/Day		Not Reported
	Cymbalta			C		60 Mg, 1x/Day		Not Reported
	Uvedose			C		1 Df, Monthly		Not Reported
	Speciafoldine			C		2 Df, Weekly		Not Reported
	Klupal Codeine			C		Unk, As Needed		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13240210	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017059802			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardiac Disorder; Chest Discomfort; Drug Ineffective; Faeces Discoloured; Haematochezia; Heart Rate Abnormal	Azithromycin			S		250 Mg, Unk		Pfizer	
	Azithromycin			S				Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13240884	EXPEDITED (15-DAY)		OT	US-TEVA-736734ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysuria; Mood Altered; Product Colour Issue; Product Quality Issue; Urinary Retention	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Feb-2017	13242494	DIRECT	Y					Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Label Confusion	Azithromycin			S				Not Reported	
	Pantoprazole			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	12286794	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2016-BI-23		77 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dermatitis Exfoliative Generalised; Eosinophilia;	Josir			S	Oral			Boehringer Ingelheim	

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

Hepatic Function Abnormal; Oedema; Skin Exfoliation	Privigen	S	Intravenous (not otherwise specified)	Not Reported
	Zithromax Monodose	S	Oral	Not Reported
	Neo-Codion Adultes 00012606	S	Oral 1 Tablespoonful	Not Reported
	Zydelig	S	Oral	Not Reported
	Zydelig	S	Oral	Not Reported
	Loperamide Base	S	Oral	Not Reported
	Desloratadine	S	Oral	Not Reported
	Avodart	S	Oral	Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2017	13241621	NON-EXPEDITED			US-PFIZER INC-2017063702		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2017	13242616	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017065366		53 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Dizziness; Ear Disorder; Otitis Media Chronic; Tinnitus	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Shiomarin			C	Intravenous drip	2 G, 1x/Day		Not Reported	
	Mucosolvin			C	Intravenous (not otherwise specified)	45 Mg, 2x/Day		Not Reported	
	Acetylcysteine			C	Oral	0.2 G, 3x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2017	13243336	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017070304		1 YR	Female	CHN

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Cough; Respiratory Distress	Zithromax			S	Oral	0.1 G, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13244358	DIRECT	Y					Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Dispensing Error; Transcription Medication Error	Azithromycin 100mg/5ml			S		Suspension		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13246235	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017069331			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pericarditis	Zithromax			S				Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13247384	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017069838		3 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Haematemesis; Vomiting	Zithromax			S	Intravenous drip	0.14 G, 1x/Day		Pfizer	
	Glucose Injection			C	Intravenous drip	150 MI, 1x/Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Feb-2017	13247689	EXPEDITED (15-DAY)		OT	PG-MYLANLABS-2017M1008631			Unknown	PNG
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Exposure During Pregnancy; Oligohydramnios;	Azithromycin			S	Unknown	Initially For Two Day; Later, Again Given At		Not Reported	

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

Premature Labour				Unknown Dosage					
	Albendazole	S	Unknown						Mylan
	Pyrimethamine W/Sulfadoxine	S	Unknown			Pyrimethamine/Sulfadoxine Of 75/1500mg; Single Dose; Later, Again Given At Unknown Dosage			Mylan
	Iron	S	Unknown						Mylan
	Folic Acid	S	Unknown						Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2017	13247692	EXPEDITED (15-DAY)		DE, OT	PG-MYLANLABS-2017M1010123			Unknown	PNG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death Neonatal; Foetal Exposure During Pregnancy; Foetal Megacystis; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental				Not Reported
	Albendazole			S	Transplacental				Mylan
	Pyrimethamine W/Sulfadoxine			S	Transplacental				Mylan
	Iron			S	Transplacental				Mylan
	Folic Acid			S	Transplacental				Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2017	13250956	NON-EXPEDITED			US-TEVA-697701USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Macular; Urticaria	Amoxicillin			S	Unknown				Teva
	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2017	13251698	NON-EXPEDITED			US-PFIZER INC-2017067695			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S		Unk			Pfizer

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2017	13251977	EXPEDITED (15-DAY)		HO	CN-JNJFOC-20170206838		35 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Tylenol		Y	S	Oral			Not Reported	
	Tylenol			S	Oral	1 Sustained-Release Tablet, Once A Day		Not Reported	
	Zithromax			S	Oral	1 Tablet, Once A Day		Not Reported	
	Zithromax			S	Oral	2 Tablet, Once A Day		Not Reported	
	Zithromax			S	Oral	1 Tablet, Once A Day		Not Reported	
	Zithromax			S	Oral	2 Tablet, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2017	12301315	EXPEDITED (15-DAY)		HO	FR-TEVA-652725ISR		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Exfoliative Generalised; Eosinophilia; Hepatic Function Abnormal; Oedema; Skin Exfoliation	Desloratadine			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Loperamide Base			S	Oral	1 Dosage Forms Daily;		Teva	
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)			S	Oral	2 Dosage Forms Daily;		Not Reported	
	Privigen			S	Intravenous (not otherwise specified)			Not Reported	
	Zithromax Monodose 250 Mg			S	Oral			Not Reported	
	Neo-Codion Adultes			S	Oral	15 MI Daily;		Not Reported	
	Zydelig 100 Mg			S	Oral	3 Dosage Forms Daily;		Not Reported	
	Josir Lp 0.4 Mg			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Avodart 0.5 Mg			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2017	13257186	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017067029		78 YR	Female	FRA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression	Novatrex			S	Oral	15 Mg, Weekly		Pfizer
	Metoject			S	Subcutaneous	1.5 Mg, Weekly		Not Reported
	Cortancyl			C	Oral	10 Mg, Daily		Not Reported
	Cortancyl			C		20 Mg, Daily		Not Reported
	Fludex /00340101/			C	Oral	1 Df, Daily		Not Reported
	Pravastatine			C	Oral	20 Mg, 1x/Day		Not Reported
	Bromazepam			C	Oral	0.25 Mg, Daily		Not Reported
	Telmisartan			C	Oral	40 Mg, 1x/Day		Not Reported
	Omeprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Folic Acid			C		2 Df, 2x/Week		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2017	13257689	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017067044		3 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Mydriasis; Petit Mal Epilepsy	Zithromax			S	Oral	Unk		Pfizer
	Primalan			S	Oral	Unk		Not Reported
	Tussidane			S	Oral	Unk		Not Reported
	Advil			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2017	9787828	NON-EXPEDITED			US-PFIZER INC-2013368861		79 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2017	13182774	EXPEDITED (15-DAY)		OT	PHHY2017CZ013358			Male	CZE

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Maculo-Papular	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2017	13259067	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-013388			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication	Opdivo			S	Unknown			Bristol Myers Squibb	
	Xalkori			S	Oral	250 Mg, Bid		Not Reported	
	Effexor			S	Unknown			Not Reported	
	Medrol /00049601/			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2017	13261615	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2017080668		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza; Oropharyngeal Pain; Pneumonia; Therapeutic Response Decreased	Enbrel			S	Subcutaneous	50 Mg, Qwk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2017	13264207	DIRECT	Y				68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Dysphagia	Lisinopril			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2017	13099367	NON-EXPEDITED			US-PFIZER INC-2017004748		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Incorrect Product Administration Duration	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Amitriptyline			C		Unk, 1x/Day (Low Dose At Night)		Not Reported	
	Spironolactone			C		Unk, 1x/Day		Not Reported	
	Wellbutrin			C		25 Mg, 1x/Day, (Daily)		Not Reported	
	Wellbutrin			C		100 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2017	13269944	NON-EXPEDITED			US-IMPAX LABORATORIES, INC-2016-IPXL-01976		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Burning Sensation; Drug Hypersensitivity; Fatigue; Fatigue; Headache; Headache; Rash	Mirtazapine Odt			S	Unknown			Impax	
	Baclofen			S	Unknown			Not Reported	
	Citalopram			S	Unknown			Not Reported	
	Eszopiclone			S	Unknown			Not Reported	
	Escitalopram			S	Unknown			Not Reported	
	Penicillin (Benzylpenicillin)			S	Unknown			Not Reported	
	Trazodone			S	Unknown			Not Reported	
	Zolpidem			S	Unknown			Not Reported	
	Lyrica			S	Unknown	200 Milligram Daily;		Not Reported	
	Daypro			S	Unknown			Not Reported	
	Levoxyl			S	Unknown			Not Reported	
	Protonix /01263204/			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Synthroid			S	Unknown			Not Reported	

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

Tegretol			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2017	13269982	EXPEDITED (15-DAY)		HO	US-SUNOVION-2017SUN000825			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Glycopyrrolate			S	Unknown	1 Df (50 Ug), Qd		Sunovion	
	Apo Azithromycin			S	Oral	1 Df (250mg), Qd		Not Reported	
	Atorvastatin			S	Oral	20 Mg, Unk		Not Reported	
	Calcium Carbonate			C				Not Reported	
	Dexilant			C				Not Reported	
	Fosamax			C				Not Reported	
	Montelukast			C				Not Reported	
	Pulmicort			C				Not Reported	
	Qvar			C				Not Reported	
	Remicade			C				Not Reported	
	Salbutamol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2017	13272213	EXPEDITED (15-DAY)		HO, LT, OT	US-BAUSCH-BL-2017-004104		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Doxycycline			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	

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

Sulfamethoxazole/Trimethoprim				S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2017	13273286	DIRECT		DS			33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Dizziness; Dizziness; Dyspnoea; Ventricular Arrhythmia	Azithromycin			S				Not Reported	
	Diltiazem Hcl Er			C				Not Reported	
	Propafenone Hcl			C				Not Reported	
	Bupropion Hcl Sr			C				Not Reported	
	Breo			C				Not Reported	
	Xopenex Hfa			C				Not Reported	
	Lorazepam			C				Not Reported	
	Tramadol Hcl			C				Not Reported	
	Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13265812	NON-EXPEDITED			US-MYLANLABS- 2012SP000393			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Vancomycin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Rifampicin			S				Mylan	
	Hydrochlorothiazide			S				Mylan	
	Codeine			S				Mylan	
	Isoniazid			S				Mylan	
	Cinobac			S				Mylan	
	Promethazine Hydrochloride			S				Mylan	
	Lyrica			C	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13275661	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-134418		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Drug Ineffective	Azithromycin	S	Unknown	Sun
	Doxycycline	S	Unknown	Sun
	Sulphamethoxazole/Trimethoprim	S	Unknown	Mutual
	Ceftriaxone	S	Unknown	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified) 60 Mg, Qid	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified) 125 Mg, Qid	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified) 60 Mg, Qid	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified) 125 Mg, Qid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13276059	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2017-30113		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo
	Methylprednisolone			S	Intravenous (not otherwise specified)	125 Mg, Unk		Aurobindo
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Mg, Unk		Aurobindo
	Methylprednisolone			S	Intravenous (not otherwise specified)	125 Mg, Unk		Aurobindo
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Mg, Unk		Aurobindo
	Trimethoprim+Sulfamethoxazole			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Doxycycline			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13276572	DIRECT	Y	HO, RI				Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Electrocardiogram Qt Prolonged	Amiodarone			S				Not Reported	
	Azithromycin			S				Not Reported	
	Levofloxacin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13277100	DIRECT		LT			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia; Muscle Spasms	Azithromycin	Y		S	Oral	2 Pills, By Mouth		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13277949	NON-EXPEDITED			US-PFIZER INC- 2017074907			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Sertraline Hcl			S		Unk		Pfizer	
	Sumatriptan Succinate			S		Unk		Pfizer	
	Venlafaxine Hcl			S		Unk		Pfizer	
	Zaleplon			S		Unk		Unknown	
	Baclofen			S		Unk		Not Reported	
	Citalopram			S		Unk		Not Reported	
	Compazine			S		Unk		Not Reported	
	Dicloxacillin			S		Unk		Not Reported	
	Haloperidol			S		Unk		Not Reported	
	Lamotrigine			S		Unk		Not Reported	
	Paroxetine			S		Unk		Not Reported	
	Fluoxetine			S		Unk		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13278222	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017080163		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Haemolytic Anaemia; Syncope; Vertigo	Zithromax			S	Oral	Unk		Pfizer	
	Coaprovel			S	Oral	1 Df, 1x/Day		Not Reported	
	Diclofenac			S	Oral	Unk		Not Reported	
	Seroplex			C		Unk		Not Reported	
	Xatral			C		Unk		Not Reported	
	Ceris			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2017	13278392	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017082280		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; International Normalised Ratio Increased	Zithromax			S	Oral	Unk		Pfizer	
	Zithromax			S				Pfizer	
	Previscan /00789001/			S	Oral	Unk		Not Reported	
	Piperacillin / Tazobactam			S	Intravenous drip	Unk		Not Reported	
	Piperacillin / Tazobactam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2017	12825206	EXPEDITED (15-DAY)		HO, OT	US-ASTELLAS-2016US039050		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Respiratory Failure; Thrombocytopenia	Micafungin			S	Unknown	Unk Unk, Unknown Freq. (One Dose)		Astellas	
	Vancomycin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Cefepime			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Levaquin			S	Unknown	Unk, Unknown Freq.		Not Reported	

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

Azithromycin	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
Rapamune	C	Oral	Unk Unk, Unknown Freq.	Not Reported
Calcium Carbonate	C	Oral		Not Reported
Omega-3 Fatty Acids	C	Oral		Not Reported
Prograf	C	Oral		Astellas
Coreg	C	Oral		Not Reported
Protonix	C	Oral		Not Reported
Ecotrin	C	Oral		Not Reported
Ferrous Sulfate	C	Oral		Not Reported
Apresolin	C	Oral		Not Reported
Mycostatin	C	Oral		Not Reported
Vitamin D3	C	Oral		Not Reported
Zyloprim	C	Oral		Not Reported
Norvasc	C	Oral		Not Reported
Pravachol	C	Oral		Not Reported
Mg-Plus-Protein	C	Oral		Not Reported
Catapress	C	Oral	0.3 Mg, Twice Daily	Not Reported
Acetaminophen	C	Unknown		Not Reported
Xanax	C	Unknown	0.5 Mg, Unknown Freq.	Not Reported
Lexapro /01588501/	C	Unknown		Not Reported
Compazine /00013302/	C	Unknown		Not Reported
Valcyte	C	Unknown		Not Reported
Bactrim	C	Unknown	Unk Unk, Unknown Freq.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2017	13135020	NON-EXPEDITED			US-PFIZER INC-2017024324		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

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

	Erythromycin		S		Unk		Pfizer		
	Cipro		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2017	13281872	DIRECT	Y	HO, RI			68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Citalopram			S				Not Reported	
	Amiodarone			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2017	11980335	NON-EXPEDITED			US-PFIZER INC-2016015894			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2017	13209292	NON-EXPEDITED			US-PFIZER INC-2017049833			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2017	13286290	NON-EXPEDITED			US-ALLERGAN-1000083714			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Viibryd			S	Oral	20 Mg, Qd		Allergan	
	Z-Pak			S	Oral	Unk Unk, Qd		Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2017	13287062	NON-EXPEDITED			US-PFIZER INC-2017080052		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Glycosylated Haemoglobin Decreased; Headache; Skin Disorder	Azithromycin			S		Daily (2 Tablets On The First Day And Then 1 Tablet Daily)		Pfizer	
	Metformin			C	Oral	1000 Mg, 2x/Day		Not Reported	
	Baby Aspirin			C	Oral	81 Mg, 1x/Day		Not Reported	
	Clopidogrel			C	Oral	75 Mg, 1x/Day		Not Reported	
	Glipizide			C	Oral	10 Mg, 2x/Day		Not Reported	
	Pioglitazone			C	Oral	45 Mg, 1x/Day		Not Reported	
	Lisinopril			C	Oral	20 Mg, 1x/Day		Not Reported	
	Simvastatin			C	Oral	40 Mg, 1x/Day		Not Reported	
	Allopurinol			C	Oral	300 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2017	13288697	NON-EXPEDITED			US-PFIZER INC-2017083930			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2017	13291533	DIRECT		OT			19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Zithromax			S	Oral	Quantity:5 Tablet(S);		Pfizer	
	Atenolol			C				Not Reported	
	Escitalopram			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	12272742	NON-EXPEDITED			US-PFIZER INC-2016197871		50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Benzocaine		Y	S		Unk		Pfizer
	Tigan			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Skelaxin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Heparin Sodium			S		Unk		Unknown
	Asa			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported
	Percodan			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Sodium Benzoate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13101487	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017004464		28 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Diarrhoea; Gastrointestinal Disorder; Product Use Issue	Zithromax			S	Oral	500 Mg, 1x/Day (The First Day)		Pfizer
	Zithromax			S		250 Mg, 1x/Day (250 Mg From Day 2 To Day 5)		Pfizer
	Zithromax Ativan			S C	Oral	0.5 Mg, 1x/Day		Pfizer Not Reported
	Ativan			C				Not Reported

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

	Diphenhydramine		C	Oral		25 Mg, As Needed (Hs Prn)			Not Reported
	Diphenhydramine		C						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13232569	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017060847		5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematemesis; Vomiting	Azithromycin			S			Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13290709	NON-EXPEDITED			US-PFIZER INC-2017086713			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S			Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13290737	NON-EXPEDITED			US-PFIZER INC-2017086343		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Miliaria	Zithromax			S			250 Mg, Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13290752	NON-EXPEDITED			US-PFIZER INC-2017088092			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Azithromycin			S		Intravenous (not otherwise specified)	Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2017	13292457	DIRECT		DE			70 YR	Male	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Respiratory Failure	Zithromax Zmax			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2017	13297497	DIRECT					31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper; Dizziness; Muscular Weakness; Nausea; Vision Blurred; Vomiting	Azithromycin			S	Oral			Not Reported	
	Tylenol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2017	13226854	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017055805		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Vasodilatation; Vomiting	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Total		Pfizer	
	Simvastatin			C	Oral	20 Mg, Unk		Not Reported	
	Coumadin			C	Oral	5 Mg, Unk		Not Reported	
	Deltacortene			C	Oral	5 Mg, Unk		Not Reported	
	Cardicor			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2017	13297666	NON-EXPEDITED			US-PFIZER INC-2017091754		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain	Zithromax			S	Oral	2 Df, Single (First Day)		Pfizer	
	Zithromax			S	Oral	1 Df, 1x/Day (Second, Third, And Fourth Day)		Pfizer	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2017	12884877	EXPEDITED (15-DAY)		OT	IL-PFIZER INC-2016492427			Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Neonatal Aspiration; Pyloric Stenosis	Azithromycin			S	Transplacental	500 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2017	13122298	NON-EXPEDITED			US-PFIZER INC-2017006408		71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S	Oral	Two 250 Mg Tab, Daily		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2017	13301989	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1013607			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Fall; Hepato-Lenticular Degeneration; Syncope	Azithromycin			S	Oral	5 Day Course		Not Reported	
	Dextromethorphan W/Promethazine			C	Other			Mylan	
	Salbutamol			C	Unknown	As Needed		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2017	13302799	NON-EXPEDITED			US-PFIZER INC-2017084099			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2017	13303451	EXPEDITED (15-DAY)		DS, HO, OT	GB-PFIZER INC-2017089674		12 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis	Azithromycin			S		Unk		Pfizer	
	Salbutamol			C	Respiratory (inhalation)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2017	13303852	EXPEDITED (15-DAY)		DS, HO, OT	GB-MYLANLABS-2017M1013780			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis	Azithromycin			S				Not Reported	
	Salbutamol			C	Respiratory (inhalation)			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2017	10138555	NON-EXPEDITED			US-PFIZER INC-2014114781			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Niacin			S		Unk		Not Reported	
	Salsalate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2017	13131394	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1002918			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hypoxia; Tachypnoea	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	

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

Ceftriaxone			S		Unknown	Unk	Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2017	13305902	NON-EXPEDITED		OT	US-WARNER CHILCOTT, LLC- 1063958			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Asacol			S	Oral			Warner Chilcott	
	Humira			S	Subcutaneous			Not Reported	
	Methotrexate (Methotrexate Sodium)			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Remicade			S	Unknown			Not Reported	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2017	13306325	EXPEDITED (15-DAY)		HO	FR-TELIGENT, INC- IGIL20170074		20 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Back Pain; Pancreatitis Acute	Ceftazidime			S				Not Reported	
	Bactrim			S	Unknown			Not Reported	
	Nebcine			S	Unknown			Not Reported	
	Triflucan			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Nureflex			S	Oral			Not Reported	
	Mucomyst			C	Unknown			Not Reported	
	Creon			C	Unknown			Not Reported	
	Inipomp			C	Unknown			Not Reported	
	Beclometasone Dipropionate			C	Unknown			Not Reported	
	Pulmozyme			C	Unknown			Not Reported	
	Innovair			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2017	13307004	EXPEDITED (15-DAY)		OT	FR-ASTELLAS-2017US009130		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dry Mouth; Graft Versus Host Disease In Skin; Weight Decreased	Ambisome			S	Intravenous (not otherwise specified)	Unk, Unknown Freq.		Astellas	
	Neoral			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Solupred /00016201/			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Zithromax			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Bactrim			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Amoxicillin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Androcur			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Amlor			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Ulcars /00434701/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Ursolvan			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Plitican			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Zophren /00955301/			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Xanax			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Seresta			C	Unknown	Unk Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2017	13307326	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017091344		41 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dry Mouth; Graft Versus Host Disease; Weight Decreased	Zithromax			S		Unk		Pfizer	
	Neoral			S		Unk		Not Reported	
	Solupred (Prednisolone)			S		Unk		Not Reported	
	Ambisome			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

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

Amoxicillin	C	Unk	Not Reported
Androcur	C	Unk	Not Reported
Amlor	C	Unk	Not Reported
Ulcarr [Sucralfate]	C	Unk	Not Reported
Ursolvan	C	Unk	Not Reported
Plitican	C	Unk	Not Reported
Zophren	C	Unk	Not Reported
Xanax	C	Unk	Not Reported
Seresta	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2017	13307656	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017096399		48 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Atrial Fibrillation	Zithromax			S	Oral	Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13310078	DIRECT	Y					Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Product Substitution Issue	Z-Pac (Azithromycin)			S				Greenstone	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Mar-2017	13311904	EXPEDITED (15-DAY)		DS, HO, OT	GB-TEVA-745298ACC		12 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cholelithiasis	Azithromycin			S				Not Reported	
	Salbutamol			C	Respiratory (inhalation)			Not Reported	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2017	13321320	EXPEDITED (15-DAY)		OT	PHHY2017FR032291			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Dry Mouth; Graft Versus Host Disease In Skin; Weight Decreased	Neoral			S	Unknown	Unk		Novartis
	Solupred (Prednisolone)			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Ambisone			S	Unknown	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Zophren			C	Unknown	Unk		Not Reported
	Amoxicillin			C	Unknown	Unk		Not Reported
	Androcur			C	Unknown	Unk		Not Reported
	Amlor			C	Unknown	Unk		Not Reported
	Ulcars [Sucralfate]			C	Unknown	Unk		Not Reported
	Ursolvan			C	Unknown	Unk		Not Reported
	Plitican			C	Unknown	Unk		Not Reported
	Xanax			C	Unknown	Unk		Not Reported
	Seresta			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2017	13322005	NON-EXPEDITED		HO	US-PFIZER INC-2017094242			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Irregular	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13315545	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-05432			Male	USA

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

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

Abdominal Pain Upper; Back Pain	Azithromycin Tablets Usp, 250 Mg		S	Unknown	Unk Unk,Unk,Unknown			Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13315547	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-05520			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	Unk Unk,Unk,Unknown		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13315551	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2016-05600			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Unknown	Unk Unk,Unk,Unknown		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13315553	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-00121			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Azithromycin Tablets Usp, 500 Mg			S	Unknown	Unk Unk,Unk,Unknown		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13315555	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2017-00574		33 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Pain In Extremity	Azithromycin Dihydrated 500 Mg Coated Tablet			S	Oral	500 Mg,As Directed,		Not Reported	
	Raltegravir			C	Oral	400 Mg,Bid,		Not Reported	
	Tenofovir			C	Oral	Unk Unk,Unk,Unknown		Not Reported	

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

Bactrim			C		Oral	Unk Unk,Qd,			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13315849	EXPEDITED (15-DAY)		HO	DE-LUPIN PHARMACEUTICALS INC.-E2B_00007191		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Azithromycin			S	Oral	500 Mg,Unk,Unknown		Lupin	
	Azithromycin			S				Lupin	
	Ibuprofen			S	Oral	800 Mg,Unk,Unknown		Not Reported	
	Salbutamol			C	Respiratory (inhalation)	Unk Unk,Prn,		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2017	13317735	NON-EXPEDITED			US-PFIZER INC- 2017096932		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Phenergan			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Compazine			S		Unk		Not Reported	
	Decadron			S		Unk		Not Reported	
	Reglan			S		Unk		Not Reported	
	Aspirin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13299809	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2017037453		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Zithromax			S	Oral	250 Mg, 2x/Day		Pfizer	

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

Navelbine			C		Oral	120 Mg, Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13330126	EXPEDITED (15-DAY)		DS, HO, OT	PHHY2017GB031864		12 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis	Azithromycin			S	Unknown			Novartis	
	Salbutamol			C	Respiratory (inhalation)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13330340	NON-EXPEDITED			US-MEDA-2017020089			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Expired Product Administered; Muscular Weakness	Dymista Nasal Spray			S				Meda	
	137mcg/50mcg								
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13332034	NON-EXPEDITED			US-PFIZER INC-2017108122		10 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Pruritic	Azithromycin			S	Oral	10 MI, Day 1 And Then 5 MI, On Day 2-5		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13333084	EXPEDITED (15-DAY)		CA, HO	US-TEVA-748061USA		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Fall; Hepato-Lenticular Degeneration; Syncope	Azithromycin			S	Oral	5 Day Course		Not Reported	
	Dextromethorphan W/Promethazine			C	Other			Not Reported	

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

Salbutamol			C	Unknown	As Needed	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13334007	EXPEDITED (15-DAY)		OT	PHHY2017JP034405			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Maternal Dose: 2 G		Novartis	
	Azithromycin			S	Unknown	500 Mg, Qd		Novartis	
	Ceftriaxone			S	Transplacental	Maternal Dose: 1 G, Qd		Not Reported	
	Piperacillin, Tazobactam			S	Transplacental	Maternal Dose: 4.5 G, Q8h		Not Reported	
	Prednisolone			S	Transplacental	Maternal Dose: 40 Mg, Qd		Not Reported	
	Heparin Sodium			S	Transplacental	Maternal Dose: 10000 U, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13334011	EXPEDITED (15-DAY)		OT	PHHY2017JP033141		35 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Labour	Azithromycin			S	Oral	2 G, Unk		Novartis	
	Azithromycin			S	Unknown	500 Mg, Qd		Novartis	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported	
	Piperacillin, Tazobactam			S	Unknown	4.5 G, Q8h		Not Reported	
	Prednisolone			S	Unknown	40 Mg, Qd		Not Reported	
	Heparin Sodium			S	Unknown	10000 U, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13334017	EXPEDITED (15-DAY)		OT	PHHY2017RO031778		55 YR	Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

Headache; Hypertension; Product Administration Error	Azitromicina	S	Oral	1000 Mg, Qd	Novartis
	Atacand	C	Oral	8 Mg, Qd	Not Reported
	Tenaxum	C	Oral	1 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2017	13334020	EXPEDITED (15-DAY)		LT	PHHY2017RO031254		59 YR	Female	ROM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cheilitis; Dysphagia; Dysphagia; Dyspnoea; Pharyngeal Inflammation; Respiratory Failure	Azitromicin Sandoz			S	Oral	500 Mg, Qd		Novartis
	Fenspiride			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13250380	EXPEDITED (15-DAY)		HO, OT	JP-UCBSA-2017005387		71 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Epilepsy; Off Label Use; Torsade De Pointes	E Keppra			S	Intravenous drip	500 Mg, 2x/Day (Bid)		Ucb
	E Keppra			S				Ucb
	5-Fu			S	Intravenous drip	Unk		Not Reported
	Cisplatin			S	Intravenous drip	Unk		Not Reported
	Ceftriaxone Sodium			S	Intravenous drip	Unk		Not Reported
	Piperacillin And Tazobactam			S	Intravenous drip	Unk		Not Reported
	Zithromac			S	Intravenous drip	Unk		Not Reported
	Crestor			C	Oral	Unk		Not Reported
	Feburic			C	Oral	Unk		Not Reported
	Carbocisteine			C	Oral	Unk		Not Reported
	Sodium Chloride			C	Oral	Unk		Not Reported
	Miya Bm			C	Oral	Unk		Not Reported
	Bromhexine Hydrochloride			C		Unk		Not Reported
	Diazepam			C	Intravenous (not	5 Mg		Not Reported

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

Aspara Potassium		C		otherwise specified) Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13332146	EXPEDITED (15-DAY)		HO, LT, OT	GB-AUROBINDO-AUR- APL-2017-30621		12 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis	Azithromycin			S	Unknown			Aurobindo	
	Salbutamol			C	Respiratory (inhalation)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13332540	EXPEDITED (15-DAY)		OT	RU-TEVA-746937ISR		9 YR	Male	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Gastritis; Duodenitis; Duodenogastric Reflux; Gastritis; Helicobacter Gastritis; Sphincter Of Oddi Dysfunction	Sumamed Forte			S	Unknown	200mg/5ml		Not Reported	
	Amixin			S	Unknown			Not Reported	
	Panavir Inlight			S	Unknown			Not Reported	
	Isofra			S	Unknown			Not Reported	
	Ceftriaxone			S		2000 Iu (International Unit) Daily;		Not Reported	
	Saline Solution			S		Inhalations		Not Reported	
	Chlorhexidine			S		Treatment Of The Oropharynx		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13332692	NON-EXPEDITED		HO, OT	US-PFIZER INC- 2017099882			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatotoxicity	Zithromax			S		Unk (Extra Strength)		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13332742	NON-EXPEDITED			US-PFIZER INC-2017099467		57 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13333332	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2017SP004392			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Prednisolone			S	Transplacental	Unk, Unknown		Not Reported	
	Azithromycin			S	Transplacental	Unk, Unknown		Not Reported	
	Vancomycin			S	Transplacental	Unk, Unknown		Strides	
	Betamethasone			S	Transplacental	Unk, Unknown		Not Reported	
	Clavulanic Acid W/Ticarcillin			S	Transplacental	Unk, Unknown		Not Reported	
	Ceftriaxone			S	Transplacental	Unk, Unknown		Not Reported	
	Oxygen			S	Transplacental	Unk, Unknown		Not Reported	
	Albuterol /00139501/			S	Transplacental	Unk, Unknown		Not Reported	
	Labetalol			S	Transplacental	Unk, Unknown		Not Reported	
	Magnesium Sulfate			S	Transplacental	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13333443	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2017SP004391			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Prednisolone			S	Transplacental	Unk, Unknown		Not Reported	
	Azithromycin			S	Transplacental	Unk, Unknown		Not Reported	
	Vancomycin			S	Transplacental	Unk, Unknown		Strides	

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

	Betamethasone	S	Transplacental	Unk, Unknown	Not Reported
	Clavulanic Acid W/Ticarcillin	S	Transplacental	Unk, Unknown	Not Reported
	Ceftriaxone	S	Transplacental	Unk, Unknown	Not Reported
	Oxygen	S	Transplacental	Unk, Unknown	Not Reported
	Albuterol /00139501/	S	Transplacental	Unk, Unknown	Not Reported
	Labetalol	S	Transplacental	Unk, Unknown	Not Reported
	Magnesium Sulfate	S	Transplacental	Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13335293	NON-EXPEDITED			US-PFIZER INC-2017110557		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Pain	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Once A Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2017	13335579	NON-EXPEDITED			US-PFIZER INC-2017108907			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2017	13335476	EXPEDITED (15-DAY)			US-CIPLA LTD.-2016US17366			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Sertraline			S	Oral	50 Mg, Qd, In The Evening		Invagen	
	Azithromycin			S	Unknown	Unk		Cipla	
	Azithromycin			S				Cipla	
	Amoxicillin			S	Unknown	Unk, Bid		Not Reported	
	Amoxicillin			S				Not Reported	

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

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13336909	NON-EXPEDITED			US-PFIZER INC-2017103571			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13337038	NON-EXPEDITED			US-PFIZER INC-2017110651		57 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Infusion Site Pain	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13337063	NON-EXPEDITED			US-PFIZER INC-2017109572		37 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Infusion Site Pain	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Mar-2017	13337740	EXPEDITED (15-DAY)		OT	PL-TEVA-749061ACC			Female	POL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Balance Disorder; Decreased Appetite; Dizziness; Ear Disorder; Headache; Hearing Disability; Nausea; Tinnitus	Sumamed 500 Mg			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13341297	EXPEDITED (15-DAY)		HO	PHHY2017ES039115		86 YR	Unknown	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rectal Haemorrhage	Sintrom			S	Oral	2 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Lorazepam			C	Unknown	1 Mg, Qd		Not Reported	
	Silodosin			C	Unknown	8 Mg, Qd		Not Reported	
	Atenolol			C	Unknown	25 Mg, Q12h		Not Reported	
	Metformin			C	Unknown	850 Mg, Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13342843	NON-EXPEDITED			US-PFIZER INC-2017106802			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Mar-2017	13343816	NON-EXPEDITED			US-MEDA-2017030005		72 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; Nasal Congestion; Nasal Discomfort; Off Label Use; Product Quality Issue	Dymista Nasal Spray			S				Meda	
	137mcg/50mcg								
	Z-Pak			S	Oral			Not Reported	
	Z-Pak			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Mar-2017	12296881	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2016GSK055336		77 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Concomitant Disease	Avodart	S	Oral	0.5 Mg, 1d	Glaxosmithkline
Aggravated; Dermatitis	Privigen	S	Intravenous (not otherwise specified)	40 G, Cyc	Glaxosmithkline
Exfoliative Generalised;	Privigen	S	Intravenous (not otherwise specified)	Unk	Glaxosmithkline
Eosinophilia; Hepatic	Privigen	S	Intravenous (not otherwise specified)	Unk	Glaxosmithkline
Function Abnormal;	Privigen	S	Intravenous (not otherwise specified)	Unk	Glaxosmithkline
Oedema; Skin Exfoliation	Privigen	S	Intravenous (not otherwise specified)	Unk	Glaxosmithkline
	Loperamide Hydrochloride	S	Oral	1 Df, 1d	Glaxosmithkline
	Desloratadine	S	Oral	1 Df, 1d	Glaxosmithkline
	Loperamide	S	Oral	1 Df, 1d	Glaxosmithkline
	Josir	S	Oral	0.4 Mg, 1d	Glaxosmithkline
	Zithromax Monodose	S	Oral	250 Mg, Z	Not Reported
	Zithromax Monodose	S	Oral	1 Df, Unk	Not Reported
	Zydelig	S	Oral	3 Df, Qd	Not Reported
	Spasfon (Phloroglucinol, Trimethylphloroglucinol)	S	Oral	2 Df, 1d	Not Reported
	Ergyphilus Confort	S	Oral	2 Df, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2017	13025720	EXPEDITED (15-DAY)		HO	PHHY2016SI166809		42 YR	Female	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia; Pulmonary Embolism	Azithromycin			S	Unknown			Novartis
	Moxifloxacin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2017	13169320	NON-EXPEDITED			US-PFIZER INC-2017038771		59 YR	Female	USA

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

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

Urticaria	Azithromycin	S	250 Mg, 2x/Day	Pfizer
	Reglan	S	5 Mg, 2x/Day	Not Reported
	Reglan	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2017	13347129	NON-EXPEDITED			US-PFIZER INC-2017106530			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Penicillin G Procaine			S		Unk		Pfizer
	Prevacid			S		Unk		Not Reported
	Lasix			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2017	13347895	EXPEDITED (15-DAY)		HO	PHHY2017TR037105		20 YR	Male	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Posterior Reversible Encephalopathy Syndrome	Azithromycin			S	Unknown			Novartis
	Vancomycin			S	Unknown			Not Reported
	Aciclovir			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Posaconazole			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2017	10842336	NON-EXPEDITED			US-PFIZER INC-2015061046			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer

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

Azithromycin	S	Unk	Pfizer
Xanax	S	Unk	Pfizer
Ciprofloxacin	S	Unk	Unknown
Demerol	S	Unk	Pfizer
Cipro	S	Unk	Not Reported
Demerol	S	Unk	Not Reported
Clinoril	S	Unk	Not Reported
Enablex	S	Unk	Not Reported
Acetaminophen W/Oxycodone	S	Unk	Not Reported
Actos	S	Unk	Not Reported
Vitamin D2	S	Unk	Not Reported
Darvon	S	Unk	Not Reported
Reglan	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2017	13348862	NON-EXPEDITED			US-TEVA-648626USA		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Adverse Event; Burning Sensation; Drug Hypersensitivity; Fatigue; Fatigue; Headache; Headache; Rash	Escitalopram			S	Unknown			Ivax
	Baclofen			S	Unknown			Ivax
	Citalopram			S	Unknown			Pliva
	Eszopiclone			S	Unknown			Teva
	Mirtazapine			S	Unknown			Teva
	Penicillin (Benzylpenicillin)			S	Unknown			Teva
	Trazodone			S	Unknown			Barr
	Zolpidem			S	Unknown			Teva
	Lyrica			S	Unknown	200 Milligram Daily;		Not Reported
	Daypro			S	Unknown			Not Reported
	Levoxyl			S	Unknown			Not Reported

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

Protonix	S	Unknown	Not Reported
Zithromax	S	Unknown	Not Reported
Synthroid	S	Unknown	Not Reported
Tegretol Xr	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2017	13350055	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170317649		36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Opportunistic Infection; Pneumocystis Jirovecii Pneumonia; Rash	Prezcobix			S	Oral			Not Reported	
	Bactrim Ds			S	Unknown	2 Tablets		Not Reported	
	Emtricitabine W/Tenofovir			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2017	13353898	DIRECT	Y	OT			69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pollakiuria	Azithromycin			S	Oral			Not Reported	
	Simvastatin			C				Not Reported	
	Lorazepam			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2017	13305180	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP007869		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Fall; Hepato-Lenticular Degeneration; Hyperhidrosis; Skin Laceration; Syncope;	Azithromycin			S	Oral	Unk		Apotex	
	Promethazine - Dextromethorphan			C	Unknown	Unk		Not Reported	
	Albuterol /00139501/			C	Unknown	Unk, Prn		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Vaginal Haemorrhage

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2017	13333571	EXPEDITED (15-DAY)		OT	KR-PFIZER INC-2017097493		5 YR	Unknown	KOR
<u>Preferred Term</u>		<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Brain Death; Cardiac Arrest; Disability; Product Use Issue		Zithromax			S	Intravenous bolus	60 Mg/Kg, Unk		Pfizer
		Ceftriaxone			C		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2017	13355361	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2017111717		80 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rectal Haemorrhage		Sutent			S		37.5 Mg, Cyclic		Pfizer
		Azithromycin			S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2017	13355451	NON-EXPEDITED			US-PFIZER INC-2017112983		39 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity		Medrol			S		Unk		Pfizer
		Augmentin			S		Unk		Not Reported
		Zithromycin			S		Unk		Not Reported
		Levaquin			S		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2017	13359278	DIRECT	Y	DE			77 YR	Female	USA
<u>Preferred Term</u>		<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death		Cyclosporine 100mg			S		Route - G Tube		Ivax

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

Azithromycin 250mg	S	Teva
Arimidex	C	Not Reported
Levothyroxin	C	Not Reported
Carb/Levo	C	Not Reported
Prednisone	C	Not Reported
Simvastatin	C	Not Reported
Omeprazole	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2017	13162624	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2016579329		70 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Feeling Hot; Hypersensitivity; Urticaria	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Micardis			S		20 Mg, Unk		Not Reported
	L-Thyroxine			C		75 Ug, Daily		Not Reported
	Nexium			C		20 Mg, Daily		Not Reported
	Presomen			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2017	13358818	NON-EXPEDITED			US-AKORN-52258			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pain	Azasite 1%			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2017	13362423	DIRECT	Y	DE			26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Unresponsive To Stimuli; Vomiting	Methadone			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2017	13362471	NON-EXPEDITED			US-PFIZER INC-2017118310			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2017	13363871	NON-EXPEDITED			US-PFIZER INC-2017118575		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Methylprednisolone Acetate			S		Unk		Pfizer	
	Norco			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Evoxac			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2017	13364498	EXPEDITED (15-DAY)		HO	GXKR2017DE001637		53 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Circulatory Collapse; Hyperhidrosis; Nausea; Syncope; Visual Field Defect	Azithromycin Hexal			S	Oral	500 Mg, Once/Single		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2017	13368501	NON-EXPEDITED			US-PFIZER INC-2017123679		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Feeling Abnormal; Pain In Extremity; Sinusitis; Taste Disorder	Zithromax	S			Unk	Pfizer
	Lenvima	S	Oral		24 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2017	13372244	DIRECT					32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain; Flatulence; Gastrointestinal Sounds Abnormal	Azithromycin Tablets Usp			S	Oral	Quantity:6 Tablet(S);Other Frequency:2/1st Day;		Teva	
	Vitamin B Complex			C				Not Reported	
	Vitamin C			C				Not Reported	
	Multivitamin (Without Iron)			C				Not Reported	
	Probiotics			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2017	13189933	NON-EXPEDITED			US-PFIZER INC-2017048218		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13256645	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017066713		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Potassium Decreased; Blood Pressure Increased; Feeling Abnormal; Heart Rate Increased; Intentional Product Misuse; Tinnitus; Transient Ischaemic Attack; Tremor; Vomiting	Azithromycin			S	Oral	500 Mg, Single		Pfizer	
	Azithromycin			S				Pfizer	
	Amlodipine			C		2.5 Mg, 1x/Day		Not Reported	
	Levothyroxine			C		50 Ug, 1x/Day		Not Reported	
	Atorvastatin			C		5 Mg, 1x/Day		Not Reported	
	Preservision Areds 2			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Organic Calcium	C	Unk	Not Reported
Vitamin C	C	500 Mg, Unk	Not Reported
Florastor Probiotic	C	Unk	Not Reported
Laxaclear Polyethylene Glycol	C	Unk	Not Reported
Qunol Coq 10	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13324318	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2017080819		3 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Papule; Product Complaint; Rash Pruritic	Zithromax			S	Oral	4 MI, Daily		Pfizer	
	Zithromax			S				Pfizer	
	Ben-U-Ron			C	Oral	5.5 MI, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13376430	NON-EXPEDITED			US-PFIZER INC-2017128192		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Metoprolol Tartrate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Toprol XL			S		Unk		Not Reported	
	Cefixime			S		Unk		Not Reported	
	Plavix			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2017	13379517	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017129109		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaphylactic Reaction; Erythema; Respiratory Distress; Sepsis; Sopor	Zitromax	S	Intravenous (not otherwise specified)	500 Mg, Single	Pfizer
	Allopurinol	C		Unk	Not Reported
	Dibase	C	Oral	20 Gtt, Unk	Not Reported
	Losazid	C		Unk	Not Reported
	Lansox	C		Unk	Not Reported
	Femara	C		Unk	Not Reported
	Movicol	C		Unk	Not Reported
	Riopan (Magaldrat)	C		Unk	Not Reported
	Oxycontin	C	Oral	40 Mg, Unk	Not Reported
	Simestat	C		Unk	Not Reported
	Spiriva	C		Unk	Not Reported
	Trittico	C		Unk	Not Reported
	Halcion	C		Unk	Not Reported
	Depakin Chrono	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2017	13381101	NON-EXPEDITED			US-PFIZER INC- 2017130713			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Toradol			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2017	13383508	EXPEDITED (15-DAY)		OT	US-TEVA-754275USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Haematochezia; Nausea		Azithromycin		S		Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2017	13384903	NON-EXPEDITED			US-PFIZER INC- 2017130827			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2017	13138757	NON-EXPEDITED			US-PFIZER INC- 2017024663		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Rocephin			S		Unk		Not Reported	
	Rocephin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2017	13232764	NON-EXPEDITED			US-PFIZER INC- 2017061464			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Arthralgia; Feeling Abnormal; Myalgia	Azithromycin			S		250 Mg, 1x/Day		Pfizer	
	Azithromycin			S				Pfizer	
	Mycobutin			C		300 Mg, 1x/Day		Not Reported	
	Mycobutin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2017	13232767	NON-EXPEDITED			US-PFIZER INC- 2017061390		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia;	Azithromycin			S		250 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Auditory Disorder; Back Pain; Cough; Eye Pain; Eye Pruritus; Eye Swelling; Gait Disturbance; Headache; Impaired Driving Ability; Myalgia; Visual Impairment	Azithromycin Mycobutin Mycobutin Ethambutol	S S S C	300 Mg, 1x/Day Unk	Pfizer Pfizer Pfizer Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2017	13384885	DIRECT	Y	HO			11 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hospitalisation	Zen Pep 15000 Units			S	Oral			Aptalis
	Azithromycin 250mg			S	Oral			Teva
	Pulmozyme			C				Not Reported
	Aquadeks			C				Not Reported
	Lansoprazole			C				Not Reported
	Ciprofloxacin			C				Not Reported
	Tobramycin			C				Not Reported
	Proair			C				Not Reported
Triamcinolone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2017	13385298	EXPEDITED (15-DAY)		DE	PHHY2017BE040851		55 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Syncope	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Litican			C	Oral	50 Mg, Tid		Not Reported
	Paracetamol Teva			C	Oral	1 G, Tid		Not Reported
	Lorazepam Eg			C	Oral	2.5 Mg, Bid		Not Reported
	Cymbalta			C	Oral	60 Mg, Qd		Not Reported
	Sumatriptan Sandoz			C	Oral	100 Mg, Prn		Not Reported
	Pantoprazole Eg			C	Oral	40 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Fenofibrate Eg	C	Oral	200 Mg, Qd				Not Reported	
	Aldactone	C	Oral	25 Mg, Qd				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2017	13386690	NON-EXPEDITED			US-PFIZER INC-2017135528			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13240029	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017019957		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Bacterial Infection; Bronchitis; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Night Sweats; Product Complaint; Product Use In Unapproved Indication; Pyrexia	Breo Ellipta Inhalation Powder			S		1 Puff(S), 1d		Glaxosmithkline	
	Breo Ellipta Inhalation Powder			S		Unk		Glaxosmithkline	
	Z-Pak			S		Unk		Not Reported	
	Z-Pak			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13389617	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-137138		35 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Pleural Effusion	Azithromycin			S	Oral	2 G, Unk		Sun	
	Azithromycin			S	Unknown	500 Mg Every 24h		Sun	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported	
	Prednisolone			S	Unknown	40 Mg, Daily		Taro	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Piperacillin/Tazobactam	S	Unknown	4.5 G, Tid		Not Reported			
	Heparin Sodium	S	Unknown	10000 U Daily		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13389987	EXPEDITED (15-DAY)		HO	CA-TEVA-753993ACC		112 DAY	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dehydration; Nausea; Vomiting	Azithromycin			S	Oral	Once		Not Reported	
	Acyclovir			C				Not Reported	
	Ceftriaxone For Injection Usp			C				Not Reported	
	Ketorolac			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13390381	NON-EXPEDITED			US-PFIZER INC- 2017136332			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cleocin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13390425	NON-EXPEDITED			US-PFIZER INC- 2017135723			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Malaise	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13390458	NON-EXPEDITED			US-PFIZER INC- 2017139358			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13390835	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Transcription Medication Error	Azithromycin Azithromycin 500 Mg			S	Oral	Suspension Oral 165 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13392877	EXPEDITED (15-DAY)		OT	PHHY2017RO044561		41 YR	Female	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Unknown			Novartis	
	Ampicillin Trihydrate W/Clavulanate Potassium			S	Unknown			Not Reported	
	Cephalosporin Nos			S	Unknown			Not Reported	
	Atosiban			S	Unknown			Not Reported	
	Progesterone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2017	13392888	EXPEDITED (15-DAY)		OT	PHHY2017RO047540			Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental			Novartis	
	Ampicillin Trihydrate W/Clavulanate Potassium			S	Transplacental			Not Reported	
	Cephalosporin Nos			S	Transplacental			Not Reported	
	Atosiban			S	Transplacental			Not Reported	
	Progesterone			S	Transplacental			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13392889	EXPEDITED (15-DAY)		OT	PHHY2017RO047539			Female	ROM
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental			Novartis	
	Ampicillin Trihydrate W/Clavulanate Potassium			S	Transplacental			Not Reported	
	Cephalosporin Nos			S	Transplacental			Not Reported	
	Atosiban			S	Transplacental			Not Reported	
	Progesterone			S	Transplacental			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-Mar-2017	13395244	DIRECT		LT			6 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Lip Swelling; Nasal Congestion; Pruritus; Rash Maculo-Papular	Zithromax			S				Pfizer	
	Prednisolone			C				Not Reported	
	Loratidine			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Apr-2017	13396723	DIRECT		DS, OT			66 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Anosmia; Quality Of Life Decreased	Azithromycin			S	Oral			Pfizer	
	Boniva			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Apr-2017	13394279	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1019581			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Circulatory Collapse; Hypotension; Vomiting	Azithromycin	S	500 Mg, Unk	Not Reported
	Ceftriaxone	S	1 G, Unk	Mylan
	Normix	C	Unk	Mylan
	Asacol	C	Unk	Mylan
	Simestat	C	Unk	Mylan
	Blopressid	C	Unk	Mylan
	Cardura	C	Unk	Mylan
	Lansoprazole	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2017	13395332	NON-EXPEDITED			US-PFIZER INC- 2017137473		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azulfidine			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Salicylate Sodium			S		Unk		Not Reported
	Disalcid			S		Unk		Not Reported
	Lodine			S		Unk		Not Reported
	Ultram			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Aciphex			S		Unk		Not Reported
	Klor-Con			S		Unk		Not Reported
	Domperidone			S		Unk		Not Reported
	Z-Pak			S		Unk		Not Reported
	Actonel			S		Unk		Not Reported
	Trazodone			S		Unk		Not Reported
	Plavix			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2017	13398042	EXPEDITED (15-DAY)		OT	IN-MYLANLABS-2017M1020555			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Intravenous (not otherwise specified)	20mg/Kg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2017	12347415	EXPEDITED (15-DAY)		OT	PHHY2015FR118476			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Pain; Eye Pain; Eye Pruritus; Growth Of Eyelashes; Keratoacanthoma; Malaise; Visual Acuity Reduced	Lucentis			S	Intraocular	0.5 Mg, Unk (1st Injection In The Left Eye)		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Lucentis			S	Intraocular	0.5 Mg, Left Eye		Not Reported	
	Travatan Polyquad			S	Unknown	Unk		Not Reported	
	Azyter			S	Unknown	Unk		Not Reported	
	Prior (Telmisartan)			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2017	13399375	EXPEDITED (15-DAY)		DE, OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-137394			Female	ROM

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Ventricle Dilatation; Foetal Exposure During Pregnancy; Hydrocephalus; Oligohydramnios; Premature Baby	Atosiban			S	Transplacental	Unk		Not Reported	
	Azithromycin			S	Transplacental	Unk		Sun	
	Progesterone			S	Transplacental	Unk		Not Reported	
	Ampicillin			S				Not Reported	
	Clavulanic Acid			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2017	13399379	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-137524		41 YR	Female	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Premature Delivery	Atosiban			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Sun	
	Progesterone			S	Unknown	Unk		Not Reported	
	Ampicillin			S	Unknown			Not Reported	
	Clavulanic Acid			S	Endocervical			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2017	13399381	EXPEDITED (15-DAY)		OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-137416			Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Atosiban			S	Transplacental	Unk		Not Reported	
	Azithromycin			S	Transplacental	Unk		Sun	
	Progesterone			S	Transplacental	Unk		Not Reported	
	Ampicillin			S				Not Reported	
	Clavulanic Acid			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2017	13402472	EXPEDITED (15-DAY)		HO	FR-INGENUS PHARMACEUTICALS NJ, LLC-ING201703- 00017		34 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure;	Probenecid And Colchicine			S				Ingenus	
Chronic Kidney Disease;	Probenecid And Colchicine			S				Ingenus	
Cough; Diarrhoea; Drug	Probenecid And Colchicine			S				Ingenus	
Interaction; Drug	Cyclosporin A			S				Not Reported	
Intolerance; Haemoptysis;	Pravastatin			S				Not Reported	
Hepatocellular Injury; Left	Azithromycin			S				Not Reported	
Ventricular Failure;	Irbesartan			C				Not Reported	
Leukocytosis;	Hydrocortisone			C				Not Reported	
Lymphopenia; Multiple	Everolimus			C				Not Reported	
Organ Dysfunction	Colimycin			C				Not Reported	
Syndrome;	Colimycin			C				Not Reported	
Rhabdomyolysis; Toxicity	Nicorandil			C				Not Reported	
To Various Agents	Lysine Acetylsalicylate			C				Not Reported	
	Ferrous Ascorbate			C				Not Reported	
	Cotrimoxazole			C				Not Reported	
	Calcium			C				Not Reported	
	Cholecalciferol			C				Not Reported	
	Pancreatin			C				Not Reported	
	Alpha Tocopherol			C				Not Reported	
	Esomeprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2017	13402733	NON-EXPEDITED			US-ROCHE-1835493		23 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oropharyngeal	Ceftriaxone			S	Intramuscular			Not Reported	
Gonococcal Infection;	Ceftriaxone			S	Intraocular			Not Reported	
Treatment Failure	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2017	13254925	NON-EXPEDITED			US-PFIZER INC-2017075147			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2017	13404368	EXPEDITED (15-DAY)		DE	AU-009507513-1703AUS013813		55 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Daptomycin			S				Merck	
	Azithromycin			S				Not Reported	
	Ceftriaxone Sodium			S				Not Reported	
	Ciprofloxacin			S				Not Reported	
	Fluconazole			S				Not Reported	
	Metronidazole			S				Not Reported	
	Piperacillin Sodium (+)			S				Not Reported	
	Tazobactam Sodium							Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2017	13405180	EXPEDITED (15-DAY)		HO, OT	US-BION-006153		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia;	Bexarotene			S				Not Reported	
Hypothyroidism;	Vancomycin			S				Not Reported	
Lymphopenia;	Ceftazidime/Ceftazidime			S				Not Reported	
Pneumocystis Jirovecii	Pentahydrate								
Pneumonia	Ciprofloxacin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Sulfamethoxazole/Trimethoprim			S				Not Reported	
	Cefuroxime			S				Not Reported	
	Atenolol/Atenolol Hydrochloride			C				Not Reported	
	Terazosin/Terazosin			C				Not Reported	
	Hydrochloride								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2017	13405386	NON-EXPEDITED			US-PFIZER INC-2017137986		5 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vertigo	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2017	13408438	DIRECT					69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Fall; Heart Rate Increased; Loss Of Consciousness; Nausea; Presyncope; Tooth Fracture	Macrozit			S	Oral	Quantity:4 Tablet(S);		Not Reported	
	General Multi Vitamin For Women			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2017	13094692	NON-EXPEDITED			US-PFIZER INC-2017000832		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Pain In Extremity; Tendon Rupture	Azithromycin			S		500 Mg, Single		Pfizer	
	Azithromycin			S		250 Mg, Daily		Pfizer	
	Nifedipine Mylan			S		90 Mg, Daily		Not Reported	
	Isosorbide Mononitrate			C		60 Mg, Daily		Not Reported	
	Isosorbide Dinitrate			C	Sublingual	5 Mg, As Needed		Not Reported	
	Clonidine			C		0.2 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2017	13126100	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017014768		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lung Adenocarcinoma; Metastases To Bone	Novatrex	S	Oral	7.5 Mg, Weekly	Pfizer
	Humira	S	Subcutaneous	40 Mg, Every 2 Weeks	Not Reported
	Eupantol	C	Oral	40 Mg, 1x/Day	Not Reported
	Lyrica	C	Oral	75 Mg, 3x/Day (One In The Morning And Two In The Evening)	Not Reported
	Movicol /01749801/	C	Oral	4 Df, 1x/Day	Not Reported
	Paracetamol	C	Oral	500 Mg Eight In One Day (As Needed)	Not Reported
	Solupred /00016201/	C	Oral	40 Mg In The Morning, 20 Mg At Noon	Not Reported
	Skenan Lp	C	Oral	60 Mg, 2x/Day (Morning And Evening)	Not Reported
	Actiskenan	C	Oral	10 Mg Six Times Daily (As Needed)	Not Reported
	Folic Acid	C	Oral	10 Mg, Weekly	Not Reported
	Perindopril	C	Oral	2 Mg, 1x/Day	Not Reported
	Atorvastatin	C	Oral	40 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2017	13278224	EXPEDITED (15-DAY)		HO	DE-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2016- BI-08		70 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Feeling Hot; Hypersensitivity; Rash; Urticaria	Micardis			S	Unknown	Permanently Withdrawn On An Unspecified Date		Boehringer Ingelheim	
	Zithromax			S	Unknown			Not Reported	
	L-Thyroxin			C				Not Reported	
	Presomen			C				Not Reported	
	Nexium			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2017	13407712	EXPEDITED (15-DAY)		OT	AU-TORRENT-		48 YR	Male	AUS

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

00000174

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Drug Ineffective; Off Label Use; Pneumothorax; Subcutaneous Emphysema	Azithromycin			S				Unknown	
	Montelukast			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2017	13409175	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration; Incorrect Dose Administered; Injury; Product Dispensing Error; Transcription Medication Error	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2017	13418752	EXPEDITED (15-DAY)		HO	PHHY2017IT045973		84 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Hypotension; Vomiting	Ceftriaxone Sandoz			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
	Blopresid			S	Unknown			Not Reported	
	Lansoprazole			C	Unknown			Not Reported	
	Normix			C	Unknown			Not Reported	
	Asacol			C	Unknown			Not Reported	
	Simestat			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardura			C			Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2017	13162897	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017032640		89 YR	Male	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Disseminated Intravascular Coagulation	Zithromac			S				Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2017	13414214	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017143302		80 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hypogammaglobulinaemia	Novatrex			S	Oral	2.5 Mg, 2x/Week		Pfizer		
	Novatrex			S	Oral	15 Mg, Weekly		Pfizer		
	Cortancyl			S	Oral	7.5 Mg, Daily		Not Reported		
	Arava			S	Oral	20 Mg, Daily		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-Apr-2017	13414222	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017143354		79 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cervix Carcinoma	Novatrex			S	Oral	2.5 Mg, 2x/Week		Pfizer		
	Novatrex			S		15 Mg, Weekly		Pfizer		
	Cortancyl			S	Oral	7.5 Mg, Daily		Not Reported		
	Anesderm			C				Not Reported		
	Lasilix /00032601/			C				Not Reported		
	Aspegic /00002703/			C				Not Reported		
	Valsartan			C				Not Reported		
	Inexium /01479302/			C				Not Reported		
	Levothyrox			C				Not Reported		
	Dalteparin			C				Not Reported		
	Contramal			C				Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paracetamol			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2017	13416245	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP009417		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2017	13416604	EXPEDITED (15-DAY)		OT	FR-SA-2017SA058563		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypogammaglobulinaemia	Arava			S	Oral			Not Reported	
	Cortancyl			S	Oral	Start Date: Since Last 10 Years		Not Reported	
	Novatrex			S	Oral	2.5 Mgx2/Week		Not Reported	
	Novatrex			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2017	13417521	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017147719		71 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Cordarone			C	Oral	200 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	10084403	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2014107717		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysfunctional Uterine Bleeding; Emotional	Ibuprofen			S		800 Mg, Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Off Label Use; Pre-Eclampsia	Zoloft	S	Oral	Unk	Pfizer
	Zoloft	S			Pfizer
	Hydroxyzine Pamoate	S	Oral	Unk	Pfizer
	Zithromax	S		Unk	Pfizer
	Spiroonolactone	S		Unk	Pfizer
	Doxepin Hcl	S	Oral	Unk	Pfizer
	Amoxicillin	S		Unk	Pfizer
	Topamax	S	Oral	Unk	Not Reported
	Topamax	S	Oral	100 Mg	Not Reported
	Topamax	S	Oral	100 Mg	Not Reported
	Topamax	S			Not Reported
	Meclizine	S	Oral	Unk	Not Reported
	Zyrtec	S	Oral	10 Mg, Unk	Not Reported
	Bactrim	S		Unk	Not Reported
	Amitriptyline Hcl	S		Unk	Not Reported
	Primacare	S	Unknown	Unk	Not Reported
	Ery-Tab	S	Oral	Unk	Not Reported
	Phenazopyridine	S	Oral	Unk	Not Reported
	Maxalt	S	Oral	Unk	Not Reported
	Ferrous Sulfate	C	Oral	Unk	Not Reported
	Iron	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	10084404	EXPEDITED (15-DAY)		CA	US-PFIZER INC- 2014107835			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Attention Deficit Hyperactivity Disorder; Cardiac Murmur; Cardiac Valve Disease; Cleft Lip; Cleft Palate; Decreased Appetite; Ear Disorder;	Ibuprofen			S	Transplacental	800 Mg, Unk		Pfizer	
	Zoloft			S	Transplacental	Dosage Form: Tablets		Pfizer	
	Zoloft			S	Transplacental			Pfizer	
	Doxepin Hcl			S	Transplacental	Dosage Form: Capsule		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Emotional Disorder; Eustachian Tube Dysfunction; Maternal Exposure During Pregnancy	Hydroxyzine Pamoate	S	Transplacental	Dosage Form: Capsule	Pfizer
	Zithromax	S	Transplacental	Dosage Form: Unspecified	Pfizer
	Spironolactone	S	Transplacental	Dosage Form: Unspecified	Pfizer
	Amoxicillin	S	Transplacental	Dosage Form: Unspecified	Pfizer
	Amitriptyline Hydrochloride	S	Transplacental	Dosage Form: Unspecified	Not Reported
	Phenazopyridine	S	Transplacental	Dosage Form: Unspecified	Not Reported
	Bactrim	S	Transplacental	Dosage Form: Unspecified	Not Reported
	Topamax	S	Transplacental	Maternal Dosing	Not Reported
	Topamax	S	Transplacental	100 Mg, Unk	Not Reported
	Topamax	S			Not Reported
	Topamax	S			Not Reported
	Maxalt	S	Transplacental	Dosage Form: Tablets	Not Reported
	Meclizine	S	Transplacental	Dosage Form: Tablet	Not Reported
	Zyrtec	S	Transplacental	10 Mg, Unk	Not Reported
	Primacare	S	Transplacental	Unk	Not Reported
	Ery-Tab	S	Transplacental	Dosage Form: Tablet	Not Reported
	Ferrous Sulfate	C	Transplacental	Dosage Form: Tablet	Not Reported
	Iron	C	Transplacental	Dosage Form: Tablet	Not Reported
	Prenatal Vitamins	C	Transplacental	Dosage Form: Unspecified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	10086307	EXPEDITED (15-DAY)		CA, OT	US-PFIZER INC- 2014104276			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Ear Disorder; Maternal Exposure During Pregnancy	Ibuprofen			S	Transplacental	800 Mg, Unk		Pfizer	
	Zoloft			S	Transplacental	Unk		Pfizer	
	Zoloft			S				Pfizer	
	Hydroxyzine Pamoate			S	Transplacental	Unk		Pfizer	
	Zithromax			S	Transplacental	Unk		Pfizer	
	Amoxicillin			S	Transplacental	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amoxicillin	S		Unk	Pfizer
Spironolactone	S	Transplacental	Unk	Pfizer
Doxepin Hcl	S	Transplacental	Unk	Pfizer
Topamax	S	Transplacental	Unk	Not Reported
Topamax	S	Transplacental	Unk	Not Reported
Topamax	S	Transplacental	Unk	Not Reported
Topamax	S	Transplacental	Unk	Not Reported
Maxalt	S	Transplacental	Unk	Not Reported
Meclizine	S	Transplacental	Unk	Not Reported
Bactrim	S	Transplacental	Unk	Not Reported
Amitriptyline Hydrochloride	S	Transplacental	Unk	Not Reported
Primacare	S	Transplacental	Unk	Not Reported
Ery-Tab	S	Transplacental	Unk	Not Reported
Phenazopyridine	S	Transplacental	Unk	Not Reported
Zyrtec	S	Transplacental	10 Mg, Unk	Not Reported
Ferrous Sulfate	C	Transplacental	Unk	Not Reported
Iron	C	Transplacental	Unk	Not Reported
Prenatal Vitamins	C	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	12249962	EXPEDITED (15-DAY)		HO, OT	US-ENDO PHARMACEUTICALS INC.-2016-002407		65 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Furosemide Tablets			S	Unknown	Unk		Dava
Atelectasis; Bacterial	Lisinopril Tablets			S	Unknown			Vintage
Disease Carrier; Body	Spironolactone Tablets			S	Unknown			Vintage
Temperature Decreased;	Aspirin Ec			S	Unknown			Endo
Cardiac Failure	Folic Acid Tablets			S	Unknown	Unk		Vintage
Congestive; Clostridium	Atorvastatin Calcium			S	Unknown			Not Reported
Difficile Infection;								
Constipation; Decubitus								
Ulcer; Diarrhoea;								



Detailed Report

[illegible]

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	12517122	NON-EXPEDITED			US-PFIZER INC-2016287475		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Avelox /01453202/			S		Unk		Not Reported	
	E-Mycin /00020901/			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	13426741	NON-EXPEDITED		OT	US-PFIZER INC-2017149385			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity; Obstructive Airways Disorder	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	13430014	DIRECT		DS, OT			30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Anhedonia; Anxiety; Asthenia; Chest Discomfort; Chest Pain; Confusional State; Depression; Diarrhoea; Dizziness; Dyspnoea; Dysuria; Faeces Discoloured; Fatigue; Flatulence; Gastrointestinal Disorder; Hypotension; Hypothyroidism; Impaired Driving Ability; Impaired	Zithromax	Y		S	Oral	5 Tablet(S); Pack Directions; Oral		Not Reported	
	Migraine Medications			C				Not Reported	
	Riboflavin (Vitamin B2)			C				Not Reported	
	Candibactin Br			C				Not Reported	
	Magnesium Glycinate			C				Not Reported	
	Plantforce Liquid Iron			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Junior Nutrition Multivitamin			C				Not Reported	
	Nausease Ginger			C				Not Reported	
	Arctostahylos Uva-Ursi			C				Not Reported	
	Juglans Nigra			C				Not Reported	
	Glycyrrhiza Glabra			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Work Ability; Loss Of Employment; Malaise; Migraine; Muscle Spasms; Nausea; Palpitations; Palpitations; Photophobia; Postural Orthostatic Tachycardia Syndrome; Quality Of Life Decreased; Rectal Spasm; Stomatitis; Temperature Regulation Disorder; Tremor; Vertigo; Visual Impairment	Licorice Root Tincture	C C	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2017	13430758	DIRECT	Y	HO			73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13430496	NON-EXPEDITED			US-PFIZER INC- 2017153977			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13433657	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2017M1022105			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Escherichia Infection;	Vancomycin			S	Unknown			Not Reported
Gestational Diabetes;	Azithromycin			S	Unknown			Not Reported
Maternal Exposure During Delivery; Maternal	Ceftriaxone			S	Intravenous (not	2 G Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During Pregnancy	Remifentanyl	S	otherwise specified)		
			Intravenous (not otherwise specified)	0.25 Microg/Kg/Min	Not Reported
	Remifentanyl	S	Intravenous (not otherwise specified)	0.22 Microg/Kg/Min	Not Reported
	Rocuronium	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Propofol	S	Intravenous (not otherwise specified)	150 Mg	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13433663	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1022542			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Endotracheal Intubation; Foetal Exposure During Delivery; Foetal Exposure During Pregnancy; Premature Baby	Vancomycin			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Ceftriaxone			S	Transplacental			Not Reported
	Remifentanyl			S	Transplacental			Not Reported
	Rocuronium			S	Transplacental			Not Reported
	Propofol			S	Transplacental			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2017	13439460	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1022404			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg Daily		Not Reported
	Cordarone			C	Oral	200 Mg, Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13434515	NON-EXPEDITED			US-PFIZER INC-2017151410			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13438874	NON-EXPEDITED		OT	US-ROCHE-682153		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Rocephin			S	Unknown			Not Reported	
	Zithromax			S	Intravenous (not otherwise specified)	Form: Powder For Solution For Infusion		Not Reported	
	Alpha Lipoic Acid			C	Unknown			Not Reported	
	Aspirin C			C	Unknown			Not Reported	
	Milk Thistle			C	Oral			Not Reported	
	Unknown Medication			C	Unknown			Not Reported	
	Super B Complex			C	Oral			Not Reported	
	Gabapentin			C	Unknown			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13439059	NON-EXPEDITED			US-ROCHE-1475979		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Diarrhoea; Hyperhidrosis; Oropharyngeal Pain; Rash; Urticaria; White Blood Cell Count Decreased	Rocephin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	250 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2017	13439458	NON-EXPEDITED			US-PFIZER INC-2017157096		41 YR	Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Effexor			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2017	13251705	NON-EXPEDITED			US-PFIZER INC-2017064145		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Zithromax			S		250 Mg, 6 Tabs		Pfizer	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2017	13444943	NON-EXPEDITED			US-PFIZER INC-2017160600			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Extravasation	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2017	13447328	DIRECT		DS, HO			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Burns Second Degree; Burns Third Degree; Economic Problem; Photosensitivity Reaction; Scar; Visual Impairment	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Pliva	
	Multivitamin			C				Not Reported	
	Centrum Silver			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2017	13446977	DIRECT		OT			54 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Photosensitivity Reaction; Product Label Issue; Sunburn	Aziithromycin			S	Oral	Quantity:5 Tablet(S);		Greenstone
	Viagra			C				Not Reported
	Triamcinolone			C				Not Reported
	Ventolin			C				Not Reported
	Proctozone			C				Not Reported
	Men'S Multivitamins And Minerals			C				Not Reported
	Vitamin C And Zinc (Rda 100% Only)			C				Not Reported
	Staminol			C				Not Reported
	High T			C				Not Reported
	Nasacort			C				Not Reported
	Pb8 Probiotics			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2017	13449108	NON-EXPEDITED			US-PFIZER INC-2017156910			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Feeling Abnormal	Azithromycin			S		250 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2017	13449597	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017160063		41 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Condition Aggravated; Headache; Malaise; Product Use In Unapproved Indication; Raynaud'S Phenomenon	Novatrex			S	Oral	20 Mg, Weekly		Pfizer
	Cortancyl			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	10566981	NON-EXPEDITED			US-PFIZER INC-2014304627			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Macrobid	S	Unk	Not Reported
	Cyprohepatadine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	12929104	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2016504780		53 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Scarletiform	Zithromax			S	Oral	Unk		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer
	Augmentin			C		Unk		Not Reported
	Augmentin			C				Not Reported
	Augmentin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13375599	EXPEDITED (15-DAY)		HO	CA-ROCHE-1912135		72 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension	Atezolizumab			S	Intravenous (not otherwise specified)	The Most Recent Dose Of Atezolizumab Was 03/Mar/2017		Not Reported
	Bevacizumab			S	Intravenous (not otherwise specified)	The Most Recent Dose Of Bevacizumab Was 1400 Mg On 03/Mar/2017		Not Reported
	Azithromycin			S	Oral	Dose Unit Marked As Microgram; Should Be Mg		Not Reported
	Norvasc			S	Oral			Not Reported
	Avalide			C	Oral			Not Reported
	Calcitriol			C	Oral			Not Reported
	Crestor			C	Oral			Not Reported
	Fragmin			C	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Advair	C	Respiratory (inhalation)		Not Reported
Hydrocortisone	C	Topical	1 Other	Not Reported
Tamiflu	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13451762	DIRECT						Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain; Back Pain; Balance Disorder; Constipation; Dyspepsia; Headache; Insomnia; Nephrolithiasis; Product Formulation Issue; Product Substitution Issue; Renal Pain; Tinnitus; Urinary Retention	Azithromycin			S				Greenstone

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13452258	EXPEDITED (15-DAY)		OT	PHHY2017PL052294			Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage	Azitlek			S	Oral			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13455630	NON-EXPEDITED		LT, OT	US-BAYER-2017-071339		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Moxifloxacin Oral			S		Unk		Bayer
	Azithromycin			S				Not Reported
	Clofazimine			S				Not Reported
	Rifampin			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2017	13456353	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017164142			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspiration; Inappropriate Schedule Of Product Administration	Zithromac Sr 2g			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13414727	EXPEDITED (15-DAY)		HO	IT-TEVA-755168ACC		84 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Hypotension; Vomiting	Azithromycin			S				Not Reported	
	Ceftriaxone Sandoz Gmbh - 1 G			S				Not Reported	
	Normix			C				Not Reported	
	Asacol			C				Not Reported	
	Simestat			C				Not Reported	
	Blopresid			C				Not Reported	
	Cardura - 2 Mg Compresse			C				Not Reported	
	Lansoprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13455280	NON-EXPEDITED			US-PFIZER INC-2017164500			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2017	13457021	EXPEDITED (15-DAY)		OT	UA-TEVA-757788ISR			Unknown	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Suspected	Sumamed			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Counterfeit Product

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457041	EXPEDITED (15-DAY)		OT	UA-TEVA-758873ISR			Unknown	UKR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Suspected Counterfeit Product	Sumamed			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457122	EXPEDITED (15-DAY)		OT	UA-TEVA-758874ISR			Unknown	UKR

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia; Suspected Counterfeit Product	Sumamed			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Apr-2017	13457123	EXPEDITED (15-DAY)		OT	CN-009507513-1704CHN007563		5 YR	Unknown	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Peritonsillar Abscess; Pharyngeal Disorder	Singulair (Local Dist)			S	Oral	1 Df, Qd		Merck
	Seretide			S	Respiratory (inhalation)	1 Puff, Bid		Not Reported
	Azithromycin			S	Oral	1 Df, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2017	13389338	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017131547		84 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Circulatory Collapse; Hypotension; Vomiting	Azithromycin			S		500 Mg, Unk		Pfizer
	Ceftriaxone Sandoz			S		1 G, Unk		Not Reported
	Normix			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Asacol			C					Not Reported
	Simestat			C					Not Reported
	Cardura			C					Not Reported
	Blopresid			C					Not Reported
	Lansoprazole			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13460433	NON-EXPEDITED		OT	US-PFIZER INC-2017165691		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Stevens-Johnson Syndrome	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13460518	NON-EXPEDITED			US-PFIZER INC-2017164306			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea	Azithromycin			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13460624	EXPEDITED (15-DAY)		OT	PHHY2017VE054461			Male	VEN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Metformin			S	Transplacental	Maternal Dose: 1500 Mg/Day		Novartis	
	Levothyroxine			S	Transplacental	Maternal Dose: 50 Mg/Day		Not Reported	
	Azithromycin			S	Transplacental	Maternal Dose: 1 G, Unk		Not Reported	
	Gonal-F			S	Transplacental	Maternal Dose: 225 Iu, Unk		Not Reported	
	Cetrotide			S	Transplacental	Maternal Dose: 0.25 Mg, Unk		Not Reported	
	Aspirin			S	Transplacental	Maternal Dose: 81 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Transplacental	Maternal Dose: 5 Mg, Unk	Not Reported
Ovidrel	S	Transplacental	Maternal Dose: 250 Mg, Unk	Not Reported
Utrogestan	S	Transplacental	Maternal Dose: 200 Mg, Every 8 Hours	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13460625	EXPEDITED (15-DAY)		OT	PHHY2017VE054468		36 YR	Female	VEN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Premature Delivery	Metformin			S	Unknown	1500 Mg, Qd		Novartis
	Levothyroxine			S	Unknown	50 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	1 G, Unk		Not Reported
	Gonal-F			S	Unknown	225 Iu, Unk		Not Reported
	Cetrotide			S	Unknown	0.25 Mg, Unk		Not Reported
	Aspirin			S	Unknown	81 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	5 Mg, Unk		Not Reported
	Ovidrel			S	Unknown	250 Mg, Unk		Not Reported
	Utrogestan			S	Vaginal	200 Mg, Q8h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2017	13461184	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP010493		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Treatment Failure	Azithromycin			S	Oral	Unk		Apotex
	Ethambutol			S	Oral	Unk		Not Reported
	Rifampin			S	Oral	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Sulfamethizole W/Trimethoprim			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13375022	NON-EXPEDITED			US-PFIZER INC-2017129340		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Diarrhoea; Dyspepsia; Faeces Discoloured; Insomnia; Malaise; Nausea; Pain; Vomiting	Azithromycin			S	Oral	500 Mg, On Day 1		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13381025	NON-EXPEDITED			US-PFIZER INC-2017125898		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13398059	EXPEDITED (15-DAY)		DS	JP-PFIZER INC-2017006694		65 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diffuse Alopecia; Drug Eruption; Pruritus	Zithromac 250mg			S	Oral	500 Mg, Daily		Pfizer	
	Sisaal			C	Oral	30 Mg, 3x/Day		Not Reported	
	Carbocisteine			C	Oral	500 Mg, 3x/Day		Not Reported	
	Ambroxol			C	Oral	15 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13465996	NON-EXPEDITED			US-PFIZER INC-2017169600		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Ineffective	Zithromax		S			250 Mg, Unk		Pfizer	
	Levaquin		S			500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2017	13466014	NON-EXPEDITED			US-PFIZER INC-2017169349		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Dyspnoea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2017	13469711	EXPEDITED (15-DAY)		LT, OT	US-TORRENT-00002688		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S				Unknown	
	Moxifloxacin			S				Unknown	
	Rifampin			S				Unknown	
	Clofazimine			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13448667	EXPEDITED (15-DAY)		OT	US-CELGENEUS-163-21880-13083542			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystitis; Genital Blister; Rash	Revlimid			S	Oral	15 Milligram		Celgene	
	Revlimid			S	Oral	10 Milligram		Celgene	
	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13471654	NON-EXPEDITED		OT	US-PFIZER INC-2017170864			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13471726	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016R1-112274		35 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Fixed Eruption	Azithromycin			S	Oral	Unk		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13476031	DIRECT	Y	HO			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Azithromycin			S	Oral			Not Reported	
	Levoxyl			C				Not Reported	
	Calcium			C				Not Reported	
	Vit D			C				Not Reported	
	Vitamin C			C				Not Reported	
	Probiotic Drink			C				Not Reported	
	Fish Oil			C				Not Reported	
	Aspirin 81			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2017	13476283	DIRECT		DS, HO, LT, OT			25 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotonia; Joint Range Of Motion Decreased; Muscular Weakness; Musculoskeletal Pain	Zithromax Z-Pak			S	Oral			Not Reported	
	Ritalin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13451016	EXPEDITED (15-DAY)		DE, LT, OT	US-DRREDDYS- USA/USA/17/0088927		57 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chorioretinal Disorder;	Moxifloxacin			S	Unknown			Not Reported
Condition Aggravated;	Azithromycin			S	Unknown			Not Reported
Endocarditis;	Rifampin			S	Unknown			Not Reported
Mycobacterial Infection;	Clofazimine			S	Unknown			Not Reported
Thrombocytopenia; Visual	Linezolid			S	Unknown			Not Reported
Acuity Tests Abnormal								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13476244	EXPEDITED (15-DAY)		LT, OT	US-AUROBINDO-AUR- APL-2017-32929		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo
	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Clofazimine			S	Unknown	Unk		Not Reported
	Rifampin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13476698	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2017172889			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain; Back Pain; Balance Disorder; Condition Aggravated; Constipation; Dyspepsia; Headache; Insomnia; Reaction To Excipient; Renal Pain; Tinnitus; Urinary Retention	Azithromycin			S		500 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13483595	DIRECT	Y	OT			33 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Headache; Hyperhidrosis; Nausea; Pruritus; Rash; Therapy Cessation	Azithromycin 600mg Pliva Inc.			S	Oral	30tab Qd Orally		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13485168	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-138977		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Sun	
	Moxifloxacin			S	Unknown			Not Reported	
	Clofazimine			S	Unknown			Not Reported	
	Rifampin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2017	13485457	NON-EXPEDITED			US-PFIZER INC-2017173338			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	11345017	EXPEDITED (15-DAY)		OT	US-TEVA-573587USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Blood Pressure Fluctuation; Blood Pressure Increased;	Azithromycin			S	Unknown			Not Reported	
Cerebrovascular Accident;	Adalat Cc			C	Oral	90 Milligram Daily;		Not Reported	
Deafness; Ear Pain;	Allegra			C	Oral	120 Milligram Daily;		Not Reported	
Emotional Distress;	Aspirin			C	Oral	81 Milligram Daily;		Not Reported	
Eustachian Tube	Avapro			C	Oral	300 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dysfunction; Gait Inability;	Calcium 600mg Plus D2	C						Not Reported
Headache; Hypoacusis;	Celexa	C	Oral	20 Milligram Daily;				Not Reported
Malaise; Meniere'S	Derm Optic Oil	C						Not Reported
Disease; Oropharyngeal	Fish Oil	C	Oral					Not Reported
Pain; Otitis Media;	Flonase	C						Not Reported
Syncope; Tinnitus;	Lipitor	C	Oral	10 Milligram Daily;				Not Reported
Tinnitus; Tinnitus;	Meclizine	C	Oral	75 Milligram Daily;				Not Reported
Tympanic Membrane	Tramadol	C	Oral	Q6hrs As Needed				Not Reported
Disorder; Vertigo	Xanax	C	Oral	3 Milligram Daily;				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	12761783	NON-EXPEDITED			US-PFIZER INC-2016438019		81 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Motrin			S		Unk		Not Reported
	Baclofen			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Endocet			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13462429	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2017068133		18 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use Issue;	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer
Tubulointerstitial Nephritis;	Zithromac 250mg			S				Pfizer
Tubulointerstitial Nephritis	Unasyn-S			S	Intravenous (not	1.5 G, 4x/Day		Pfizer
And Uveitis Syndrome								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					otherwise specified)				
	Unasyn-S	S						Pfizer	
	Minomycin 100mg	S			Intravenous (not otherwise specified)	100 Mg, 2x/Day		Pfizer	
	Minomycin 100mg	S						Pfizer	
	Gracevit	S			Oral	200 Mg, Daily		Not Reported	
	Gracevit	S						Not Reported	
	Meropen	S			Intravenous (not otherwise specified)	4 G, Daily		Not Reported	
	Meropen	S						Not Reported	
	Sword	S			Oral	Unk		Not Reported	
	Sword	S						Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13484568	NON-EXPEDITED			US-PFIZER INC-2017175030			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Zosyn			S		Unk		Pfizer	
	Piperacillin			S		Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13485756	NON-EXPEDITED			US-AKORN-55185		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Malaise; Rash	Azasite 1% Ophthalmic Solution			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2017	13487508	NON-EXPEDITED			US-ALKERMES INC.-ALK-2016-003060		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased;	Vivitrol			S	Intramuscular	380 Mg, Qmo		Alkermes	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Loss Of Consciousness;	Thorazine	S	Unk	Not Reported
Mobility Decreased;	Zithromycin	S	Unk	Not Reported
Muscle Spasms; Pain;	Lisinopril	C	30 Mg, Unk	Not Reported
Pain In Extremity;	Omeprazole	C	20 Mg, Unk	Not Reported
Paranoia; Seizure;	Promethazine	C	25 Mg, Unk	Not Reported
Somnolence	Methadone	C		Not Reported
	Robaxin	C		Not Reported
	Diazepam	C	5 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13167546	NON-EXPEDITED			US-PFIZER INC-2017039133		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Tetris			S		Unk		Not Reported
	Uripas			S				Not Reported
	Urispas			S		Unk		Not Reported
	Macrodantin			S		Unk		Not Reported
	Tetanus Vaccine			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Tussionex			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Savella			S		Unk		Not Reported
	Pravastatin			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Zetia			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Livalo	S		Unk	Not Reported
Enduracin	S		Unk	Not Reported
Cipro	S		Unk	Not Reported
Biaxin	S		Unk	Not Reported
Keflex	S		Unk	Not Reported
Sulfamethizole	S		Unk	Not Reported
Doxycycline	S		Unk	Not Reported
Floxin	S		Unk	Not Reported
Ceftin	S		Unk	Not Reported
Miralax	C		Unk (Take 1 Capful Daily As Directed)	Not Reported
Vitamin D3	C		2000 Iu, Unk, (1 Capsule Daily)	Not Reported
Lasix	C	Oral	20 Mg, 2x/Day, (Take 1 Tablet By Mouth Twice Daily)	Not Reported
Furosemide	C	Oral	40 Mg, 1x/Day	Not Reported
Hydrocortisone	C	Oral	10 Mg, Daily	Not Reported
Codeine And Guaifenesin	C		Unk Unk, As Needed [Guaifenesin: 100 Mg] / [Codeine: 10 Mg] (2 Tsp Q 4-6 Hours)	Not Reported
Metoprolol Succinate	C	Oral	25 Mg, Daily	Not Reported
Metoprolol Succinate	C	Oral	25 Mg, Daily (Twice)	Not Reported
Xeljanz	C	Oral	5 Mg, 2x/Day	Not Reported
Fenofibrate	C	Oral	160 Mg, 1x/Day (At Supper)	Not Reported
Plaquenil	C	Oral	200 Mg, 2x/Day	Not Reported
Red Yeast Rice	C	Oral	Unk, 2x/Day	Not Reported
Norco	C		1 Df, As Needed [Hydrocodone: 7.5 Mg] / [Acetaminophen: 325mg]	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			(One Tablet Every 6 Hours)	
Tramadol Hcl	C		200 Mg, Daily	Not Reported
Sodium Chloride	C		Unk (Use As Directed)	Not Reported
Hyaluronic Acid-Vitamin C Caps	C		Unk Unk, Daily (Take 3 Table Spoons Daily (Take 3 Table Spoons Taking Liquid))	Not Reported
Cyclobenzaprine Hcl	C	Oral	10 Mg, 3x/Day	Not Reported
Folic Acid	C	Oral	1 Mg, As Needed (Daily)	Not Reported
Serevent Diskus	C		50 Ug, Unk (Take Twice Daily As Directed)	Not Reported
Singulair	C		10 Mg, Unk (Take At Bedtime As Directed)	Not Reported
Prevacid	C		30 Mg, Unk (Twice Daily As Directed)	Not Reported
Psyllium	C		Unk, 3x/Day, (2 Caps Three Times Daily)	Not Reported
Sanctura Xr	C	Oral	60 Mg, Daily	Not Reported
Calcium	C		Unk (Take Twice Daily As Directed)	Not Reported
Lunesta	C	Oral	3 Mg, 1x/Day	Not Reported
Domperidone	C		10 Mg, 2x/Day (One Tablet Before Meal And At Bedtime)	Not Reported
Neurontin	C		600 Mg, 3x/Day (With Meals)	Not Reported
Coenzyme Q10	C	Oral	200 Mg, Daily	Not Reported
Promethazine Hcl	C		25 Mg, Unk (One Three To Four Times Daily)	Not Reported
Proventil Hfa	C	Oral	2 Df, As Needed (Use 2 Puffs Orally Every 4 Hours)	Not Reported
Qvar	C	Respiratory	2 Df, 2x/Day (2 Inhalations	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Tylenol	C	(inhalation)	Twice A Day)	Not Reported
Levothyroxine Sodium	C	Oral	500 Mg, Unk (Take As Needed As Directed) 75 Ug, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13387911	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-003889			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchitis; Drug Ineffective	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	3 G, Bid		Jazz
	Azithromycin			S				Not Reported
	Epipen 2-Pak			C		Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported
	Abilify			C	Oral			Not Reported
	Ativan			C	Oral			Not Reported
	Benadryl Allergy /00000402/			C		Unk		Not Reported
	Hydrocodone/Acetaminophen /00607101/			C		Unk		Not Reported
	Hydroxyzine Hcl			C	Oral			Not Reported
	Kelnor			C	Oral			Not Reported
	Prevacid			C	Oral			Not Reported
	Ritalin			C	Oral			Not Reported
	Zoloft			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13488692	EXPEDITED (15-DAY)		OT	BR-CIPLA LTD.-2017BR07494			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Exposure During Pregnancy	Lamivudine/Tenofovir			S	Oral	600 Mg, Per Day		Cipla
	Zidovudine			S	Intravenous (not	2 Mg/Kg/Hr, At Delivery		Cipla

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zidovudine	S	otherwise specified)	Intravenous (not otherwise specified)	1 Mg/Kg/Hr, At Delivery	Cipla
Ritonavir	S	Oral		100 Mg, Per Day	Cipla
Folic Acid	S	Unknown		Unk	Invagen
Trimethoprim/Sulfamethoxazole	S	Unknown		Unk	Cipla
Fluconazole	S	Unknown		Unk	Cipla
Azithromycin	S	Unknown		Unk	Cipla
Reyataz	S	Oral		300 Mg, Per Day	Not Reported
Ferrous Sulfate	S	Unknown		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13488756	EXPEDITED (15-DAY)		CA	BR-CIPLA LTD.-2017BR07495			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Naevus; Foetal Exposure During Pregnancy	Lamivudine/Tenofovir			S	Transplacental	Unk		Cipla
	Ritonavir			S	Transplacental	Unk		Cipla
	Zidovudine			S	Transplacental	Unk		Cipla
	Folic Acid			S	Transplacental	Unk		Invagen
	Trimethoprim/Sulfamethoxazole			S	Transplacental	Unk		Cipla
	Fluconazole			S	Transplacental	Unk		Cipla
	Azithromycin			S	Transplacental	Unk		Cipla
	Reyataz			S	Transplacental	Unk		Not Reported
	Ferrous Sulfate			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13495257	DIRECT	Y	OT			58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Pain	Azithromycin	Y		S	Intravenous (not			Auromedics

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2017	13495273	DIRECT	Y	OT			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Pain	Azithromycin	Y		S	Intravenous (not otherwise specified)			Auromedics	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13423588	EXPEDITED (15-DAY)		HO, OT	NL-PFIZER INC-2017147577		21 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urinary Retention	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13494495	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-139302		22 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Macular Fibrosis; Retinal Detachment; Subretinal Fibrosis; White Blood Cell Count Decreased	Azithromycin			S	Unknown	500 Mg, Qd		Sun	
	Clindamycin			S	Unknown	300 Mg, Tid		Sun	
	Sulphamethoxazole/Trimethoprim			S	Unknown	160 Mg/800 Mg, Bid		Mutual	
	Pyrimethamine			S	Unknown	25 Mg, Bid		Not Reported	
	Dexamethasone			C	Topical	Unk, Qid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13496567	EXPEDITED (15-DAY)		OT	PT-LUPIN PHARMACEUTICALS INC.-2017-02046		88 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Generalised Exanthematous Pustulosis	Amoxicillin/Clavulanic Acid	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Lupin
	Bisoprolol	C	Unknown	Unk	Not Reported
	Bromazepam	C	Unknown	Unk	Not Reported
	Pentoxifylline	C	Unknown	Unk	Not Reported
	Triflusal	C	Unknown	Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Cyamemazine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13496686	EXPEDITED (15-DAY)		DE	GB-MYLANLABS- 2017M1025250			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Product Use In Unapproved Indication	Azithromycin			S		Unk		Not Reported	
	Codeine			S		Unk		Mylan	
	Paracetamol			S		Unk		Mylan	
	Cytotec			S	Vaginal	Unk		Mylan	
	Mifegyne			S		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2017	13497600	NON-EXPEDITED			US-PFIZER INC- 2017179755		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Palpitations; Stress	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2017	13498996	DIRECT		DE			20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Completed Suicide; Unevaluable Event		Azithromycin		S	Oral		Quantity:5 Tablet(S);		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
01-May-2017	13498734	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-112535			Unknown	BRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	500 Mg, Daily		Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-May-2017	11718355	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015US-105789		13 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cholestatic Liver Injury	Azithromycin			S	Unknown	Unk		Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-May-2017	13414667	EXPEDITED (15-DAY)		OT	GB-EISAI MEDICAL RESEARCH-EC-2017- 025816		11 YR	Female	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Clumsiness; Drug Interaction; Product Use Issue	Fycompa			S		Unknown		Not Reported		
	Fycompa			S		8 Mg Alternating With 10 Mg		Not Reported		
	Azithromycin			S		10 MI		Not Reported		
	Clarithromycin			S		Unknown		Not Reported		
	Clobazam			C		Unknown		Not Reported		
	Lacosamide			C		Unknown		Not Reported		
	Lansoprazole			C		Unknown		Not Reported		
	Prednisolone			C				Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Phenobarbital			C			Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13501954	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-138732		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury; Liver Transplant	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13502497	EXPEDITED (15-DAY)		OT	US-TEVA-764074USA		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder; Hepatotoxicity; Histiocytosis; Nephropathy Toxic; Ototoxicity	Azithromycin			S	Oral			Not Reported	
	Amikacin			S	Unknown			Teva	
	Clofazimine			S	Oral	200mg Daily		Not Reported	
	Imipenem			C	Unknown			Not Reported	
	Tigecycline			C	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13503191	NON-EXPEDITED			US-PFIZER INC- 2017184548			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13503334	DIRECT		DS			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Depression; Fear; Gait Disturbance; Inflammation; Swelling	Azithromycin 250 Mg	S	Oral	Quantity:12 Tablet(S);	Central
	Levothyroxine	C			
	Bromelain	C			
	Turmeric	C			
	Fish Oil	C			
	Calcium Magnesium	C			
	B Vitamins	C			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13504053	EXPEDITED (15-DAY)		DE	US-KNIGHT THERAPEUTICS (USA) INC.-2020114		4 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use	Impavido (Miltefosine) Capsules			S	Oral			Knight Therapeutics
	Amphotericin B			S				Not Reported
	Fluconazole			S				Not Reported
	Rifampin			S				Not Reported
	Azithromycin			S				Not Reported
	Dexamethasone			S				Not Reported
	Lorazepam			S				Not Reported
	Fosphenytoin			S				Not Reported
	Midazolam Hydrochloride			S				Not Reported
	Pentobarbital			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13504084	EXPEDITED (15-DAY)		DE	US-KNIGHT THERAPEUTICS (USA) INC.-2020115		14 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use	Impavido (Miltefosine) Capsules			S				Knight Therapeutics
	Vancomycin			S				Not Reported
	Ceftriaxone And Dextrose			S				Not Reported
	Amphotericin B			S				Not Reported
	Fluconazole			S				Not Reported
	Rifampin			S				Not Reported
	Azithromycin			S				Not Reported
	Pentobarbital			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2017	13507266	DIRECT					63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nasal Pruritus; Night Sweats	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Pliva	
	Vitamin D Nos			C				Not Reported	
	Vitamin C			C				Not Reported	
	Tylenol			C				Not Reported	
	Flonase			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	12965832	EXPEDITED (15-DAY)		OT	GB-SA-2016SA210812		10 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Off Label Use	Renvela			S	Unknown	Powder		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Levothyroxine			S	Unknown			Not Reported	
	Warfarin			S	Unknown			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	13507599	EXPEDITED (15-DAY)		DE	PHFR2017GB002916			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Novartis	
	Codeine			S	Unknown	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	
	Cytotec			S	Vaginal	Unk		Not Reported	
	Mifegyne			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	13508225	NON-EXPEDITED		OT	US-APOTEX-2017AP010991		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Hepatotoxicity; Transaminases Increased	Azithromycin			S	Oral			Apotex	
	Amikacin			C	Oral			Not Reported	
	Imipenem			C	Unknown			Not Reported	
	Tigecycline			C	Unknown			Not Reported	
	Levofloxacin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	13510484	NON-EXPEDITED			US-PFIZER INC-2017190622			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk (Course 1)		Pfizer	
	Zithromax			S		Unk (Course 2)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2017	13510763	DIRECT		HO			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper; Anogenital Warts; Musculoskeletal Pain; Pain In Extremity; Pain In Extremity; Palpitations; Rash	Azithromycin 250mg (Zithromax 250mg) 6-Pack			S	Oral	2 Pills On Day One 1 Pill Next Four Days (6) 2 Pills Day One 1 Pill Daily Mouth		Pliva	
	Cane			C				Not Reported	
	Walker			C				Not Reported	
	Metoprolol Er			C				Not Reported	
	Nifedipine Er			C				Not Reported	
	Aspirin			C				Not Reported	
	Ferrous Sulfate			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2017	13512818	EXPEDITED (15-DAY)		DE	GB-JNJFOC-20170423557			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Product Use In Unapproved Indication	Codeine W/Paracetamol			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Mifegyne			S	Unknown	Unk		Not Reported	
	Cytotec			S	Vaginal	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2017	13513817	NON-EXPEDITED			US-PFIZER INC-2017189727		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough	Zithromax			S		Unk		Pfizer	
	Levothyroxine			C		Unk Unk, Daily		Not Reported	
	Atenolol			C		25 Mg, Daily		Not Reported	
	Losartan			C		50 Mg, 2x/Day, One Now And One At Night Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2017	13515339	EXPEDITED (15-DAY)		DS, OT	FR-PFIZER INC-2017186853		65 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chiasma Syndrome; Optic Neuritis	Novatrex			S	Oral	Unk		Pfizer	
	Novatrex			S	Oral	1 Df, Weekly		Pfizer	
	Coaprovel			C				Not Reported	
	Chondrosulf			C				Not Reported	
	Crestor			C				Not Reported	
	Atenolol			C				Not Reported	
	Levothyrox			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13292731	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20161207809		34 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Bronchitis; Frequent Bowel Movements; General Physical Health Deterioration; Inappropriate Schedule Of Product Administration; Off Label Use; Therapeutic Product Effect Decreased	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Previously Reported As 480 Mg		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Questran			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13382080	EXPEDITED (15-DAY)		HO, OT	PHHY2017AU044739			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Disease Progression; Drug Ineffective; Dyspnoea; Exercise Tolerance Decreased; Graft Versus Host Disease In Lung; Pneumothorax; Subcutaneous Emphysema	Azithromycin			S	Unknown			Novartis	
	Fludarabine			S	Unknown			Not Reported	
	Glivec			S	Oral	100 Mg, Qd		Not Reported	
	Mycophenolate			S	Unknown			Not Reported	
	Montelukast			C	Unknown			Not Reported	
	Alemtuzumab			C	Unknown			Not Reported	
	Melphalan			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13500107	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2017169761		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Diarrhoea	Varenicline Tartrate			S	Oral	0.5 Mg, 1x/Day Days1-3		Pfizer	
	Varenicline Tartrate			S	Oral	0.5 Mg, 2x/Day Days 4-7		Pfizer	
	Zithromax			S	Oral	500 Mg (2 Tablets), 1x/Day		Pfizer	
	Zithromax			S	Oral	250 Mg (1 Tablet), 1x/Day		Pfizer	
	Opdivo			C		Unk		Not Reported	
	Synthroid			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13501976	EXPEDITED (15-DAY)		DE, HO	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-139452		60 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Pseudomembranous Colitis; Sepsis	Azithromycin			S	Oral	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13515881	EXPEDITED (15-DAY)		DE	GB-AUROBINDO-AUR-APL-2017-33247			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circulatory Collapse; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo	
	Codeine			S	Unknown	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Aurobindo	
	Cytotec			S	Vaginal	Unk		Not Reported	
	Mifegyne			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13517583	NON-EXPEDITED		OT	US-AMGEN- USASL2017067339		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Gait Inability; Malaise; Off Label Use; Pneumonia; Rheumatoid Arthritis; Sinusitis; Sleep Disorder Due To A General Medical Condition	Enbrel			S	Unknown	Unk		Amgen	
	Enbrel			S	Unknown	50 Mg, Q2wk		Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-May-2017	13519318	NON-EXPEDITED			US-PFIZER INC- 2017192083		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2017	13521759	DIRECT		OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Dizziness; Feeling Abnormal; Frequent Bowel Movements; Heart Rate Decreased; Hyperhidrosis; Nausea; Pain	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Pliva	
	Tylenol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13085424	NON-EXPEDITED			US-PFIZER INC- 2016600806		79 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Pfizer	
	Z-Pak			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13494503	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-136950		42 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chemical Phlebitis	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2017	13521306	NON-EXPEDITED			US-PFIZER INC- 2017192800			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Celebrex			S				Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Methotrexate Sodium			S				Pfizer	
	Methotrexate Sodium			S				Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Humira			S		Unk		Not Reported	
	Humira			S				Not Reported	
	Humira			S				Not Reported	
	Cipro			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Tetanus Toxoid Adsorbed (Vaccine)			S		Unk		Not Reported	
	Entex			S		Unk		Not Reported	
	Entex			S				Not Reported	
	Orencia			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simponi	S	Unk	Not Reported
Plaquenil	S	Unk	Not Reported
Remicade	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2017	12996566	EXPEDITED (15-DAY)		OT	GB- GLAXOSMITHKLINE- GB2016174424		10 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Off Label Use	Azithromycin			S	Unknown	120 Mg, Unk		Glaxosmithkline	
	Folic Acid			S	Unknown	2.5 Mg, Unk		Glaxosmithkline	
	Levothyroxine			S	Unknown	50 ?G, Unk		Glaxosmithkline	
	Salbutamol			S	Unknown	Unk		Glaxosmithkline	
	Warfarin			S	Unknown	0.5 Mg, Unk		Glaxosmithkline	
	Renvela			S	Unknown	Powder		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2017	13023075	EXPEDITED (15-DAY)		OT	US-TEVA-696035USA		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Haemorrhage; Eye Pain; Headache; Temporal Arteritis; Visual Impairment	Azithromycin			S		500 Milligram Daily;		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Lorazepam			C	Oral	3 Milligram Daily;		Not Reported	
	Tramadol Hydrochloride			C	Oral	Every 6 Hrs		Not Reported	
	Paroxetine Hydrochloride			C	Oral	12.5 Milligram Daily;		Not Reported	
	Losartan Potassium			C	Oral	25 Milligram Daily;		Not Reported	
	Synthroid			C		25 Microgram Daily;		Not Reported	
	Prednisone			C		10 Milligram Daily;		Not Reported	
	Mylanta			C	Oral	200-200-20 Mg/Sml Suspension		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Flax Seed Oil	C	Oral					Not Reported
	Vitamin B Complex	C	Oral					Not Reported
	Vitamin D3	C			400 Iu			Not Reported
	Atorvastatin	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2017	13527025	DIRECT		DS				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Z-Pak			S				Not Reported
	Prilosec			C				Not Reported
	Lantus			C				Not Reported
	Cozaar			C				Not Reported
	Glimepiride			C				Not Reported
	Imitrex			C				Not Reported
	Luxiq			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2017	13527253	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017193198		88 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia Macrocytic; Folate Deficiency; General Physical Health Deterioration; Thrombocytopenia; Vitamin B12 Deficiency	Novatrex			S	Oral	7.5 Mg, Weekly (3 Df Once Weekly Sundays)		Pfizer
	Kardegic			C		Unk		Not Reported
	Doliprane			C		Unk		Not Reported
	Speciafoldine			C		Unk		Not Reported
	Nebivolol			C		2 Df, Weekly		Not Reported
	Fosinopril			C		Unk		Not Reported
	Sodium/Hydrochlorothiazide							
	Vesicare			C		Unk		Not Reported
	Omeprazole			C		Unk		Not Reported
	Meteospasmyl (Alverine Citrate\Dimethicone)			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	12648253	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2016AP010381		67 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Apo-Azithromycin			S	Oral	250 Mg, Bid		Apotex
	Apo-Atorvastatin			S	Oral	20 Mg, Unk		Apotex
	Seebri Breezhaler			S	Respiratory (inhalation)	50 Mg, Once Daily		Not Reported
	Alendronate Sodium			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Dexilant			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Pulmicort			C	Unknown			Not Reported
	Qvar			C	Unknown			Not Reported
	Remicade			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	12842457	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD-2016US-125913		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Pantoprazole			S	Oral	Unk		Sun
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Sun
	Ciprofloxacin			S	Oral	Unk;Cyclical		Sun
	Montelukast			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Mycophenolate Mofetil	S	Oral	Unk	Not Reported
	Voriconazole	S	Oral	Unk	Not Reported
	Voriconazole	S	Oral	Unk	Not Reported
	Nifedipine	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Mutual
	Sulphamethoxazole/Trimethoprim	S	Oral	Unk	Sun
	Tacrolimus	S	Oral	Unk	Not Reported
	Candida	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pms Azithromycin	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13361971	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP008452		15 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Photodermatitis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Apo-Prednisone			S	Oral	Unk		Apotex
	Apo-Atorvastatin			S	Oral	Unk		Apotex
	Apo-Azithromycin Tablets 250 Mg			S	Oral	Unk		Apotex
	Apo-Lansoprazole			S	Oral	Unk		Not Reported
	Apo-Mycophenolate			S	Oral	Unk		Apotex
	Apo-Pantoprazole			S	Oral	Unk		Apotex
	Apo-Sulfatrim			S	Oral	Unk		Not Reported
	Apo-Voriconazole			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13439661	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-BAXTER-2017BAX015689		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alveolitis; Atrial Fibrillation; Hypoxia	Procytox (Cyclophosphamide) 2000mg/Vial	S	Intravenous (not otherwise specified)	Three Doses	Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial	S	Intravenous (not otherwise specified)	Fourth Dose	Baxter
	Doxorubicin	S	Intravenous (not otherwise specified)	Four Dosages	Not Reported
	Paclitaxel	S	Intravenous (not otherwise specified)		Not Reported
	Trastuzumab	S	Unknown		Not Reported
	Amiodarone	S	Unknown	Infusion	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)		Not Reported
	Ceftriaxone	S	Intravenous (not otherwise specified)		Not Reported
	Digoxin	S	Intravenous (not otherwise specified)	Prn (As Required)	Not Reported
	Digoxin	S	Intravenous (not otherwise specified)	Infusion	Not Reported
	Diltiazem Cd	S	Oral		Not Reported
	Dimenhydrinate	S	Intravenous (not otherwise specified)	Prn (As Required)	Not Reported
	Enoxaparin	S	Subcutaneous		Not Reported
	Furosemide	S	Oral		Not Reported
	Hydralazine	S	Intravenous (not otherwise specified)	As Required	Not Reported
	Hydromorphone	S	Intravenous (not otherwise specified)	0.25-0.5mg; Q4-6hrs; Prn (As Required)	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)		Not Reported
	Metoprolol	S	Intravenous (not otherwise specified)		Not Reported
	Metoprolol	S	Intravenous (not otherwise specified)	Dose Increased	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine	S	Intravenous (not otherwise specified)	1-2mg; Prn (As Required)	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	Infusion	Not Reported
Gabapentin	C	Oral	Prn (As Required)	Not Reported
Metoclopramide	C	Oral	Prn (As Required)	Not Reported
Ondansetron	C	Oral		Not Reported
Aprepitant	C	Oral		Not Reported
Dexamethasone	C	Oral		Not Reported
Filgrastim	C	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13504625	EXPEDITED (15-DAY)		DE	GB-TEVA-763222ACC			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Circulatory Collapse; Product Use In Unapproved Indication	Azithromycin			S				Not Reported
	Codeine			S				Not Reported
	Paracetamol			S	Unknown			Not Reported
	Cytotec			S	Vaginal			Not Reported
	Mifegyne			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13515344	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017186863		44 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Asthenia; Chills; Facial Pain; Hypertransaminasaemia; Malaise; Muscular Weakness; Musculoskeletal Stiffness; Oropharyngeal Pain; Pain In Jaw; Paralysis	Novatrex			S	Oral	2.5 Mg, 2x/Cycle (On Friday And Saturday)		Pfizer
	Ebastine			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2017	13533602	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2017200442		11 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Clumsiness; Drug Interaction	Azithromycin			S		10 MI, Unk		Pfizer	
	Fycompa			S		8 Mg Alternating With 10 Mg; Daily		Not Reported	
	Clobazam			C		Unk		Not Reported	
	Lacosamide			C		Unk		Not Reported	
	Lansoprazole			C		Unk		Not Reported	
	Phenobarbital			C		Unk		Not Reported	
	Prednisolone			C		40 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13507718	EXPEDITED (15-DAY)		HO	FR-UCBSA-2017016474		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Keppra			S	Oral	500 Mg, 2x/Day (Bid)		Ucb	
	Zithromax			S	Oral	Unk		Not Reported	
	Malocide (Pyrimethamine)			C		50 Mg, Once Daily (Qd)		Not Reported	
	Cortancyl			C				Not Reported	
	Dexafree			C				Not Reported	
	Atropine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13535338	EXPEDITED (15-DAY)		HO	CH-PFIZER INC-2017198322		16 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia;	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Minac			S	Oral	50 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lymphadenopathy; Mixed	Kettesse	S	Oral	Unk	Not Reported
Liver Injury; Rash Maculo-Papular	Paracetamol	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13535345	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017197892		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Normochromic Normocytic Anaemia	Novatrex			S	Oral	15 Mg, Weekly		Pfizer	
	Lyrica			S	Oral	75 Mg, Daily		Pfizer	
	Xarelto			S	Oral	20 Mg, Daily		Not Reported	
	Kardegic			S	Oral	75 Mg, Daily		Not Reported	
	Cortancyl			S	Oral	20 Mg, Daily		Not Reported	
	Fluoxetine Hydrochloride			S	Oral	20 Mg, Daily		Not Reported	
	Perindopril			S	Oral	2 Mg, Daily		Not Reported	
	Inexium			S	Oral	20 Mg, Daily		Not Reported	
	Speciafoldine			C		5 Mg, Weekly		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13536870	NON-EXPEDITED			US-PFIZER INC-2017205723		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Bupropion Hcl			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2017	13537218	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011573		73 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Fall; Forced Vital Capacity Decreased; Lung Diffusion Test Decreased; Nausea; Pulmonary Function Test Abnormal; Upper Limb Fracture	Apo-Azithromycin			S	Unknown	250 Mg, Q.3w		Apotex
	Esbriet			S	Oral	801 Mg, Q.3w		Not Reported
	Esbriet			S	Oral	534 Mg, Tid		Not Reported
	Esbriet			S	Oral	267 Mg, Tid		Not Reported
	Slow K			C	Unknown	600 Mg, Bid		Not Reported
	Salbutamol			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown	10 Mg, Unk		Not Reported
	Ramipril			C	Unknown	10 Mg, Unk		Not Reported
	Quinine Sulfate			C	Unknown	200 Mg, Unk		Not Reported
	Omeprazole			C	Unknown	20 Mg, Unk		Not Reported
	Nitro /00003201/			C	Unknown	0.2 Mg, Unk		Not Reported
	Metformin			C	Unknown	500 Mg, Unk		Not Reported
	Gliclazide			C	Unknown	80 Mg, Bid		Not Reported
	Furosemide			C	Unknown	40 Mg, Unk		Not Reported
	Fluoxetine			C	Unknown	20 Mg, Unk		Not Reported
	Brilinta			C	Unknown	90 Mg, Bid		Not Reported
	Bisoprolol			C	Unknown	5 Mg, Unk		Not Reported
	Atrovent			C	Unknown			Not Reported
	Acetylsalicylic Acid			C	Unknown	81 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	7190007	EXPEDITED (15-DAY)		OT	HR-PFIZER INC- 2009298966		62 YR	Male	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome; Vanishing Bile Duct Syndrome	Azithromycin			S		500 Mg, Daily		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	12475318	NON-EXPEDITED		OT	US-AMGEN- USASL2016076142		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arterial Disorder;	Enbrel			S	Unknown	Unk		Amgen
Bronchitis; Labile	Z-Pak			S	Unknown	Unk		Not Reported
Hypertension;	Z-Pak			S				Not Reported
Nasopharyngitis; Off Label	Coq 10			C				Not Reported
Use; Pneumonia; Upper	Naproxen			C		220 Mg, Bid		Not Reported
Respiratory Tract Infection	Niacin			C		500 Unk, Unk		Not Reported
	Losartan/Hydrochlorothiazide			C		50 Mg, Unk		Not Reported
	Asa			C		81 Mg, Qd		Not Reported
	Vitamin B12			C		Unk		Not Reported
	Vit D3			C		Unk		Not Reported
	Paroxetine			C		30 Mg, Unk (Hs)		Not Reported
	Gabapentin			C		Up To 2400 Mg A Day		Not Reported
	Tylenol			C		Unk Unk, As Necessary		Not Reported
	Ambien			C		Unk Unk, As Necessary		Not Reported
	Atorvastatin			C		Unk		Not Reported
	Nexium			C		40 Mg, Qd		Not Reported
	Metoprolol			C		50 Mg, Unk		Not Reported
	Metoprolol			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	12801901	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-125129		32 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Generalised Exanthematous Pustulosis		Azithromycin		S	Oral	500 Mg, Qd		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13539589	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011569		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extravasation; Injection Site Erythema; Injection Site Pain; Injection Site Swelling	Azithromycin For Injection			S	Intravenous (not otherwise specified)	500 Mg, Qid		Apotex	
	Solumedrol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13539656	EXPEDITED (15-DAY)		DS	CA-APOTEX-2017AP011570		23 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Apo-Azithromycin			S	Oral	250 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13539912	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE48464		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Normochromic Normocytic Anaemia	Inexium			S	Oral			Astrazeneca	
	Xarelto			S	Unknown			Not Reported	
	Novatrex			S	Unknown			Not Reported	
	Kardegic			S	Unknown			Not Reported	
	Cortancyl			S	Unknown			Not Reported	
	Fluoxetine Hydrochloride			S	Unknown			Not Reported	
	Perindopril			S	Unknown			Not Reported	
	Lyrica			S	Unknown			Not Reported	
	Speciafoldine			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13540186	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011572		42 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Off Label Use	Apo-Azithromycin			S	Unknown	250 Mg, Qd		Apotex	
	Apo-Azithromycin			S	Unknown	500 Mg, Qd		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13540236	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP011571		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Crying; Diarrhoea; Dyspnoea; Hot Flush; Insomnia; Mental Disorder; Nausea; Panic Attack; Paranoia	Apo-Azithromycin Tablets 250 Mg			S	Oral	250 Mg, Qd		Apotex	
	Apo-Azithromycin Tablets 250 Mg			S	Oral	500 Mg, Total		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-May-2017	13541129	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20170509982		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Normochromic Normocytic Anaemia	Xarelto			S	Oral			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Kardegic			S	Oral			Not Reported	
	Cortancyl			S	Oral			Not Reported	
	Fluoxetine Hydrochloride			S	Oral			Not Reported	
	Perindopril			S	Oral			Not Reported	
	Inexium			S	Oral			Not Reported	
	Lyrica			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13541442	NON-EXPEDITED			US-PFIZER INC-2017203539			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
	Savella			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-May-2017	13541957	EXPEDITED (15-DAY)		OT	NO-PFIZER INC-2017202638		44 YR	Female	NOR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Peripheral Swelling; Thrombosis	Azitromax			S		500 Mg Once Daily		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2017	13543198	NON-EXPEDITED		OT	US-ANIPHARMA-2016-US-007754			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Muscle Spasms; Seizure	Promethazine Hcl (Non-Specific)			S	Oral	3 Teaspoons 3 Times Daily		Ani	
	Azithromycin Z Pak			S	Oral	2 Tablets On Day One, Then 1 Tablet Daily		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2017	13543199	NON-EXPEDITED		OT	US-ANIPHARMA-2016-US-009042		55 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Muscle Spasms; Seizure; Tremor	Promethazine Hcl (Non-Specific)			S	Oral			Ani	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	Not Reported
Phenylephrine Hydrochloride	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	9969823	EXPEDITED (15-DAY)	OT		FR-ROCHE-1359416		73 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Eye Swelling;	Lucentis			S	Other	Right Eye		Not Reported
Eyelid Sensory Disorder;	Lucentis			S	Other	Right Eye		Not Reported
Hypersensitivity;	Lucentis			S	Other	Right Eye		Not Reported
Hypotension; Injection Site	Lucentis			S	Other	Right Eye		Not Reported
Pain; Insomnia; Intraocular	Lucentis			S	Other	Right Eye		Not Reported
Pressure Increased;	Lucentis			S	Other	Left Eye		Not Reported
Presyncope	Lucentis			S	Other			Not Reported
	Azyter			S	Unknown	Unk		Not Reported
	Carteolol Hydrochloride			C	Unknown	Unk		Not Reported
	Mydriaticum			C	Unknown	Unk		Not Reported
	Oxybuprocaine			C	Unknown	Unk		Not Reported
	Tetracaine			C	Unknown	Unk		Not Reported
	Chibroxine			C	Unknown			Not Reported
	Povidone Iodine			C	Unknown			Not Reported
	Betadine			C	Ophthalmic	Unk Unk, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	11767347	NON-EXPEDITED			US-PFIZER INC- 2015391803		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Metoprolol Tartrate			S		Unk		Unknown

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	13486627	NON-EXPEDITED			US-PFIZER INC-2017174984			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2017	13546156	EXPEDITED (15-DAY)		OT	CA-BAYER-2017-089038		22 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysbiosis; Gastroenteritis Staphylococcal	Moxifloxacin Oral			S		Unk		Bayer	
	Ciprofloxacin			S		Unk		Bayer	
	Azithromycin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Cefixime			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13245388	EXPEDITED (15-DAY)			CN-GLAXOSMITHKLINE-CN2017GSK018687			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Nasopharyngitis; Productive Cough; Pyrexia; Wrong Technique In Product Usage Process	Seretide Accuhaler			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline	
	Singulair			S		Unk		Glaxosmithkline	
	Azithromycin Powder			S		Unk Unk, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13299941	NON-EXPEDITED			US-PFIZER INC-2017089877		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Potassium Decreased; Dehydration; Drug Ineffective; Extrasystoles; Palpitations	Zithromax	S		250 Mg, Unk	Pfizer
	Azithromycin	S		250 Mg, Unk	Pfizer
	Losartan	C		25 Mg, 2x/Day	Not Reported
	Metoprolol	C		25 Mg, 2x/Day	Not Reported
	Lipitor	C		40 Mg, 1x/Day	Not Reported
	Hctz	C		25 Mg, 1x/Day	Not Reported
	Amlodipine	C		2.5 Mg, 2x/Day	Not Reported
	Aspirin	C		81 Mg, 1x/Day	Not Reported
	Levothyroxine	C		50 Ug, 1x/Day	Not Reported
	Dymista	C	Nasal	Unk, 1x/Day	Not Reported
	Breo-Ellipta	C		1x/Day, 100/25mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13548901	NON-EXPEDITED			US-PFIZER INC-2017206196			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13549559	EXPEDITED (15-DAY)		LT, OT	HK-AUROBINDO-AUR-APL-2017-33815		21 YR	Male	HKG

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Piperacillin+Tazobactam			S	Unknown			Aurobindo
	Piperacillin+Tazobactam			S				Aurobindo
	Aktil /00852501/			S	Unknown	Unk		Not Reported
	Aktil /00852501/			S				Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13550128	NON-EXPEDITED		OT	US-APOTEX-2017AP012217			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13550538	DIRECT	Y	LT			82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Throat Tightness	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13551199	EXPEDITED (15-DAY)		DE	PHHY2017ZA066270			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Azithromycin Sandoz			S	Oral	500 Mg, Unk		Novartis	
	Ecotrin			C	Oral	81 Mg, Unk		Not Reported	
	Foxair			C	Oral	1 Df, Unk		Not Reported	
	Forvent			C	Oral	18 Ug, Unk		Not Reported	
	Calciferol [Colecalciferol]			C	Oral	50000 Iu, Unk		Not Reported	
	Glucophage			C	Oral	500 Mg, Unk		Not Reported	
	Florinef			C	Oral	0.1 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2017	13554869	DIRECT	Y	HO			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Liver Function Test Increased; Product Dose Omission	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	9855855	NON-EXPEDITED			US-PFIZER INC-2014024940			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
	Penicillin-V			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	12852471	NON-EXPEDITED		OT	US-APOTEX-2016AP012997			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13004184	EXPEDITED (15-DAY)		OT	PHHY2016GB162232		10 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Off Label Use	Azithromycin			S	Unknown	120 Mg,		Novartis	
	Salbutamol			S	Unknown			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Folic Acid			S	Unknown	2.5 Mg,		Not Reported	
	Levothyroxine			S	Unknown	50 Ug,		Not Reported	
	Renvela			S	Unknown	4.8 G, Qd (Powder)		Not Reported	
	Renvela			S	Unknown	Powder		Not Reported	
	Warfarin			S	Unknown	0.5 Mg,		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13004840	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2016-14744		10 YR	Female	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lower Respiratory Tract Infection; Off Label Use	Azithromycin			S	Unknown	120 Mg, Unk		Aurobindo
	Azithromycin			S	Unknown			Aurobindo
	Folic Acid			S	Unknown	2.5 Mg, Unk		Not Reported
	Folic Acid			S	Unknown			Not Reported
	Levothyroxine			S	Unknown	50 Mg, Unk		Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Renvela			S	Unknown	2.4 G, Two Times A Day		Not Reported
	Renvela			S	Unknown	Powder		Not Reported
	Salbutamol			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Warfarin			S	Unknown	0.5 Mg, Unk		Not Reported
	Warfarin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13516288	EXPEDITED (15-DAY)		DE	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-139547			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Circulatory Collapse; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Sun
	Codeine			S	Unknown	Unk		Ranbaxy
	Paracetamol			S	Unknown	Unk		Ohm Lab
	Cytotec			S	Vaginal	Unk		Not Reported
	Mifegyne			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13549036	NON-EXPEDITED			US-PFIZER INC- 2017212880			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Malaise	Zithromax			S	Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13553191	EXPEDITED (15-DAY)		OT	PHFR2017GB003262		11 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clumsiness; Drug Interaction; Product Use Issue	Azithromycin			S	Unknown	10 MI, Unk		Novartis	
	Clarithromycin			S	Unknown	Unknown		Not Reported	
	Fycompa			S	Unknown	8 Mg Alternating With 10 Mg		Not Reported	
	Clobazam			C	Unknown	Unknown		Not Reported	
	Lacosamide			C	Unknown	Unknown		Not Reported	
	Lansoprazole			C	Unknown	Unknown		Not Reported	
	Phenobarbital			C	Unknown	Unknown		Not Reported	
	Prednisolone			C	Unknown	40 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13553341	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2017-33756		11 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clumsiness; Drug Interaction; Product Use Issue	Clarithromycin			S	Unknown	Unknown		Aurobindo	
	Azithromycin			S	Unknown	10 MI		Not Reported	
	Fycompa			S	Unknown	8 Mg Alternating With 10 Mg		Not Reported	
	Clobazam			C	Unknown	Unknown		Not Reported	
	Lacosamide			C	Unknown	Unknown		Not Reported	
	Lansoprazole			C	Unknown	Unknown		Not Reported	
	Phenobarbital			C	Unknown	Unknown		Not Reported	
	Prednisolone			C	Unknown	40 Mg, Once A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13554491	NON-EXPEDITED			US-PFIZER INC-2017208655			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13554499	NON-EXPEDITED			US-PFIZER INC-2017208531			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash; Urticaria	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13554542	NON-EXPEDITED			US-PFIZER INC-2017208874			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13555197	EXPEDITED (15-DAY)		OT	PL-JNJFOC-20170512487		51 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Reconstitution Inflammatory Syndrome; Myelitis; Neurosyphilis	Rezolsta			S	Oral			Not Reported	
	Truvada			S	Unknown			Not Reported	
	Cotrimoxazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2017	13557444	DIRECT					46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Emotional Disorder; Impaired Work Ability; Nausea; Vertigo	Azithromycin 250 Mg			S	Oral	Quantity:1 Tablet(S);		Pliva	
	Synthroid			C				Not Reported	
	Metoprolol			C				Not Reported	
	Furosemide			C				Not Reported	
	One-A-Day Women'S Vitamin			C				Not Reported	
	Iron Supplement			C				Not Reported	
	Calcium Supplement			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13547899	EXPEDITED (15-DAY)		LT, OT	HK-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-140363		21 YR	Male	HKG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Amoxicillin And Clavulanate Potassium			S	Unknown	Unk		Ranbaxy	
	Amoxicillin And Clavulanate Potassium			S				Ranbaxy	
	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S				Sun	
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported	
	Piperacillin/Tazobactam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13556922	EXPEDITED (15-DAY)		DE, HO, OT	RS-STRIDES ARCOLAB LIMITED- 2017SP007878			Unknown	SRB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain; Clostridium Difficile Infection; Dehydration;	Vancomycin			S	Unknown	1 G, Every 12 Hrs		Strides	
	Hemomycin			S	Unknown	500 Mg, Every 12 Hrs		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; General Physical Health Deterioration;	Meronem	S	Unknown	1 G, Every 8 Hours	Not Reported
Haemodynamic Instability;	Levomax	S	Unknown	500 Mg, Every 24 Hours	Not Reported
Lactic Acidosis; Megacolon; Multiple Organ Dysfunction Syndrome; Nausea; Pallor; Tachycardia; Vomiting	Amikacin	S	Unknown	500 Mg, Every 24 Hours	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13559537	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-140392		11 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clumsiness; Drug Interaction; Product Use Issue	Azithromycin			S	Unknown	10 MI		Sun
	Clarithromycin			S	Unknown	Unknown		Sun
	Fycompa			S	Unknown	8 Mg Alternating With 10 Mg		Not Reported
	Fycompa			S	Unknown	Unknown		Not Reported
	Clobazam			C	Unknown	Unknown		Not Reported
	Lacosamide			C	Unknown	Unknown		Not Reported
	Lansoprazole			C	Unknown	Unknown		Not Reported
	Phenobarbital			C	Unknown	Unknown		Not Reported
	Prednisolone			C	Unknown	40 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13560091	NON-EXPEDITED			US-PFIZER INC-2017211415		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		500 Mg Day 1 Followed By 250 Mg Days 2-5		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13560935	NON-EXPEDITED			US-PFIZER INC-2017212896		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
	Macrochantin			S		Unk		Not Reported	
	Pyridium			S		Unk		Not Reported	
	Xylocaine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13560941	NON-EXPEDITED			US-PFIZER INC-2017211007		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea; Nasal Congestion	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2017	13561614	EXPEDITED (15-DAY)		OT	GB-TEVA-767220ACC		11 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clumsiness; Drug Interaction; Product Use Issue	Azithromycin			S		10 MI		Not Reported	
	Clarithromycin			S				Not Reported	
	Fycompa			S		8 Mg Alternating With 10 Mg		Not Reported	
	Fycompa			S		Unknown		Not Reported	
	Clobazam			C				Not Reported	
	Lacosamide			C				Not Reported	
	Lansoprazole			C				Not Reported	
	Phenobarbital			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisolone

C

40 Milligram Daily;

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	11848132	NON-EXPEDITED			US-PFIZER INC-2015417317			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer
	Lidocaine Hcl			S		Unk		Pfizer
	Norvasc			S		Unk		Pfizer
	Cortisone Acetate			S		Unk		Unknown
	Ibuprofen			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Motrin			S		Unk		Not Reported
	Potassium			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	12987099	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2016549465		10 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lower Respiratory Tract Infection; Product Use Issue	Azithromycin			S		120 Mg, Unk		Pfizer
	Folic Acid			S		2.5 Mg, Unk		Not Reported
	Levothyroxine			S		50 Ug, Unk		Not Reported
	Renvela			S		2.4 G, 2x/Day		Not Reported
	Salbutamol			S		Unk		Not Reported
	Warfarin			S		0.5 Mg, Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13004511	EXPEDITED (15-DAY)		OT	GB-CIPLA LTD.- 2016GB22706		10 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Off Label Use	Warfarin			S	Unknown	0.5 Mg, Unk		Invagen	
	Folic Acid			S	Unknown	2.5 Mg, Unk		Invagen	
	Azithromycin			S	Unknown	120 Mg, Unk		Cipla	
	Salbutamol			S	Unknown	Unk		Not Reported	
	Levothyroxine			S	Unknown	50 Mg, Unk		Not Reported	
	Renvela			S	Unknown	4.8 G, Qd, Powder		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13006667	EXPEDITED (15-DAY)		OT	GB-TEVA-716315ACC		10 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Off Label Use	Salbutamol			S	Unknown			Barr	
	Levothyroxine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Folic Acid			S	Unknown			Not Reported	
	Renvela			S	Unknown	4.8 Gram Daily; Powder		Not Reported	
	Warfarin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13008398	EXPEDITED (15-DAY)		OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-128678		10 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lower Respiratory Tract Infection; Off Label Use	Azithromycine			S	Unknown	120 Mg, Unk		Sun	
	Folic Acid			S	Unknown	2.5 Mg, Unk		Sun	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Salbutamol	S	Unknown	Unk	Mutual
Warfarin	S	Unknown	0.5 Mg, Unk	Taro
Levothyroxine	S	Unknown	50 Mg, Unk	Not Reported
Renvela	S	Unknown	4.8 G, Qd (Powder)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13369031	NON-EXPEDITED			US-PFIZER INC-2017118923		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Blood Ph Increased; Drug Ineffective; Dry Mouth; Dry Throat; Dysgeusia; Dysgeusia; Eructation; Gastric Ph Decreased	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily		Pfizer
	Azithromycin			S	Oral	500 Mg, Single		Pfizer
	Azithromycin			S	Oral	250 Mg, Daily For Four Days		Pfizer
	Levothyroxine			C	Oral	100 Ug, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13544664	EXPEDITED (15-DAY)		OT	BR-VIIV HEALTHCARE LIMITED-BR2017GSK069183			Male	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Tivicay			S		Unk		Viiv
	Valproic Acid			S		1 Df, Qd		Not Reported
	Azithromycin			S				Glaxosmithkline
	Bactrim			S				Glaxosmithkline
	Phenobarbital Sodium			C				Not Reported
	Raltegravir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13563937	EXPEDITED (15-DAY)		OT	US-SA-2017SA086848		50 YR	Female	TWN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abscess Limb; Abscess Rupture; Biopsy Skin Abnormal; Culture Tissue Specimen Positive; Drug Ineffective; Mycobacterium Avium Complex Infection; Pyrexia; Skin Lesion; Skin Mass	Mycophenolate Mofetil	S	Unknown	Not Reported
	Mycophenolate Mofetil	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Amoxicillin/Clavulanic Acid	S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Rifampicin	S	Unknown	Not Reported
	Ethambutol	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13564357	NON-EXPEDITED			US-PFIZER INC-2017215167		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13565398	EXPEDITED (15-DAY)		OT	PHHY2017HR068937		66 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Lymphopenia; Neutropenia	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Not Reported	
	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Cefixime			S	Oral	400 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-May-2017	13565402	EXPEDITED (15-DAY)		OT	PHHY2017DK068804			Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaphylactic Shock;	Azithromycin Sandoz			S	Oral			Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chills; Deafness;	Ciprofloxacin	S	Unknown		Not Reported
Diarrhoea; Dizziness;	Vibradox	S	Oral		Not Reported
Erythema; Headache;	Surlid	S	Oral		Not Reported
Nausea; Peripheral	Telfast	C	Oral		Not Reported
Coldness; Pharyngeal	Pamol	C	Unknown	1 G, Tid	Not Reported
Swelling; Pyrexia; Rash;	Ibuprofen	C	Oral	600 Mg, Bid	Not Reported
Swelling Face; Tinnitus;	Todolac	C	Oral	300 Mg, Unk	Not Reported
Tremor; Vision Blurred	Selo-Zok	C	Oral		Not Reported
	Innovair	C	Respiratory (inhalation)		Not Reported
	Singulair	C	Unknown		Not Reported
	Spiriva	C	Respiratory (inhalation)		Not Reported
	Venlafaxin	C	Oral		Not Reported
	Prednisolon	C	Unknown		Not Reported
	Fluconazol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2017	13567178	DIRECT	Y	OT			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Tachycardia	Azithromycin			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	12783175	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-124532		47 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Azithromycin			S	Unknown				Sun

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13507812	NON-EXPEDITED		OT	US-PFIZER INC-2017186074		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S	Oral	500 Mg (Day 1)		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
	Losartan			C		1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2017	13568501	EXPEDITED (15-DAY)		OT	DK-TEVA-767958ACC			Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaphylactic Shock; Chills; Deafness; Diarrhoea; Dizziness; Erythema; Headache; Nausea; Peripheral Coldness; Pharyngeal Swelling; Pyrexia; Rash; Swelling Face; Tinnitus; Tremor; Vision Blurred	Ciprofloxacin			S				Not Reported	
	Surlid			S	Oral			Not Reported	
	Vibradox			S	Oral			Not Reported	
	Azithromycin "Sandoz"			S	Oral	Styrke: 500 Mg.		Not Reported	
	Telfast			C	Oral			Not Reported	
	Pamol			C		3 Gram Daily;		Not Reported	
	Ibumetin			C	Oral	1200 Milligram Daily;		Not Reported	
	Todolac			C	Oral	Dosis: 300 Mg Ved Behov.		Not Reported	
	Selo-Zok			C	Oral			Not Reported	
	Innovair			C	Respiratory (inhalation)			Not Reported	
	Singulair			C				Not Reported	
	Spiriva			C	Respiratory (inhalation)			Not Reported	
	Venlafaxin			C	Oral			Not Reported	
	Prednisolon			C				Not Reported	
	Fluconazol			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	11613640	EXPEDITED (15-DAY)		HO, LT, OT	JP-GLAXOSMITHKLINE-JP2015JPN142003		32 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia;	Lamictal			S	Oral	25 Mg, Qod		Glaxosmithkline	
Dysgeusia; Erythema	Lamictal			S	Oral	25 Mg, Qd		Glaxosmithkline	
Multiforme; Hepatic	Zithromac			S	Oral	500 Mg, 1d		Not Reported	
Function Abnormal; Lip	Coughcode-N			C				Not Reported	
Erosion; Lip Swelling;	Allegra			C				Not Reported	
Ocular Hyperaemia;	Depakene-R			C		300 Mg, Bid		Not Reported	
Oculomucocutaneous								Not Reported	
Syndrome; Oral Mucosa									
Erosion; Oral Mucosa									
Erosion; Pyrexia; Rash									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13571252	EXPEDITED (15-DAY)		DE, HO, OT	RS-WEST-WARD PHARMACEUTICALS CORP.-RS-H14001-17-01		56 YR	Female	SRB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile	Amikacin			S	Unknown			Eurohealth	
Infection; Drug Ineffective;	Vancomycin			S	Unknown			International	
Megacolon; Metabolic	Vancomycin			S	Oral			Not Reported	
Acidosis; Multiple Organ	Levomax			S	Unknown			Not Reported	
Dysfunction Syndrome	Hemomycin			S	Unknown			Not Reported	
	Orvagil			S	Intravenous (not otherwise specified)			Not Reported	
	Merone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13572451	DIRECT	Y	HO			37 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Cholelithiasis; Cholestasis; Drug-Induced Liver Injury; Dyspnoea; Malaise; Nausea; Retching	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2017	13573809	EXPEDITED (15-DAY)		OT	CN-ABBVIE-17P-035-1984473-00		69 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutrophil Count Decreased	Depakine Chrono			S	Oral	Extended Release		Not Reported	
	Propylthiouracil			S	Oral			Not Reported	
	Qi Xian			S	Intravenous drip			Not Reported	
	Sodium Chloride			C	Other			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13496875	EXPEDITED (15-DAY)		OT	CZ-TEVA-762781ROM			Unknown	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Azithromycin			S	Oral			Not Reported	
	Ciprofloxacin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13561380	EXPEDITED (15-DAY)		OT	US-TEVA-769557USA		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Drug Ineffective; Palpitations	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13575322	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL		22 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

INDUSTRIES LTD-
2017US-141163

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysbiosis; Gastroenteritis Staphylococcal	Ciprofloxacin			S	Oral			Sun
	Azithromycin			S		Unk		Sun
	Azithromycin			S	Unknown	Single Course		Sun
	Cefixime			S	Unknown	Single Course		Not Reported
	Moxifloxacin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13575935	NON-EXPEDITED			US-PFIZER INC- 2017221938		56 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13575943	NON-EXPEDITED			US-PFIZER INC- 2017222457			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Zithromax			S	Oral	500 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13575946	NON-EXPEDITED			US-PFIZER INC- 2017223245			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13576015	NON-EXPEDITED			US-PFIZER INC-2017222949		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S	Oral	250 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2017	13576987	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017171782		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myelodysplastic Syndrome; Neutropenia	Novatrex			S	Oral	2 Df, Weekly		Pfizer	
	Plaquenil /00072603/			S	Oral	2 Df, Daily		Not Reported	
	Metformin Mylan			S	Oral	500 Mg, 3x/Day		Not Reported	
	Xultophy			S	Subcutaneous	14 Df, Daily		Not Reported	
	Allopurinol Merck			S	Oral	100 Mg, Daily		Not Reported	
	Ultibro Breezhaler			S	Respiratory (inhalation)	1 Df, Daily		Not Reported	
	Folic Acid Arrow			S	Oral	5 Mg, Daily		Not Reported	
	Irbesartan Mylan			S	Oral	300 Mg, Daily		Not Reported	
	Clopidogrel Mylan			S	Oral	75 Mg, Daily		Not Reported	
	Amlodipine Merck-Generics			S	Oral	5 Mg, Daily		Not Reported	
	Victoza			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13580475	EXPEDITED (15-DAY)		OT	KR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-141336		42 YR	Male	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Ineffective; Eosinophilia; Pyrexia;	Levofloxacin			S	Unknown	750 G, Unk		Ranbaxy	
	Azithromycin			S	Unknown	500 Mg, Daily		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Therapeutic Product	Ceftriaxone	S	Unknown	2 G, Daily	Not Reported
Effect Incomplete	Doxycycline	S	Unknown	On Day 10 Of Hospitalization	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13580666	EXPEDITED (15-DAY)		HO	US-JUBILANT CADISTA PHARMACEUTICALS- 2017JUB00151		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Failure; Malaise; Pancreatitis	Prednisone			S	Oral	Unk, As Directed Took For 5 Days Then Stopped		Jubilant
	Prednisone			S	Oral	Unk, As Directed Restarted Then Took For 5 Days And Stopped		Jubilant
	Zpak			S		Unk, As Directed		Not Reported
	Zpak			S	Oral	Unk, As Directed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2017	13580990	NON-EXPEDITED			US-PFIZER INC- 2017228357			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropod Bite; Rash	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	12500271	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2016304231		59 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; International Normalised Ratio Increased	Azithromycin			S	Oral	2 G, Single		Pfizer
	Warfarin			S		2.5 Mg, Daily		Not Reported
	Warfarin			S				Not Reported
	Tamsulosin Hydrochloride			C		0.2 Mg, Daily		Not Reported
	Furosemide			C		20 Mg, Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ferrous Sulfate	C	210 Mg, Daily	Not Reported
	Fluvoxamine Maleate	C	50 Mg, Daily	Not Reported
	Olopatadine Hydrochloride	C	10 Mg, Daily	Not Reported
	Etizolam	C	1.5 Mg, Daily	Not Reported
	Mosapride Citrate	C	15 Mg, Daily	Not Reported
	Morphine Hydrochloride	C	10 Mg, Daily	Not Reported
	Morphine Sulfate	C	20 Mg, Daily	Not Reported
	Flunitrazepam	C	1 Mg, Daily	Not Reported
	Magnesium Oxide	C	990 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	12500272	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2016304348		85 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; International Normalised Ratio Increased	Azithromycin			S	Oral	2 G, Single		Pfizer	
	Warfarin			S		1 Mg, Daily		Not Reported	
	Urapidil			C		15 Mg, Daily		Not Reported	
	Digoxin			C		0.125 Mg, Alternate Day		Not Reported	
	Verapamil Hydrochloride			C		40 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	12957799	EXPEDITED (15-DAY)		CA, DE, OT	FR-ABBVIE-16P-056-1786082-00			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Foetal Death; Foetal Exposure During Pregnancy; Foetal Growth Restriction	Creon			S	Transplacental			Not Reported	
	Aerius (Desloratadine)			S	Transplacental			Not Reported	
	Pariet			S	Transplacental			Not Reported	
	Orelox			S	Transplacental			Not Reported	
	Zithromax			S	Transplacental			Not Reported	
	Ventilastin Novolizer			S	Transplacental			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Singulair		S	Transplacental				Not Reported	
	Tobi		S	Transplacental				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	12957888	EXPEDITED (15-DAY)		OT	FR-ABBVIE-16P-056-1786065-00			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Arrhythmia; Foetal Exposure During Pregnancy; Premature Baby	Creon			S	Transplacental			Not Reported	
	Aerius (Ebastine)			S	Transplacental			Not Reported	
	Orelox			S	Transplacental			Not Reported	
	Zithromax			S	Transplacental			Not Reported	
	Singulair			S	Transplacental			Not Reported	
	Speciafoldine			S	Transplacental			Not Reported	
	Mopral			S	Transplacental			Not Reported	
	Augmentin			S	Transplacental			Not Reported	
	Ventilastin Novolizer			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	12957892	EXPEDITED (15-DAY)		OT	FR-ABBVIE-16P-056-1786086-00			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Pre-Eclampsia	Creon			S	Oral	7 Capsules Per Day		Not Reported	
	Aerius (Desloratadine)			S	Oral	1 Dosage Form Per Day		Not Reported	
	Orelox			S	Oral			Not Reported	
	Zithromax			S	Oral	5 Days Over 7 Days For A Dose Not Specified		Not Reported	
	Ventilastin Novolizer			S	Respiratory (inhalation)			Not Reported	
	Singulair			S	Oral			Not Reported	
	Speciafoldine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mopral	S	Unknown		Not Reported
Augmentin	S	Unknown	Alternating Every 15 Days For A Dose Not Specified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13541865	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2017M1028338			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clumsiness; Drug Interaction; Product Use Issue	Clarithromycin			S		Unknown		Not Reported
	Azithromycin			S		10 MI		Mylan
	Fycompa			S		8 Mg Alternating With 10 Mg		Mylan
	Fycompa			S		Unknown		Mylan
	Clobazam			C		Unknown		Mylan
	Lacosamide			C		Unknown		Mylan
	Lansoprazole			C		Unknown		Mylan
	Phenobarbital			C		Unknown		Mylan
	Prednisolone			C				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13584276	NON-EXPEDITED			US-PFIZER INC- 2017227522			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2017	13587501	DIRECT		DS, OT			56 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Tinnitus	Azithromycin 250mg	Y		S	Oral	Quantity:1 Tablet(S);		Teva
	Enalapril			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atorvastatin	C	Not Reported
Claritin	C	Not Reported
Flonase	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2017	13571575	NON-EXPEDITED			US-PFIZER INC-2017225822		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Doxycycline Monohydrate			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Keflex			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13502216	EXPEDITED (15-DAY)		HO	FR-CONCORDIA PHARMACEUTICALS INC.-GSH201704-002615		82 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia	Plaquenil			S	Oral	Daily, Few Month		Not Reported
	Novatrex			S	Oral			Not Reported
	Metformin			S	Oral			Not Reported
	Xultophy			S	Subcutaneous	At Bedtime		Not Reported
	Allopurinol			S	Oral			Not Reported
	Ultibro			S				Not Reported
	Folic Acid			S	Oral			Not Reported
	Irbesartan			S	Oral			Not Reported
	Clopidogrel			S	Oral			Not Reported
	Amlodipine			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13541568	EXPEDITED (15-DAY)		OT	GB-ABBVIE-17P-167-1974081-00		11 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clumsiness; Drug Interaction; Product Administered To Patient Of Inappropriate Age	Clarithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Fycompa			S	Unknown	8 Mg Alternating With 10 Mg.		Not Reported	
	Fycompa			S	Unknown			Not Reported	
	Clobazam			C	Unknown			Not Reported	
	Lacosamide			C	Unknown			Not Reported	
	Lansoprazole			C	Unknown			Not Reported	
	Phenobarbital			C	Unknown			Not Reported	
	Prednisolone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13590122	EXPEDITED (15-DAY)		HO, OT	AU-IBIGEN-2017.02710		39 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Eosinophilia; Pyrexia	Piptaz			S		4.5 G		Not Reported	
	Azithromycin			S		500 Mg Daily		Not Reported	
	Ceftriaxone			S				Not Reported	
	Ciprofloxacin			S		800 Mg Daily		Not Reported	
	Meropenem			S		1 G		Not Reported	
	Vancomycin			S		750 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13591460	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-9812408		2 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrioventricular Block	Zithromax	S		10 Mg/Kg, Unk	Pfizer
Second Degree;	Zithromax	S	Oral	5 Mg/Kg, Daily	Pfizer
Decreased Appetite;	Digoxin	S	Oral	60 Ug, 2x/Day	Not Reported
Diarrhoea; Drug	Digoxin	S	Oral	50 Ug, 2x/Day	Not Reported
Interaction; Sinus Arrest;	Lasix /00032601/	C	Oral	15 Mg, Daily	Not Reported
Supraventricular	Chlorothiazide	C	Unknown	Unk	Not Reported
Extrasystoles; Toxicity To	Potassium Chloride	C	Oral	10 Meq, Daily	Not Reported
Various Agents	Salbutamol Sulfate	C	Unknown	Unk	Not Reported
	Calamine Lotion Phenolated	C	Topical	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13592543	EXPEDITED (15-DAY)		OT	CH-TEVA-771766ISR		18 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder;	Azithromycin Mepha			S	Intravenous drip	1000 Milligram Daily;		Not Reported
Dyspnoea;	Cipralax			S	Unknown	160 Milligram Daily;		Not Reported
Gastrointestinal Disorder;								
Neck Pain								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2017	13594072	NON-EXPEDITED			US-PFIZER INC-2017229411			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pre-Existing Condition	Zithromax			S		500 Mg Day 1 And Then		Pfizer
Improved; Therapeutic						250 Mg Daily Days 2-5		
Response Unexpected	Zithromax			S		500 Mg Day 1 And Then		Pfizer
						250 Mg Daily Days 2-5		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	12957778	EXPEDITED (15-DAY)		CA, DE, OT	FR-ABBVIE-16P-056-1786083-00			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Foetal Death; Foetal Exposure During Pregnancy; Foetal Growth Restriction	Creon	S	Transplacental	Not Reported
	Aerius (Desloratadine)	S	Transplacental	Not Reported
	Pariet	S	Transplacental	Not Reported
	Orelax	S	Transplacental	Not Reported
	Zithromax	S	Transplacental	Not Reported
	Ventilastin	S	Transplacental	Not Reported
	Singulair	S	Transplacental	Not Reported
	Tobi	S	Transplacental	Not Reported
			300mg/5ml	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13368025	EXPEDITED (15-DAY)			US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-136563		22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Unevaluable Event	Azithromycin			S	Unknown	Unk		Sun
	Omalizumab			S	Unknown	Unk, Monthly		Not Reported
	Roflumilast			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13455694	NON-EXPEDITED			US-PFIZER INC- 2017164751		16 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2017	13596755	NON-EXPEDITED			US-PFIZER INC- 2017234461		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13598064	EXPEDITED (15-DAY)		OT	CO-PFIZER INC-2017233674			Male	COL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Haematochezia	Zitromax Md			S				Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13598511	DIRECT		DS			81 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Muscular Weakness; Rotator Cuff Syndrome	Azithromycin 250mg			S	Oral	Quantity:4 Tablet(S);		Unknown	
	Breo			C				Not Reported	
	Spiriva			C				Not Reported	
	Lisinopril			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2017	13601787	DIRECT		DS, LT			9 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Label Confusion	Azythromycin Oral Suspension	Y		S	Oral	Quantity:1 Teaspoon(S);		Greenstone	
	Albuterol Inhaler			C				Not Reported	
	Gummy Vitamins			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2017	13505346	EXPEDITED (15-DAY)		HO	US-SUNOVION-2017SUN001829			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Neutropenia	Utibron			S	Respiratory (inhalation)	1 Puff, Qd		Sunovion	
	Novatrex			S	Oral	2 Df, Weekly		Not Reported	
	Plaquenil			S	Oral	2 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Metformin Mylan	S	Oral	500 Mg, Tid	Not Reported
	Xultophy	S	Subcutaneous	100 U/MI + 3.6 Mg/MI, Hs	Not Reported
	Allopurinol Merck	S	Oral	100 Mg, Qd	Not Reported
	Folic Acid Arrow	S	Oral	5 Mg, Qd	Not Reported
	Irbesartan Mylan	S	Oral	300 Mg, Qd	Not Reported
	Clopidogrel Mylan	S	Oral	75 Mg, Qd	Not Reported
	Amlodipine Merck-Generics	S	Oral	5 Mg, Qd	Not Reported
	Prevenar	C			Not Reported
	Pneumo 23	C			Not Reported
	Movicol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13602134	NON-EXPEDITED			US-PFIZER INC-2017236227			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Product Administration Error; Product Label Issue	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13603303	EXPEDITED (15-DAY)		LT, OT	US-PFIZER INC-2015387922		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Long Qt Syndrome; Sudden Cardiac Death	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2017	13603607	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1032359			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium Febrile; Eosinophilia; Neutrophilia; Oxygen Saturation	Clozapine			S		Unk		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxone			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Tachycardia; Tachypnoea; White Blood Cell Analysis Abnormal	Esomeprazole Metoprolol Paracetamol Quetiapine Risperidone Rosuvastatin Valproate Sodium Duloxetine /01749302/ Multi Vitamin Aspirin /00002701/ Budesonide Linagliptin Gliclazide Lorazepam Thyroxine Metformin /00082702/	C C C C C C C C C C C C C C C C	Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13606934	EXPEDITED (15-DAY)		OT	US-BEH-2017080802		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pharyngitis Streptococcal	Privigen			S	Intravenous (not otherwise specified)	45 G, Qmt		Csl Behring
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring
	Privigen			S	Intravenous (not otherwise specified)	Unk		Csl Behring
	Prenatal Vitamins /02014401/			C				Not Reported
	Zofran /00955301/			C				Not Reported
	Vitamin B-6			C				Not Reported
	Unisom /00000402/			C				Not Reported
	Vitamin D3			C				Not Reported
	Loperamide			C				Not Reported
	Cholestyramin			C				Not Reported
	Viibryd			C				Not Reported
	Acetaminophen			C				Not Reported
	Diphenhydramine			C				Not Reported
	Lidocaine			C				Not Reported
	Sodium Chloride			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Epipen	C	Not Reported
	Furosemide	C	Not Reported
	Tylenol Extra Strength	C	Not Reported
	Protonix	C	Not Reported
	Z-Pak	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609564	NON-EXPEDITED			US-PFIZER INC-2867548		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Pain; Infusion Site Rash; Poor Quality Product Administered; Product Colour Issue	Azithromycin			S	Intravenous drip	500 Mg, Daily		Pfizer	
	Sodium Chloride			S	Intravenous drip	Unk		Unknown	
	Carvedilol			C	Oral	2.5 Mg, Daily; Freq: 2 Day; Interval: 1		Not Reported	
	Lovastatin			C	Oral	40 Mg, Daily		Not Reported	
	Omeprazole			C	Oral	20 Mg, Daily		Not Reported	
	Spironolactone			C	Oral	25 Mg, Daily		Not Reported	
	Warfarin			C	Oral	2 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609565	NON-EXPEDITED			US-PFIZER INC-2867545		93 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Infusion Site Pain; Infusion Site Rash; Peripheral Swelling; Poor Quality Product Administered; Product Colour Issue	Azithromycin			S	Intravenous drip	500 Mg, Daily		Pfizer	
	Sodium Chloride			S	Intravenous drip	Unk		Unknown	
	Imdur			C	Oral	60 Mg, Daily		Not Reported	
	Losartan			C	Oral	50 Mg, Daily		Not Reported	
	Norvasc			C	Oral	2.5 Mg, Daily		Not Reported	
	Warfarin			C	Oral	Variable Dose, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2017	13609566	NON-EXPEDITED			US-PFIZER INC-		47 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2867539

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infusion Site Erythema; Infusion Site Pain; Injection Site Pruritus; Poor Quality Product Administered; Product Colour Issue; Rash Macular	Azithromycin			S	Intravenous drip	500 Mg, Daily		Pfizer
	Sodium Chloride			S	Intravenous drip	Unk		Unknown
	Bactrim			C	Oral	0.5 Unit Not Provided Freq: 2 Day; Interval: 1		Not Reported
	Nexium /01479302/			C	Oral	20 Mg, Hs		Not Reported
	Oxycodone			C	Oral	10 Mg, Freq: 1 Hour; Interval: 4		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13587260	EXPEDITED (15-DAY)		DE, HO, OT	IT-PFIZER INC- 2017231131		76 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholelithiasis; Drug Abuse; Hepatic Enzyme Increased; Jaundice	Azithromycin			S	Oral	500 Mg, Alternate Day		Pfizer
	Deltacortene			C	Oral	25 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13610230	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2017-01333		52 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Tachycardia; Vulvovaginal Burning Sensation	Azithromycin			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13610232	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2017-01337		42 YR	Female	BRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chemical Phlebitis	Azithromycin			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13610234	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2017-01781		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity	Azithromycin			S	Oral	Unk		Lupin
	Azithromycin			S	Oral	Unk		Lupin
	Levofloxacin			C	Unknown	Unk		Not Reported
	Amikacin			C	Unknown			Not Reported
	Imipenem			C	Unknown	Unk		Not Reported
	Imipenem			C	Unknown	Unk		Not Reported
	Tigecycline			C	Unknown	Unk		Not Reported
	Tigecycline			C	Intravenous (not otherwise specified)	50 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13612501	EXPEDITED (15-DAY)		OT	PHHY2017BR078779			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Hypersensitivity; Streptococcal Infection; Wheezing	Azithromycin			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13613122	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2017240118		15 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Lip Swelling; Peripheral Swelling;	Azithromycin			S	Oral	500 Mg, Daily		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Reaction To Excipient	Azithromycin	S	Oral	250 Mg, Daily	Pfizer				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13616035	DIRECT	Y	RI			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme;	Azithromycin			S	Oral				Not Reported
Pruritus; Rash	Codeine/Guaifenesin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2017	13616144	DIRECT	Y	RI			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme	Codeine/Guaifenesin			S	Oral				Not Reported
	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	10900873	NON-EXPEDITED			US-PFIZER INC-2015084352		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
	Dilaudid			S		Unk			Not Reported
	Lisinopril			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13557698	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017210606		40 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Altered State Of Consciousness; Fall; Syncope	Zithromac 250mg			S	Oral	500 Mg			Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13614605	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1033234			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Eosinophilia;	Azithromycin			S		Unk		Not Reported	
Leukocytosis;	Clozapine			S		Unk		Not Reported	
Neutrophilia;	Ceftriaxone			S		Unk		Not Reported	
Polychromasia; Pyrexia;	Duloxetine			C		Unk		Mylan	
Tachycardia; Tachypnoea	Metformin			C		Unk		Mylan	
	Multivitamins /00116001/			C		Unk		Mylan	
	Aspirin /00002701/			C		Unk		Mylan	
	Budesonide			C		Unk		Mylan	
	Esomeprazole			C		Unk		Mylan	
	Gliclazide			C		Unk		Mylan	
	Linagliptin			C		Unk		Mylan	
	Lorazepam			C		Unk		Mylan	
	Metoprolol			C		Unk		Mylan	
	Paracetamol			C		Unk		Mylan	
	Quetiapine			C		Unk		Mylan	
	Risperidone			C		Unk		Mylan	
	Rosuvastatin			C		Unk		Mylan	
	Valproate Sodium			C		Unk		Mylan	
	Thyroxine			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13616200	NON-EXPEDITED			US-PFIZER INC-2017241937		20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bedridden; Condition	Zithromax			S	Oral	500 Mg (Two 250 Mg		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aggravated; Feeding Disorder; General Physical Health Deterioration; Myalgia; Nausea; Pharyngitis Streptococcal; Vomiting; Weight Decreased	Ibuprofen	C	Oral	Tablets), 1x/Day	Not Reported
	Ibuprofen	C	Oral	"Over 2000 Or 2500mg", Daily 200 Or 400, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13616203	NON-EXPEDITED			US-PFIZER INC-2017241738			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response Decreased	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13618497	NON-EXPEDITED		HO, OT	US-PFIZER INC-2017240059		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dehydration; Hepatic Failure; Malaise; Pancreatitis	Zithromax			S	Oral	Unk, Used As Directed		Pfizer	
	Zithromax			S	Oral	Unk, Used As Directed		Pfizer	
	Zithromax			S				Pfizer	
	Prednisone			S	Oral	Unk, Used As Directed		Not Reported	
	Prednisone			S	Oral	Unk, Used As Directed		Not Reported	
	Prednisone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13618709	NON-EXPEDITED			US-PFIZER INC-2017243563			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Topamax			S		Unk		Not Reported	
	Ultram			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tramadol	S	Unk	Not Reported
Ceclor	S	Unk	Not Reported
Toradol	S	Unk	Not Reported
Singulair	S	Unk	Not Reported
Amitriptyline	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13619843	EXPEDITED (15-DAY)		OT	PHHY2017AU078697			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium; Eosinophilia;	Clozapine			S	Unknown	Unk		Not Reported
Leukocytosis;	Azithromycin			S	Unknown	Unk		Novartis
Neutrophilia;	Ceftriaxone			S	Unknown	Unk		Not Reported
Polychromasia; Pyrexia;	Duloxetine			C	Unknown	Unk		Not Reported
Tachycardia; Tachypnoea	Metformin			C	Unknown	Unk		Not Reported
	Multivitamins			C	Unknown	Unk		Not Reported
	Aspirin			C	Unknown	Unk		Not Reported
	Budesonide			C	Unknown	Unk		Not Reported
	Esomeprazole			C	Unknown	Unk		Not Reported
	Gliclazide			C	Unknown	Unk		Not Reported
	Linagliptin			C	Unknown	Unk		Not Reported
	Lorazepam			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Quetiapine			C	Unknown	Unk		Not Reported
	Risperidone			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Valproate Sodium			C	Unknown	Unk		Not Reported
	Thyroxine			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2017	13619853	EXPEDITED (15-DAY)		OT	PHHY2017AU077846			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium Febrile; Eosinophilia; Neutrophilia; Oxygen Saturation Decreased; Tachycardia; Tachypnoea; White Blood Cell Analysis Abnormal	Clozapine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Novartis
	Ceftriaxone			S	Unknown			Not Reported
	Esomeprazole			C	Unknown			Not Reported
	Metoprolol			C	Unknown			Not Reported
	Paracetamol			C	Unknown			Not Reported
	Quetiapine			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported
	Rosuvastatin			C	Unknown			Not Reported
	Valproate Sodium			C	Unknown			Not Reported
	Duloxetine			C	Unknown			Not Reported
	Multi Vitamin			C	Unknown			Not Reported
	Aspirin			C	Unknown			Not Reported
	Budesonide			C	Unknown			Not Reported
	Linagliptin			C	Unknown			Not Reported
	Gliclazide			C	Unknown			Not Reported
	Lorazepam			C	Unknown			Not Reported
	Thyroxine			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13620703	DIRECT	Y	HO			10 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt	Azithromycin, 500 Mg			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prolonged; Fall; Gait
Disturbance; Headache;
Hypopnoea; Hypotension;
Loss Of Consciousness;
Ventricular Fibrillation;
Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13621265	NON-EXPEDITED			US-PFIZER INC- 2017243231			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Tamoxifen Citrate			S		Unk		Pfizer
	Cephalexin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Phenergan			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13621499	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-142473		53 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Ranbaxy
	Azithromycin			S	Unknown	Unk		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13622145	DIRECT	Y	DS			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Azithromycin 250mg			S	Oral		5 DAY	Teva
	Acyclovir			C				Not Reported
	Macrobid			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13622434	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2017-34966		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Hypertension	Azithromycin Film-Coated Tablets			S	Oral	500 Mg, Daily		Aurobindo	
	Lasix /00032601/			C	Oral	Unk		Not Reported	
	Levofloxacin Hemihydrate			C	Intramuscular	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13627840	DIRECT		HO			51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Chest Pain; Condition Aggravated; Cough; Dyspnoea; Flank Pain; Poor Venous Access; Pulmonary Embolism; Pyrexia; Vein Rupture	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2017	13628767	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017240471		55 YR	Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Melaena	Zithromac 250mg			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	12315053	NON-EXPEDITED			US-PFIZER INC-2016205993		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Clindamycin Hcl		S		Unk		Pfizer		
	Vibramycin		S		Unk		Pfizer		
	Erythromycin		S		Unk		Pfizer		
	Compazine		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	12803933	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2016457154		32 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Oral	500 Mg, Daily (Every 24 H)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13624617	NON-EXPEDITED			US-PFIZER INC-2017247735			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Naprosyn			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13626357	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2017GSK087874		24 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activated Partial Thromboplastin Time Prolonged; Blood Creatine Phosphokinase Increased; Cough; Haemoptysis; Myalgia; Prothrombin Level Decreased; Transaminases Increased	Seretide Diskus 250			S				Glaxosmithkline	
	Lumacaftor			S	Oral	2 Unk, Bid		Not Reported	
	Tobi			S				Glaxosmithkline	
	Zitromax			S		Unk		Glaxosmithkline	
	Xyzall			S		Unk		Glaxosmithkline	
	Mopral			S		Unk		Glaxosmithkline	
	Creon			C				Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Delursan			C					Not Reported
	Toco			C					Not Reported
	Uvedose			C					Glaxosmithkline
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13627103	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017233166		41 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Hypertension	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Lasix			C	Oral	Unk		Not Reported	
	Levofloxacin Hemihydrate			C	Intramuscular	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13628713	EXPEDITED (15-DAY)		HO, OT	GB-SA-2017SA098282		72 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased	Dronedarone			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Aminophylline			C				Not Reported	
	Eliquis			C				Not Reported	
	Bisoprolol			C				Not Reported	
	Duoresp Spiromax			C				Not Reported	
	Furosemide			C				Not Reported	
	Omeprazole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2017	13628938	NON-EXPEDITED			US-PFIZER INC-2017246234			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	12124554	EXPEDITED (15-DAY)		HO, OT	FR-JNJFOC-20151014896		45 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Diarrhoea	Tmc207			S	Oral			Not Reported	
Haemorrhagic;	Tmc207			S	Oral			Not Reported	
Hemiparesis;	Tmc207			S	Oral			Not Reported	
Hepatocellular Injury;	Tmc207			S	Oral			Not Reported	
Hepatotoxicity; Off Label	Tmc207			S	Oral			Not Reported	
Use; Papilloedema;	Azithromycine			S	Oral			Not Reported	
Product Use In	Azithromycine			S	Oral			Not Reported	
Unapproved Indication;	Azithromycine			S	Oral			Not Reported	
Tuberculosis	Azithromycine			S	Oral			Not Reported	
	Azithromycine			S	Oral			Not Reported	
	Clofazimine			S	Oral			Not Reported	
	Clofazimine			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Mikicort			S	Oral			Not Reported	
	Racecadotril			C	Unknown			Not Reported	
	Morphine Sulfate			C	Unknown			Not Reported	
	Mianserine			C	Unknown			Not Reported	
	Clonazepam			C	Unknown			Not Reported	
	Clonazepam			C	Unknown			Not Reported	
	Methylprednisolone			C	Unknown			Not Reported	
	Ondansetron			C	Unknown			Not Reported	
	Dexamethasone			C	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13286663	NON-EXPEDITED		HO, OT	US-PFIZER INC-2017085262		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Tachycardia	Zithromax			S		500 Mg The First Day And Then 250 Mg Days 2-5		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13635330	NON-EXPEDITED			US-PFIZER INC-2017248493			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13638745	EXPEDITED (15-DAY)		DE, OT	TW-TAKEDA-2017TUS012744		65 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Febuxostat			S	Other	Unk		Takeda	
	Azithromycin			S	Other	Unk		Not Reported	
	Ampicillin/Sulbactam Actavis			S	Other	Unk		Not Reported	
	Piperacillin/Tazobactam			S	Other	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13639065	NON-EXPEDITED		OT	GXBR2017US001923			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Azithromycin 250 Mg			S	Unknown	Unk Df, Unk		Novartis	
	Prednisone			S	Unknown	Unk Df, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jun-2017	13641594	DIRECT	Y	HO			58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S	Oral			Not Reported	
	Dextromethorphan/Guaifenesin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2017	13641625	DIRECT	Y	OT			73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia	Azithromycin			S	Oral	Other Frequency:Zpak Dosing;		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	11756763	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015RR-106239			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2017	13642367	EXPEDITED (15-DAY)		OT	US-DRREDDYS- USA/USA/17/0091153		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Neutropenia; Platelet Count Decreased	Moxifloxacin			S	Unknown			Not Reported	
	Ciprofloxacin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	12476038	EXPEDITED (15-DAY)		OT	GB-TEVA-668674ISR		20 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S				Not Reported	
	Bedaquiline			S		For 2 Weeks		Not Reported	
	Bedaquiline			S		200 Mg Three Times Weekly		Not Reported	
	Clofazimine			S				Not Reported	
	Pyrazinamide			C				Not Reported	
	Cycloserine			C				Not Reported	
	Para-Aminosalicylic Acid			C				Not Reported	
	Linezolid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13491847	EXPEDITED (15-DAY)		OT	US-BAYER-2017-079483		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cervical Dysplasia; Device Placement Issue; Medical Device Repositioning; Obesity; Uterine Perforation	Mirena			S	Intra-uterine	20 Mcg/24hr, Cont		Bayer	
	Zithromax			S	Oral	250 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13615628	NON-EXPEDITED			US-PFIZER INC-2017243790		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Amiodarone Hcl			S		Unk		Pfizer	
	Benzocaine W/Cetylpyridinium			S		Unk		Not Reported	
	Benadryl			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cephalexin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13645680	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE60768		24 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activated Partial Thromboplastin Time Prolonged; Blood Creatine Phosphokinase Increased; Cough; Haemoptysis; Myalgia; Prothrombin Level Decreased; Prothrombin Time Ratio Decreased; Transaminases Increased	Mopral			S	Oral			Not Reported	
	Ivacaftor			S	Oral			Not Reported	
	Ivacaftor			S	Oral			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Xyzall			S	Unknown			Not Reported	
	Seretide Diskus			S	Unknown	250/50, Unknown		Not Reported	
	Tobi			S	Unknown			Not Reported	
	Creon			C				Not Reported	
	Delursan			C				Not Reported	
	Toco			C				Not Reported	
	Uvedose			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2017	13648781	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017248627		24 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activated Partial Thromboplastin Time Prolonged; Blood Creatine Phosphokinase Increased; Cough; Haemoptysis; Myalgia; Prothrombin Level Decreased; Prothrombin Time Ratio Increased; Transaminases Increased	Zithromax			S		Unk		Pfizer	
	Orkambi			S	Oral	2 Df, 2x/Day		Not Reported	
	Seretide Discus			S		Unk		Not Reported	
	Tobi			S		Unk		Not Reported	
	Xyzall			S		Unk		Not Reported	
	Mopral			S		Unk		Not Reported	
	Creon			C		Unk		Not Reported	
	Delursan			C		Unk		Not Reported	
	Toco			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Uvedose			C			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Jun-2017	13359858	EXPEDITED (15-DAY)		DS, HO	FR-SA-2017SA045464		79 YR	Female	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anal Incontinence; Extradural Haematoma; Sensorimotor Disorder; Spinal Cord Compression	Cortancyl			S	Oral			Not Reported		
	Hydrocortisone		Y	S	Oral			Not Reported		
	Hydrocortisone		Y	S	Oral			Not Reported		
	Lovenox			S	Subcutaneous			Not Reported		
	Eliquis			S	Oral			Not Reported		
	Novatrex			S	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Jun-2017	13650830	EXPEDITED (15-DAY)		OT	RO-MYLANLABS-2017M1035616			Unknown	ROM	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental			Not Reported		
	Ampicillin			S	Transplacental			Not Reported		
	Atosiban			S	Transplacental			Mylan		
	Progesterone			S	Transplacental			Mylan		
	Clavulanic Acid			S	Transplacental			Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Jun-2017	13650831	EXPEDITED (15-DAY)		OT	RO-MYLANLABS-2017M1035632			Unknown	ROM	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental			Not Reported		
	Ampicillin			S	Transplacental			Not Reported		
	Atosiban			S	Transplacental			Mylan		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Progesterone	S	Transplacental	Mylan
Clavulanic Acid	S	Transplacental	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2017	13651032	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2017090786		24 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Activated Partial Thromboplastin Time Prolonged; Blood Creatine Phosphokinase Increased; Cough; Haemoptysis; Myalgia; Prothrombin Level Decreased; Prothrombin Time Ratio Increased; Transaminases Increased	Xyzall			S		Unk		Glaxosmithkline
	Mopral			S		Unk		Glaxosmithkline
	Zithromax			S		Unk		Not Reported
	Tobi			S				Glaxosmithkline
	Fluticasone Propionate+Salmeterol Xinafoate			S		250/50 ?G/ Dose, Inhalaton Powder In Single Dose Container		Glaxosmithkline
	Creon (Pancreatin)			C				Not Reported
	Delursan			C		Unk		Not Reported
	Tocopheryl Acetate			C				Not Reported
	Uvedose			C				Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	10014483	EXPEDITED (15-DAY)		OT	CA-009507513-1403CAN003893		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Foetal Exposure During Pregnancy	Isentress			S	Transplacental	400 Mg, Bid		Merck
	Abacavir			S	Transplacental	300 Mg, Bid		Not Reported
	Acyclovir			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	2 Every 1 Days		Not Reported
	Bactrim			S	Transplacental	400 Mg, Bid		Not Reported
	Intelence			S	Transplacental	200 Mg, Bid		Not Reported
	Lamivudine			S	Transplacental	150 Mg, Bid		Not Reported
	Prezista			S	Transplacental	600 Mg, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ritonavir	S	Transplacental	100 Mg, Bid	Not Reported
Tenofovir	S	Transplacental	300 Mg, Qd	Not Reported
Zidovudine	S	Transplacental	300 Mg, Bid	Not Reported
Folic Acid	C	Transplacental		Not Reported
Iron (Unspecified)	C	Transplacental	Unk	Not Reported
Magnesium Gluconate	C	Transplacental		Not Reported
Iron (Unspecified) (+) Minerals (Unspecified) (+) Vitamins (Unspecifie	C	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	11196290	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2015197859		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	12310955	NON-EXPEDITED			US-PFIZER INC- 2016230261			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Ceclor			S		Unk		Not Reported	
	Excedrin Back And Body			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13468609	NON-EXPEDITED			US-PFIZER INC- 2017171487			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lexapro			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2017	13559013	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2017212567		22 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Dysbiosis; Gastroenteritis Staphylococcal	Azithromycin			S		Unk; (Single Course)		Pfizer		
	Azithromycin			S		Unk		Pfizer		
	Ciprofloxacin			S	Oral	Unk		Unknown		
	Cefixime			S		Unk; (Single Course)		Not Reported		
	Moxifloxacin			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2017	13577813	EXPEDITED (15-DAY)		OT	CH-ALLERGAN-1721293US		18 YR	Male	CHE	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cardiac Disorder; Dyspnoea; Gastrointestinal Disorder; Neck Pain; Overdose	Escitalopram Oxalate - Bp			S	Oral	Unk, Qd		Allergan		
	Azithromycin Mepha			S	Intravenous drip	500 Mg, Q12h		Not Reported		
	Azithromycin Mepha			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2017	13655592	NON-EXPEDITED			US-PFIZER INC-2017259220		57 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Malaise	Zithromax			S		Unk		Pfizer		
	Zofran			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Jun-2017	13655688	NON-EXPEDITED			US-PFIZER INC-2017258646		61 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer
	Biaxin	S	Unk	Not Reported
	Cephalexin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2017	13657331	NON-EXPEDITED			US-PFIZER INC-2017256416			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2017	13661104	EXPEDITED (15-DAY)		HO	CA-APOTEX-2017AP012969		62 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Eye Swelling; Impaired Healing; Knee Operation; Lip Swelling; Urticaria	Apo-Metformin - Tab 500mg			S	Oral	500 Mg, Bid		Apotex	
	Apo-Tobramycin			S	Unknown	0.3 %, Unk		Apotex	
	Apo-Rabeprazole			S	Oral	20 Mg, Unk		Not Reported	
	Apo-Tamsulosin Cr			S	Oral	0.4 Mg, Unk		Not Reported	
	Pms Azithromycin			S	Oral	250 Mg, Unk		Not Reported	
	Supeudol			S	Oral	5 Mg, Unk		Not Reported	
	Tylenol /00020001/			C	Unknown			Not Reported	
	Zantac			C	Unknown			Not Reported	
	Hydroxyzine Hydrochloride			C	Unknown			Not Reported	
	Aerius /01009701/			C	Unknown			Not Reported	
	Amlodipine			C	Unknown			Not Reported	
	Cozaar			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Jun-2017	13662131	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017258785		73 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea; Tachycardia	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jun-2017	13662672	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS-2017M1035854			Unknown	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Alkaline Phosphatase Increased; Blood Lactic Acid Increased; Hepatic Function Abnormal; Lymphocyte Stimulation Test Positive; Toxic Skin Eruption	Biperiden Mylan Fluvoxamine Vegetamin A Flunitrazepam Azithromycin Azithromycin Calonal Calonal			S S S S S S S S	Oral Oral Oral Oral Oral	3 Mg, Unk Unk 1 Df, Unk 1 Df, Unk 500 Mg, Prn		Mylan Not Reported Mylan Mylan Mylan Mylan Mylan Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	11774215	EXPEDITED (15-DAY)		OT	PHHY2015ES150054		71 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Generalised Exanthematous Pustulosis; Pustule	Azithromycin			S	Unknown			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Jun-2017	13351687	EXPEDITED (15-DAY)		DS, HO	FR-PFIZER INC-2017112262		79 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anal Incontinence; Extradural Haematoma; Sensorimotor Disorder; Spinal Cord Compression	Novatrex	S	Oral	2.5 Mg, Weekly, 2.5 Mg Tablet At A Dose Of 1 Tablet Weekly	Pfizer
	Eliquis	S	Oral	1 Tab, Bid, In The Morning And In The Evening	Not Reported
	Hydrocortisone	S	Oral	20 Mg, 1x/Day	Not Reported
	Hydrocortisone	S	Oral	20 Mg, 1x/Day	Not Reported
	Cortancyl	S	Oral	4 Df, Qd	Not Reported
	Lovenox	S	Subcutaneous	1 Df, 2x/Dayin The Morning And In The Evening	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2017	13664623	EXPEDITED (15-DAY)		OT	FR- GLAXOSMITHKLINE- FR2017GSK093468		27 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Muscle Spasms; Respiratory Failure	Valaciclovir			S	Oral	500 Mg, Bid		Glaxosmithkline
	Jakavi			S	Oral	15 Mg, Bid		Not Reported
	Delursan			S	Oral	1 Df, Tid		Not Reported
	Cortancyl			S	Oral	Unk		Not Reported
	Orocal D3			S	Oral	1 Df, 1d		Not Reported
	Inexium			S	Oral	1 Df, 1d		Not Reported
	Bactrim			S	Oral	Unk		Glaxosmithkline
	Zithromax			S		2 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2017	13667933	DIRECT					55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Balance Disorder; Hypoaesthesia; Hypoaesthesia;	Azithromycin 500 Mg			S	Oral	Quantity:5 Tablet(S);		Not Reported
	Womens 50+ Multi-Vitamin			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hypoaesthesia; Muscle
Tightness; Neuropathy
Peripheral; Paraesthesia;
Peripheral Coldness

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	11196348	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC- 2015197857		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Bronchiolitis; Drug- Induced Liver Injury; Stevens-Johnson Syndrome	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13668958	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2017257196		28 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Respiratory Failure	Zithromax			S	Oral	Unk Unk, 2x/Day		Pfizer	
	Valaciclovir			S	Oral	500 Mg, 2x/Day		Not Reported	
	Jakavi			S	Oral	15 Mg, 2x/Day		Not Reported	
	Delursan			S	Oral	1 Df, Thrice Every 3 Days		Not Reported	
	Cortancyl			S	Oral	Unk		Not Reported	
	Orocal D3			S	Oral	1 Df, 1x/Day		Not Reported	
	Inexium /01479302/			S	Oral	1 Df, 1x/Day		Not Reported	
	Bactrim			S	Oral	3 Df, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13669165	EXPEDITED (15-DAY)		OT	PHHY2017FR085938		24 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Activated Partial	Tobi			S	Unknown			Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Thromboplastin Time	Orkambi	S	Oral	2 Df, Bid	Not Reported
Prolonged; Blood Creatine	Seretide	S	Unknown		Not Reported
Phosphokinase Increased;	Zithromax	S	Unknown		Not Reported
Cough; Haemoptysis;	Xyzal	S	Unknown		Not Reported
Myalgia; Prothrombin	Mopral	S	Unknown		Not Reported
Level Decreased;	Creon	C	Unknown		Not Reported
Prothrombin Time Ratio	Delursan	C	Unknown		Not Reported
Increased; Transaminases	Toco	C	Unknown		Not Reported
Increased	Uvedose	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13669315	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2017SE63415		28 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Respiratory Failure	Inexium			S	Oral			Astrazeneca	
	Jakavi			S	Oral			Not Reported	
	Valaciclovir			S	Oral			Not Reported	
	Delursan			S	Oral			Not Reported	
	Cortancyl			S	Oral			Not Reported	
	Orocal D3			S	Oral			Not Reported	
	Bactrim			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2017	13672309	DIRECT	Y	OT			51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Disorder; Hypoaesthesia; Lethargy; Muscle Twitching	Azithromycin			S	Oral	Other Frequency:2 Tab Day 1;	2 DAY	Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	11901857	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2015451705		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hemiparesis; Myelitis Transverse; Paraesthesia	Novatrex			S	Oral	1 Df, Weekly		Pfizer	
	Tenormin			S	Oral	1 Df, Once Daily		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	250 Mg, 1 Injection Every 10 Weeks		Not Reported	
	Speciafoldine			S	Oral	1 Mg, Weekly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13456373	EXPEDITED (15-DAY)		OT	GXBR2017US001400		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amnesia; Buttock Injury; Head Injury; Headache; Loss Of Consciousness	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2017	13635528	NON-EXPEDITED			US-PFIZER INC-2017252599			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Epinephrine			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	11881224	EXPEDITED (15-DAY)		HO	FR-ALVOGEN-2015-ALVOGEN-020623		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hemiparesis; Myelitis Transverse; Paraesthesia	Tenormin			S	Oral			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Speciafoldine			S	Oral			Not Reported	
	Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13074483	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX-2016AP016188		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Clostridium Difficile Infection; Leukaemoid Reaction; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome; Septic Shock; Urinary Tract Infection	Azithromycin			S	Unknown			Apotex	
	Pantoprazole Sodium Delayed-Release Tablets Usp			S	Unknown			Apotex	
	Ceftriaxone			S	Unknown			Not Reported	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Other	500 Mg, Qid, By Nasogastric Tube		Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
	Diltiazem			C	Unknown			Not Reported	
	Losartan			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Aspirin /00002701/			C	Unknown			Not Reported	
	Donepezil			C	Unknown			Not Reported	
	Sertraline			C	Unknown			Not Reported	
	Budesonide W/Formoterol			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13368598	NON-EXPEDITED			US-PFIZER INC-2017127584		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Bethanechol			C	Oral	25 Mg, 2x/Day		Not Reported	
	Finasteride			C	Oral	5 Mg, 1x/Day		Not Reported	
	Tamsulosin			C	Oral	0.4 Mg, 1x/Day		Not Reported	
	Carvedilol			C	Oral	18.5 Mg, 2x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13611327	NON-EXPEDITED			US-PFIZER INC-2017239287		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Seroquel			S		Unk		Not Reported	
	Dilaudid			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13677747	EXPEDITED (15-DAY)		DE, LT	US-PFIZER INC-2013606		182 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Death; Circulatory Collapse; Off Label Use; Overdose	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
	Ceftriaxone			C	Intravenous (not otherwise specified)	50 Mg/Kg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13678523	EXPEDITED (15-DAY)		DE	US-PFIZER INC-1552583		182 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Toxicity To Various Agents	Azithromycin			S	Parenteral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13679292	EXPEDITED (15-DAY)		OT	FR-TEVA-779343ROM		28 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Respiratory Failure	Orocal Vitamine D3 [Calcium Carbonate\Cholecalciferol]			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Delursan			S	Oral	1 Dosage Forms Daily;		Teva	
	Valaciclovir			S	Oral	1000 Milligram Daily;		Not Reported	
	Cortancyl			S	Oral			Not Reported	
	Inexium			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Bactrim			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Jakavi 15 Mg			S	Oral	30 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13680002	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017267387		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Nausea; Pain; Periorbital Cellulitis; Pyrexia; Sinusitis; Swelling; Vomiting	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2017	13681723	DIRECT		LT			61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Azithromycin			S	Oral			Greenstone	
Cholelithiasis; Dyspnoea;	Alprazolam			C				Not Reported	
Feeling Abnormal;	Levothyroxine			C				Not Reported	
Headache; Hyperhidrosis;	Methylphenidate			C				Not Reported	
Intestinal Obstruction;									
Musculoskeletal Pain;									
Pancreatitis Acute;									
Pruritus; Renal Pain;									
Tinnitus									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13373718	NON-EXPEDITED			US-PFIZER INC-2017125343		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling;	Azithromycin			S	Oral	Unk, Twice A Day		Pfizer	
Photosensitivity Reaction;	Azithromycin			S				Pfizer	
Pruritus; Swelling Face;	Synthroid			C	Oral	50 Ug, Once A Day		Not Reported	
Swelling Of Eyelid;									
Urticaria									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13433851	EXPEDITED (15-DAY)		DE, OT	US-PURDUE PHARMA-GBR-2017-0044674		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abscess; Cardiac	Buprenorphine			S	Unknown			Purdue	
Tamponade; Drug Abuse;	Morphine Sulfate			S	Unknown			Purdue	
Exposure During	Hydromorphone Hydrochloride			S	Unknown			Purdue	
Pregnancy	Codeine			S	Unknown			Not Reported	
	Ibuprofene			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alprazolam	S	Unknown	90 Unk, Unk	Not Reported
Gabapentin	S	Unknown		Not Reported
Levetiracetam	S	Unknown		Not Reported
Azithromycin	S	Unknown		Not Reported
Cannabis Sativa	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13663163	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-143105		50 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Sun	
	Ceftriaxone			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13682272	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-2015-RO- 00217RO		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Renal Failure	Amikacin			S	Unknown			Eurohealth International	
	Tacrolimus			S	Unknown			Not Reported	
	Cefoxitin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Westward	
	Mycophenolate Mofetil			C	Unknown			Westward	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2017	13685304	EXPEDITED (15-DAY)		HO, LT, OT	TR- GLAXOSMITHKLINE- TR2017096573		20 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Posterior Reversible Encephalopathy Syndrome	Tacrolimus	S	Unknown	Unk	Glaxosmithkline
	Azithromycin	S	Unknown	Unk	Glaxosmithkline
	Acyclovir	S	Unknown	Unk	Glaxosmithkline
	Posaconazole	S	Unknown	Unk	Not Reported
	Vancomycin	C		Unk	Not Reported
	Vancomycin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2017	13690434	DIRECT	Y	HO, LT, RI			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Angioedema	Azithromycin			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13123704	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2017-002334		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cough; Dyspnoea; Fluid Retention; Muscle Spasms; Nausea; Wheezing	Sprycel			S	Oral	1 Tab, Qd			Bristol Myers Squibb
	Sprycel			S	Oral	1 Tab, Qd			Bristol Myers Squibb
	Welchol			S	Unknown				Not Reported
	Azithromycin			S	Unknown				Not Reported
	Prednisone			S	Unknown				Not Reported
	Tramadol			C	Unknown	Unk			Not Reported
	Xanax			C	Unknown	Unk			Not Reported
	Fluoxetine Hcl			C	Unknown	Unk			Not Reported
	Losartan Potassium			C	Unknown	Unk			Not Reported
	Dicyclomine Hcl			C	Unknown	Unk			Not Reported
	Amlodipine Besylate			C	Unknown	Unk			Not Reported
	Chlorpheniramine Maleate			C	Unknown	Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Aspirin /00002701/	C	Unknown	Unk				Not Reported	
	Vitamin D3	C	Unknown	Unk				Not Reported	
	Vitamin B12 /00056201/	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13660315	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017254385		90 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastroenteritis Staphylococcal	Zithromac			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13688439	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-03310		76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia	Moxifloxacin			S	Unknown	400 Mg, Qd		Lupin	
	Ciprofloxacin			S	Unknown	Unk Unk, Qd		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2017	13691003	EXPEDITED (15-DAY)		DE, HO, OT	RS-MYLANLABS-2017M1037840			Unknown	SRB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Megacolon	Azithromycin			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Mylan	
	Amikacin			S	Unknown			Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2017	13408018	EXPEDITED (15-DAY)		OT	IN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-137690		20 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Intravenous (not otherwise specified)	20 Mg/Kg, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2017	13694799	EXPEDITED (15-DAY)		OT	FR-INCYTE CORPORATION- 2017IN004948			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Respiratory Failure	Jakavi			S	Oral	15 Mg, Bid		Incyte	
	Valaciclovir			S	Oral	500 Mg, Bid		Not Reported	
	Delursan			S	Oral	1 Df, Unk (3 Df In 3 Days)		Not Reported	
	Cortancyl			S	Oral	Unknown		Not Reported	
	Orocal D3			S	Oral	1 Df, Qd		Not Reported	
	Inexium			S	Oral	1 Df, Qd		Not Reported	
	Bactrim			S	Oral	3 Df In 3 Days		Not Reported	
	Zithromax			S	Oral	Over 2 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	8895862	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC- 2012276062		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Medication Error	Azithromycin			S		Unk		Pfizer	
	Methadone			S		10 Mg, 3x/Day		Not Reported	
	Lisinopril W/Hydrochlorothiazide			C		20/12.5 Mg Once Daily		Not Reported	
	Benzonatate			C		100 Mg, Every 8 Hours As		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Dextromethorphan Hbr/Doxylamine Succinate/Paracetamol		C			Needed Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	9006896	EXPEDITED (15-DAY)		DE	US-PFIZER INC- 2013007324		182 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Toxicity To Various Agents	Azithromycin			S	Parenteral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	9667954	EXPEDITED (15-DAY)		DE, LT, OT	US-PFIZER INC- 2013311478		182 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Brain Death; Cardiac Arrest; Circulatory Collapse; Cyanosis; Hypotension; Listless; Off Label Use; Overdose; Unresponsive To Stimuli	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
	Ceftriaxone			C	Intravenous (not otherwise specified)	50 Mg/Kg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13351394	EXPEDITED (15-DAY)		HO	FR-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2017- BI-01		49 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenia	Spiriva			S	Respiratory (inhalation)			Boehringer Ingelheim	
	Amikacine			S	Intravenous (not otherwise specified)	Unit Dose: 1 Gram, Daily Dose: 3 Gram 1000 Mg Iv -Monday-Wednesday- Friday		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycine Anhydre	S	Oral		Not Reported
Rifadine	S	Oral		Not Reported
Dexambutol	S	Oral	750 Mg In The Morning	Not Reported
Paracetamol	S	Oral		Not Reported
Speciafoldine	S	Oral		Not Reported
Nicorette	S	Oral		Not Reported
Foradil	S	Respiratory (inhalation)	One Inhalated Dose Dose In The Morning And In The Evening	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13352560	EXPEDITED (15-DAY)	HO		PHHY2017FR041118		49 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombocytopenia	Foradil			S	Respiratory (inhalation)	Unk Unk, Bid		Novartis
	Azithromycin Anhydrous			S	Oral	250 Mg, Qd		Not Reported
	Amikacine			S	Intravenous (not otherwise specified)	3 Df, Qw		Not Reported
	Amikacine			S	Unknown	250 Mg, Bid (Amikacin In 10 MI Of Nacl 0.9%)		Not Reported
	Rifadine			S	Oral	600 Mg, Qd		Not Reported
	Dexambutol			S	Oral	750 Mg, Qd		Not Reported
	Doliprane			S	Oral	500 Mg, Maximum Dose 4g Per Day		Not Reported
	Speciafoldine			S	Oral	5 Mg, Qd		Not Reported
	Spiriva			S	Respiratory (inhalation)	18 Ug, Qd (1 Inhalation Per Day)		Not Reported
	Spiriva			S	Unknown	Unk		Not Reported
	Nicorette			S	Oral	4 Mg, Unk		Not Reported
	Alvityl			C	Unknown	Unk Unk, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bricanyl			C	Unknown	5 Mg/ML, Tid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13474369	EXPEDITED (15-DAY)		OT	US-TAKEDA-2017TUS008358			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Diarrhoea; Neoplasm; Sunburn	Vedolizumab			S	Intravenous (not otherwise specified)	Unk		Takeda	
	Z-Pak			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13696208	EXPEDITED (15-DAY)		HO, LT, OT	TR-BAUSCH-BL-2017-019949		20 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Posterior Reversible Encephalopathy Syndrome	Acyclovir			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Posaconazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Vancomycin			C				Not Reported	
	Vancomycin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13696402	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2017US11101			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated	Celecoxib			S	Unknown	Unk, Over The Past 10 Years		Cipla	
	Propranolol			S	Unknown	Unk		Cipla	
	Cidofovir			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zithromycin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Gardasil		S	Unknown	Unk			Not Reported	
	Interferon-Alpha		S	Unknown	Unk, 7-Year Course			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13697097	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2017-28045		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Erythema; Pustule; Skin Lesion	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13697143	DIRECT		LT, OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Hypertension; Palpitations	Azithromycin			S	Oral	Dose/Frequency - 2 Tablets First Day - 1 Tablet For Four Days - Po		Greenstone	
	Dicyclomin			C				Not Reported	
	Bentyl			C				Not Reported	
	Synthroid			C				Not Reported	
	Losartan			C				Not Reported	
	Citalopram			C				Not Reported	
	Zegerid			C				Not Reported	
	Biotin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13698233	NON-EXPEDITED			US-PFIZER INC- 2017275956			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Phenergan			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2017	13699048	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017272165		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Skin Exfoliation; Stomatitis; Thermal Burn	Zithromax			S	Oral	Unk		Pfizer	
	Triflucan			S	Oral	50 Mg, 1x/Day		Pfizer	
	Triflucan			S				Pfizer	
	Innovair			C		Unk		Not Reported	
	Doliprane			C		Unk		Not Reported	
	Monazol			C		Unk		Not Reported	
	Monazol			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13400023	EXPEDITED (15-DAY)		DE	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-137448		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aortic Rupture; Cardiac Tamponade; Myocardiac Abscess	Alprazolam			S	Unknown	Unk		Sun	
	Azithromycin			S	Unknown	Unk		Sun	
	Buprenorphine			S	Unknown	Unk		Sun	
	Codeine			S	Unknown	Unk		Ranbaxy	
	Gabapentin			S	Unknown	Unk		Ranbaxy	
	Ibuprofen			S	Unknown	Unk		Ranbaxy	
	Levetiracetam			S	Unknown	Unk		Sun	
	Morphine			S	Unknown	Unk		Ranbaxy	
	Hydromorphone			S	Unknown	Unk		Not Reported	
	Tetrahydrocannabinol			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13577401	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-		69 YR	Male	JPN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2017219757

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Incontinence; Delirium; Fall; Restlessness	Zithromac Sr 2g			S	Oral	2 G, Daily		Pfizer
	Loxonin			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13643444	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC- 2017247168		74 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Cold; Hyperpyrexia	Zithromac 250mg			S	Oral	250 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13681361	NON-EXPEDITED			US-PFIZER INC- 2017275745		44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Product Use In Unapproved Indication	Zithromax			S		500 Mg, Daily		Pfizer
	Zithromax			S		250 Mg, Daily		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2017	13702885	EXPEDITED (15-DAY)		OT	US-TEVA-774681USA		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Skin Exfoliation	Copaxone			S	Subcutaneous			Teva
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13576038	NON-EXPEDITED			US-PFIZER INC- 2017225734			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Extravasation	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13707857	EXPEDITED (15-DAY)		OT	PHHY2017NL093843		14 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Supraventricular Tachycardia	Azithromycin			S	Unknown			Novartis	
	Fexofenadine			S	Unknown			Not Reported	
	Fluticasone			C	Nasal			Not Reported	
	Salmeterol/Fluticasonpropionaat			C	Respiratory (inhalation)	1 Df, Bid (100/50 Ug)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2017	13711120	DIRECT	Y	HO, LT			71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Angioedema	Lisinopril			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13709327	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2017US11326			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cytomegalovirus Infection	Levofloxacin			S	Oral	Unk		Cipla	
	Tacrolimus			S	Unknown	2 Mg, Bid		Cipla	
	Tacrolimus			S	Unknown	1 Mg, Bid		Cipla	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mycophenolate Mofetil	S	Unknown	1000 Mg, Bid	Cipla
Mycophenolate Mofetil	S	Unknown	500 Mg, Bid	Cipla
Valganciclovir	S	Unknown	225 Mg, Daily	Not Reported
Valganciclovir	S	Unknown	900 Mg, Bid, Readministered	Not Reported
Trimethoprim/Sulfamethoxazole	S	Unknown	Unk, Single-Strength Every Monday, Wednesday, And Friday	Cipla
Azithromycin	S	Oral	Unk	Cipla

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13710269	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR- APL-2017-36220		20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Cardiac Arrest; Condition Aggravated; Drug-Induced Liver Injury; Dysphagia; Hepatitis; Hepatitis Cholestatic; Hepatomegaly; Jaundice; Oropharyngeal Pain; Pneumothorax; Pyrexia; Rash; Respiratory Arrest; Respiratory Failure; Splenomegaly; Toxic Epidermal Necrolysis; Vanishing Bile Duct Syndrome	Ibuprofen			S	Unknown			Aurobindo
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13711155	DIRECT					85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Ear Pain; Gingival Swelling; Lip Swelling; Lymph Node	Azithromycin 250mg Dose Pack Pfizer			S	Oral	2 Pills Day 1-/Every Day Mouth		Greenstone

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pain; Muscular Weakness; Nausea	Protonix Fentanyl Zanax Low Dose Aspirin Potassium Prochlorperazine Norco Ketorolac	C C C C C C C C	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2017	13712648	NON-EXPEDITED		HO, OT	US-APOTEX-2017AP013838		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme	Azithromycin			S	Unknown	Unk		Apotex	
	Prednisone			S	Unknown	50 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	9437171	EXPEDITED (15-DAY)		HO	JP-ROCHE-1254784		51 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Back Pain;	Valganciclovir			S	Oral			Not Reported	
Cytopenia; Diabetes	Valganciclovir			S	Oral			Not Reported	
Mellitus; Diabetic	Valganciclovir			S	Oral			Not Reported	
Neuropathy; Diarrhoea;	Valganciclovir			S	Oral			Not Reported	
Eosinophilic Pustular	Valganciclovir			S	Oral			Not Reported	
Folliculitis; Folate	Valganciclovir			S	Oral			Not Reported	
Deficiency;	Valganciclovir			S	Oral			Not Reported	
Hyperlipidaemia;	Valganciclovir			S	Oral			Not Reported	
Hyperuricaemia; Liver	Valganciclovir			S	Oral			Not Reported	
Disorder; Lymphadenitis;	Valganciclovir			S	Oral			Not Reported	
Mycobacterium Avium	Sulfamethoxazole/Trimethoprim			S	Oral	2 Tablet		Not Reported	
Complex Infection;	Sulfamethoxazole/Trimethoprim			S	Oral	1 Tablet		Not Reported	
Nausea; Osteoporosis;	Azithromycin			S	Unknown			Not Reported	
Periarthritis; Pneumonia;	Azithromycin			S	Unknown			Not Reported	
Renal Impairment;	Azithromycin			S	Unknown			Not Reported	
Sinusitis	Azithromycin			S	Unknown			Not Reported	

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Ritonavir	S	Oral		Not Reported
Darunavir Ethanolate	S	Oral		Not Reported
Rifabutin	S	Oral		Not Reported
Enteronon-R	S	Oral		Not Reported
Truvada	S	Oral	1 Tablet	Not Reported
Epzicom	S	Oral	1 Tablet.	Not Reported
Esanbutol	S	Oral		Not Reported
Esanbutol	S	Oral		Not Reported
Mycobutin	S	Oral		Not Reported
Triumeq	S	Oral	1 Dosage Forms (1 Dosage Forms,1 In 1 D)	Not Reported
Fosamax	C	Oral		Not Reported
Sawacillin	C	Oral		Not Reported
Sawacillin	C	Oral		Not Reported
Cephadol	C	Oral		Not Reported
Talion (Japan)	C	Oral		Not Reported
Myslee	C	Oral		Not Reported
Myslee	C	Oral		Not Reported
Risumic	C	Oral		Not Reported
Vfend	C	Oral		Not Reported
Fluconazole	C	Oral		Not Reported
Fluconazole	C	Oral		Not Reported
Omeprazole	C	Unknown		Not Reported
Lopemin (Japan)	C	Unknown		Not Reported
Lopemin (Japan)	C	Unknown		Not Reported
Myonal (Japan)	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported
Loxonin	C	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Loxonin	C	Unknown	Not Reported
Loxonin	C	Unknown	Not Reported
Tannalbin	C	Oral	Not Reported
Nauzelin	C	Oral	Not Reported
Gasmotin	C	Oral	Not Reported
Marzulene-S	C	Oral	Not Reported
Marzulene-S	C	Oral	Not Reported
Rohypnol	C	Oral	Not Reported
Foliamin	C	Unknown	Not Reported
Rebamipide	C	Oral	Not Reported
Rebamipide	C	Oral	Not Reported
Rebamipide	C	Oral	When Headache Occured
Denosine (Japan)	C	Intravenous drip	Not Reported
Zyloric	C		Not Reported
Samtarel	C	Oral	Not Reported
Calonal	C	Oral	Not Reported
Foscavir	C	Parenteral	Not Reported
Methycobal	C	Unknown	Not Reported
Lyrica	C	Unknown	Not Reported
Kindavate	C	Topical	Not Reported
Dolutegravir	C	Oral	Not Reported
Mucodyne	C	Unknown	Not Reported
Neuzym	C	Unknown	Not Reported
Allermist	C	Nasal	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	9503236	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1193288		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Cardiac	Rituxan			S	Intravenous (not	Last Dose: 17/Feb/2015		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Dizziness; Drug Ineffective; Dyspnoea; Finger Deformity; Hand Deformity; Headache; Infarction; Infusion Related Reaction; Joint Range Of Motion Decreased; Lip Swelling; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Noninfective Gingivitis; Pain; Paraesthesia; Product Use In Unapproved Indication; Psoriasis; Rash Pruritic; Seasonal Allergy; Synovitis; Tenderness; Tooth Abscess; Tooth Extraction; Tooth Infection; Tooth Loss; Vasculitis; Weight Decreased	Rituxan	S	otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified)	Not Reported
	Rituxan	S	Intravenous (not otherwise specified) Recent Rituximab Infusion: 26/Jul/2016	Not Reported
	Naprosyn	S	Oral	Not Reported
	Naprosyn	S		Not Reported
	Azithromycin	S	Unknown	Not Reported
	Leflunomide	S	Unknown	Not Reported
	Tylenol #3 (Canada)	C	Oral	Not Reported
	Tylenol #3 (Canada)	C	Unknown	Not Reported
	Synthroid	C		Not Reported
	Omega 3-6-9 (Canada)	C		Not Reported
	Diphenhydramine Hcl	C	Oral	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Orencia	C	Unknown	Not Reported
	Prednisone	C	Oral	Not Reported
	Prednisone	C		Not Reported
	Acetaminophen	C	Oral	Not Reported
	Acetaminophen	C	Oral	Not Reported
	Reactine (Canada)	C	Intravenous (not otherwise specified)	Not Reported
	Maxeran	C	Intravenous (not otherwise specified)	Not Reported
	Metoclopramide	C	Intravenous (not otherwise specified)	Not Reported
	Claritin (Canada)	C		Not Reported
	Ferrous Fumarate	C		Not Reported
	Ramipril	C		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pantoprazole	C	Not Reported
Rosuvastatin	C	Not Reported
Ticagrelor	C	Not Reported
Acetylsalicylic Acid	C	Not Reported
Unknown		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13684831	EXPEDITED (15-DAY)		HO, OT	TR-ASTELLAS-2017US024284		20 YR	Male	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased;	Tacrolimus			S	Unknown	Unk, Unknown Freq.		Astellas
Device Related Infection;	Tacrolimus			S	Unknown	Unk Unk, Unknown Freq.		Astellas
Drug Interaction;						(Dose Adjusted)		
Dyspnoea; Off Label Use;	Posaconazole			S	Unknown	Unk, Unknown Freq.		Not Reported
Paraplegia; Posterior	Azithromycin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
Reversible	Acyclovir /00587301/			S	Unknown	Unk Unk, Unknown Freq.		Not Reported
Encephalopathy	Vancomycin			C	Unknown	Unk, Unknown Freq.		Not Reported
Syndrome; Staphylococcal	Vancomycin			C				Not Reported
Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13713477	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-143244		71 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	Unk		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2017	13717039	DIRECT		DS			33 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Feeling Abnormal; Nausea	Azithromycin			S	Oral	Other Strength:Mg;Quantity:4 Tablet(S);		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13406881	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017141508		75 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Lip Oedema; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13716335	NON-EXPEDITED		HO	US-APOTEX-2017AP013979		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13717362	EXPEDITED (15-DAY)		OT	NL-APOTEX-2017AP013805		14 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Supraventricular Tachycardia	Azithromycin Apotex			S	Unknown	Unk		Apotex	
	Filmomhulde Tabletten								
	Fexofenadine			S	Unknown	Unk		Not Reported	
	Fluticasone W/Salmeterol			C	Nasal	Unk, 100/50 ?G		Not Reported	
	Fluticasone			C	Nasal	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2017	13718128	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017280137		63 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adenocarcinoma Of Colon	Novatrex			S	Oral	2.5 Mg, Unk		Pfizer	
	Valium			C	Oral	Unk		Not Reported	
	Prozac			C	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levothyrox	C	Oral						Not Reported
Cortancyl	C	Oral	Unk					Not Reported
Avlocardyl /00030001/	C	Oral						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13641828	NON-EXPEDITED			US-PFIZER INC-2017250763		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13643721	EXPEDITED (15-DAY)		DE, HO, LT, OT	JP-PFIZER INC-2017248424		11 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Near Drowning	Zithromac 100mg			S	Oral	400 Mg, 1x/Day		Pfizer	
	Biofermin R			S	Oral	1 Df, 3x/Day		Not Reported	
	Talion (Bepotastine Besylate)			S	Oral	10 Mg, 2x/Day		Not Reported	
	Singulair			S	Oral	5 Mg, 1x/Day		Not Reported	
	Nasonex			S	Nasal	1 Df, 1x/Day		Not Reported	
	Azunol [Sodium Gualenate]			S	Oral	Unk Unk, 3x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13704063	EXPEDITED (15-DAY)		OT	PHHY2017CA094683		35 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Tract Infection Bacterial	Tobramycin			S	Respiratory (inhalation)	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13720762	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2017-36305		27 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Spasms; Respiratory Failure	Orocal (Calcium Carbonate\Cholecalciferol)			S	Oral	Unk		Not Reported	
	Valaciclovir 500mg			S	Oral	500 Mg, Two Times A Day		Aurobindo	
	Jakavi			S	Oral	15 Mg, Two Times A Day		Not Reported	
	Delursan			S	Oral	1 Df, 3 Times A Day		Not Reported	
	Cortancyl			S	Oral	Unk		Not Reported	
	Inexium /01479302/			S	Oral	1 Df, Once A Day		Not Reported	
	Bactrim			S	Oral	3 Df In 3 Days		Not Reported	
	Zithromax			S	Oral	2 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13722166	NON-EXPEDITED			US-PFIZER INC-2017285259		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ampicillin Sodium			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13724553	EXPEDITED (15-DAY)		HO	ZA-PFIZER INC-2017289616		5 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Henoch-Schonlein Purpura	Zithromax			S		15 MI, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13724902	NON-EXPEDITED			US-PFIZER INC-2017285930		56 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13725595	DIRECT		DS, HO				Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Nausea; Product Quality Issue; Somnolence; Tinnitus; Vomiting	Azithromycin			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);Other Route:Take 2 Tablets Day One, Then Take 1 Able		Teva	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13726069	EXPEDITED (15-DAY)		DS, OT	GB-PFIZER INC-2017285002		20 YR	Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Confusional State; Diarrhoea; Dizziness; Dyspnoea; Eye Irritation; Nausea; Palpitations; Presyncope; Pyrexia; Somnolence; Tension Headache; Vision Blurred	Azithromycin Propranolol			S C	Oral	2 G, Unk Unk		Pfizer Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2017	13726195	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017285940		8 YR	Unknown	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Haematochezia	Zithromax			S	Oral	2 Bags		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13726806	NON-EXPEDITED			US-PFIZER INC-2017290976		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Peripheral Swelling; Swelling; Tenderness	Xeljanz Xr			S		11 Mg, Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13726853	NON-EXPEDITED			US-PFIZER INC-2017292578		20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2017	13726921	NON-EXPEDITED			US-PFIZER INC-2017291169			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	12250400	EXPEDITED (15-DAY)		OT	PHHY2016US042668		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Implant Site Swelling; Infection; Swelling	Calcium Carbonate			S	Other	600 Mg, Qd		Glaxosmithkline	
	Acetaminophen			S	Other	5 Mg, Unk		Glaxosmithkline	
	Azithromycin			S	Other	300 Mg, Unk		Not Reported	
	Omeprazole			S	Other	60 Mg, Bid		Not Reported	
	Baclofen Intrathecal			S	Intrathecal	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Baclofen	S	Oral	Unk, 10 Mg Every 6 Hours	Not Reported
Budesonide	S	Respiratory (inhalation)	2 Df, Qd	Not Reported
Albuterol Sulfate Tablets Usp	S	Respiratory (inhalation)	2 Df, Qd	Not Reported
Albuterol Sulfate Tablets Usp	S	Respiratory (inhalation)	Unk, 2.5mg Inhalation Every Two Hours As Needed	Not Reported
Lidocaine	S	Topical	Unk, As Needed To G Tube Stoma Site	Not Reported
Lidocaine	S	Topical	Unk, 2percent As Needed For Catheterization Every 4 Hours	Not Reported
Tizanidine	S	Other	1 Mg, Qid	Not Reported
Diazepam	S	Other	5 Mg, Qd	Not Reported
Diazepam	S	Other	Unk, 5mg Every 4 Hours As Needed	Not Reported
Cetirizine	S	Other	10 Mg, Qd	Not Reported
Clotrimazole	S	Topical	Unk, 4 Times Daily As Needed	Not Reported
Clotrimazole	S			Not Reported
Clotrimazole	S			Not Reported
Diphenhydramine	S	Other	25 Mg, Unk	Not Reported
Diphenhydramine	S			Not Reported
Diphenhydramine	S			Not Reported
Diphenhydramine	S			Not Reported
Gabapentin	S	Other	800 Mg, Tid	Not Reported
Lamotrigine	S	Other	200 Mg, Tid	Not Reported
Lorazepam	S	Other	Unk, 0.25mg To 1 Mg As Needed	Not Reported
Mupirocin	S	Topical	Unk, As Needed To The Stoma Site	Not Reported
Nystatin	S	Topical	Unk, 4 Times Daily As Needed	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glycopyrrolate	S	Other	2 Mg, Qid	Glaxosmithkline
Duoneb	S	Respiratory (inhalation)	3 MI, Unk	Not Reported
Melatonin	S	Other	3 Mg, Qd	Glaxosmithkline
Mononessa	S	Oral	1 Df, Qd	Not Reported
Probiotic /07343501/	S	Oral	1 Df, Qd	Not Reported
Simethicone	S	Other	40 Mg, Qid	Glaxosmithkline
Sucralfate	S	Other	500 Mg, Qid	Glaxosmithkline
Diastat	S	Rectal	50 Mg, Unk	Glaxosmithkline
Gabitril	S	Other	6 Mg, Qid	Not Reported
Zinc Oxide	S	Topical	Unk, As Needed For G Tube, J Tube	Not Reported
Zinc Oxide	S			Not Reported
Zinc Oxide	S			Not Reported
Bacitracin	S	Topical	Unk, As Needed To Stoma Site	Not Reported
Calcium Carbonate	S			Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13702671	EXPEDITED (15-DAY)		DE, OT	PHHY2017CA094772		81 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Acute Kidney Injury; Adjustment Disorder; Anaemia;	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Q12mo		Novartis
Angina Pectoris; Atrophy; Back Pain; Bundle Branch Block Left; Drug	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Unk		Novartis
Hypersensitivity; Drug Intolerance; Hepatic Steatosis;	Aclasta			S	Intravenous drip	Unk		Novartis
Hypercalcaemia;	Aclasta			S	Intravenous drip	Unk		Novartis
Hypertension; Monoclonal Gammopathy;	Aclasta			S	Intravenous drip	Unk		Novartis
Musculoskeletal Pain;	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Q12mo		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Osteoarthritis; Palmar Erythema; Plasma Cell Myeloma; Sacroiliitis; Spinal Disorder; Toxicity To Various Agents	Amoxil	S	Unknown	Unk	Not Reported
	Zithromax	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown		Not Reported
	Actonel	S	Unknown	Unk	Not Reported
	Nexium	C	Unknown	40 Mg, Qd	Not Reported
	Inderal	C	Unknown	80 Mg, Qd	Not Reported
	Mylan Nitro SI	C	Oral	1 Df, Unk Under Tongue	Not Reported
	Dilaudid	C	Unknown	1 Mg, 4 H As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13727658	NON-EXPEDITED			US-PFIZER INC-2017291135			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13728890	NON-EXPEDITED			US-PFIZER INC-2017294752		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Advil			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13731780	NON-EXPEDITED			US-PFIZER INC-2017294253			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Vicodin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2017	13731783	NON-EXPEDITED			US-PFIZER INC-2017291226			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2017	13735604	DIRECT		DE			20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Diarrhoea; Feeling Abnormal; Head Discomfort	Azithromycin Tablets Usp			S	Oral	Other Strength:Mg;Quantity:6 Tablet(S);		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2017	13734417	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001388			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ureteric Obstruction	Metformin			S		500 Mg, Unk		Ipca	
	Azithromycin			S		500 Mg, Unk		Not Reported	
	Cetirizine			S				Ipca	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2017	13734431	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001404			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea; Menorrhagia; Metrorrhagia	Metformin			S		500 Unk, Unk		Ipca	
	Azithromycin Tablet			S		500 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxycycline			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2017	13299786	EXPEDITED (15-DAY)		DE, HO, OT	JP-PFIZER INC-2016590284		77 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Inadequately Controlled;	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
Diabetes Mellitus Inadequate Control;	Makyokansekitto			S	Oral	7.5 G, 3x/Day		Not Reported	
Eosinophilic Pneumonia;	Blopress			C	Oral	4 Mg, 1x/Day		Not Reported	
Interstitial Lung Disease;	Allopurinol			C	Oral	100 Mg, 1x/Day		Not Reported	
Pneumonia	Norvasc			C	Oral	5 Mg, 1x/Day		Not Reported	
Staphylococcal	Lyrica			C	Oral	75 Mg, 1x/Day		Not Reported	
	Meloxicam			C	Oral	10 Mg, 1x/Day		Not Reported	
	Omeprazole			C	Oral	20 Mg, 1x/Day		Not Reported	
	Tokakujokito			C	Oral	5 G, Alternate Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	11180178	EXPEDITED (15-DAY)		HO, OT	US-SA-2015SA019540		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Appendicitis Perforated; Cd4	Lemtrada			S	Intravenous drip			Not Reported	
Lymphocytes Decreased;	Lemtrada			S	Intravenous drip			Not Reported	
Constipation; Cough;	Macrobid			S	Unknown			Not Reported	
Cystitis; Drug	Cortisone			S	Unknown			Not Reported	
Hypersensitivity; Dry Skin;	Z Pack			S	Unknown			Not Reported	
Fatigue; Flushing;	Lorazepam			C				Not Reported	
Increased Upper Airway Secretion; Joint Range Of Motion Decreased;	Acyclovir			C				Not Reported	
Laboratory Test Abnormal; Loss Of Personal Independence In Daily Activities; Lymphocyte									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Count Decreased;
Neutrophil Count
Decreased;
Oropharyngeal Pain; Pain
Of Skin; Peroneal Nerve
Palsy; Platelet Count
Decreased; Pruritus;
Pruritus; Pulmonary
Congestion; Rash; Rash;
Seborrheic Dermatitis;
Sensory Disturbance; Skin
Burning Sensation; Skin
Disorder; Skin Exfoliation;
Temperature Intolerance;
Thyroid Disorder; Thyroid
Function Test Abnormal;
Toothache; Urticaria;
White Blood Cell Count
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	11244076	NON-EXPEDITED			US-PFIZER INC- 2015221449			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	
	Avandia			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	12492839	NON-EXPEDITED			US-PFIZER INC- 2016285898			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Celebrex	S	Unk	Pfizer
Erythromycin	S	Unk	Pfizer
Fentanyl Citrate	S	Unk	Unknown
Norvasc	S	Unk	Pfizer
Buspar	S	Unk	Not Reported
Catapres	S	Unk	Not Reported
Codeine	S	Unk	Not Reported
Dilaudid	S	Unk	Not Reported
Kenalog	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Macrochantin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13251805	NON-EXPEDITED			US-PFIZER INC-2017072132		73 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		250 Mg, 1x/Day, 2 On The First Day And Then One		Pfizer
	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13657357	NON-EXPEDITED			US-PFIZER INC-2017257007			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ees			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13741478	EXPEDITED (15-DAY)		HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2015US-104087		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Tamponade; Drug Interaction; Pericardial Haemorrhage; Pericarditis	Azithromycin			S	Unknown	Unk		Sun	
	Rivaroxaban			S	Unknown	Unk		Not Reported	
	Aspirin			C	Unknown			Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Metoprolol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13742603	NON-EXPEDITED			US-PFIZER INC- 2017295876			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13742618	NON-EXPEDITED			US-PFIZER INC- 2017298097			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Metoprolol Tartrate			S		Unk		Unknown	
	Tetracycline Hcl			S		Unk		Pfizer	
	Verapamil Hcl			S		Unk		Pfizer	
	Erythromycin Base			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13743235	EXPEDITED (15-DAY)		DS, OT	GB-MYLANLABS- 2017M1040377			Unknown	GBR

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Confusional State; Diarrhoea; Dizziness; Dyspnoea; Eye Irritation; Nausea; Palpitations; Presyncope; Pyrexia; Somnolence; Tension Headache; Vision Blurred	Azithromycin			S	Oral	2 G, Unk		Not Reported	
	Propranolol			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2017	13743393	EXPEDITED (15-DAY)		DS, OT	PHFR2017GB005174		20 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Confusional State; Diarrhoea; Dizziness; Dyspnoea; Eye Irritation; Nausea; Palpitations; Presyncope; Pyrexia; Somnolence; Tension Headache; Vision Blurred	Azithromycin			S	Oral	2 G, Unk		Novartis	
	Propranolol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13457076	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2017165819		40 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Incorrect Dose Administered	Misoprostol			S	Oral	500 Ug, 1x/Day		Pfizer	
	Azithromycin			S	Oral	1 G, Unk		Pfizer	
	Mifegyne			S	Oral	200 Mg, 1x/Day		Not Reported	
	Flagyl /00012501/			S		1 G, Unk		Not Reported	
	Diclofenac			S	Oral	100 Mg, Unk		Not Reported	
	Stemetil			S		12.5 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13743861	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1021286			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Lip Oedema; Urticaria	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13743945	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001351			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease	Metformin			S		1000 Mg, Unk		Ipca	
	Azithromycin			S		500 Mg, Unk		Not Reported	
	Terbutaline			S				Not Reported	
	Ipratropium			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2017	13744477	EXPEDITED (15-DAY)		OT	IN-IPCA LABORATORIES LIMITED-IPC-2017-IN-001658			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Pain; Post-Traumatic Pain	Metformin			S		500 Mg, Unk		Ipca	
	Azithromycin			S		500 Mg, Unk		Not Reported	
	Terbutaline			S		500 Mg, Unk		Not Reported	
	Ipratropium			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2017	13748350	EXPEDITED (15-DAY)		HO, OT	DE-ABBVIE-17K-062-2031499-00			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper;	Humira	S	Subcutaneous		Not Reported
Arthralgia; Back Pain;	Dominal Forte	S	Unknown		Not Reported
Burning Sensation; Chills;	Olanzapin	S	Unknown		Not Reported
Dizziness; Dry Mouth;	Pantozol	S	Unknown		Not Reported
Erythema; Fall;	Venlafaxin	S	Unknown		Not Reported
Hypersensitivity;	Dekristol	S	Unknown		Not Reported
Hypoacusis; Insomnia;	Dekristol	S	Unknown		Not Reported
Liver Function Test	Vitamine B12	S	Unknown		Not Reported
Increased; Mood Altered;	Otezla	S	Unknown	10/20/30 Mg	Not Reported
Mouth Swelling;	Otezla	S	Unknown		Not Reported
Musculoskeletal Pain;	Prednisolon Acis	S	Unknown		Not Reported
Myalgia; Nasal	Prednisolon Acis	S	Unknown		Not Reported
Congestion; Nasal	Prednisolon Acis	S	Unknown		Not Reported
Dryness; Nausea;	Prednisolon Acis	S	Unknown	Package With 100 Tablets	Not Reported
Oedema Peripheral; Pain	Triamgalen	S	Topical	0.1%	Not Reported
In Extremity; Pharyngeal	Doxycyclin Al	S	Unknown		Not Reported
Inflammation;	Azithromycin/Teva	S	Unknown		Not Reported
Photosensitivity Reaction;	Cefixdura	S	Unknown	Package With 10 Tablets	Not Reported
Psoriasis; Psoriasis;	Stelara	S	Unknown		Not Reported
Pulpitis Dental;	Fumaderm	S	Unknown	4 Times	Not Reported
Rhinorrhoea; Sensitivity	Mtx	S	Unknown		Not Reported
To Weather Change;					
Somnolence; Stomatitis;					
Thirst; Tinnitus; Vomiting					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2017	13748512	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR-APL-2017-36735		20 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin			S	Oral	2 G, Unk		Aurobindo	
Confusional State;	Propranolol			C	Unknown			Not Reported	
Diarrhoea; Dizziness;									
Dyspnoea; Eye Irritation;									
Nausea; Palpitations;									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Presyncope; Pyrexia;
Somnolence; Tension
Headache; Vision Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2017	13751221	EXPEDITED (15-DAY)		DS, OT	GB-TEVA-784016ACC		20 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Azithromycin			S	Oral			Not Reported
Confusional State;	Propranolol			C				Not Reported
Diarrhoea; Dizziness;								
Dyspnoea; Eye Irritation;								
Nausea; Palpitations;								
Presyncope; Pyrexia;								
Somnolence; Tension								
Headache; Vision Blurred								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	12828139	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2016463374		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Disturbance	Methylprednisolone			S		4 Mg, Unk		Pfizer
In Attention; Fear; Feeling	Zithromax			S		Unk		Pfizer
Abnormal; General	Gabapentin			C		Unk		Not Reported
Physical Condition								
Abnormal; Headache;								
Insomnia; Malaise; Pain;								
Psychotic Disorder;								
Quality Of Life Decreased;								
Sensory Disturbance								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13242288	EXPEDITED (15-DAY)		OT	FR-ABBVIE-17K-056-1870392-00		10 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury;	Humira Vial			S	Subcutaneous			Not Reported
Weight Increased								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Humira Vial		S	Subcutaneous				Not Reported	
	Novatrex		S	Oral				Not Reported	
	Novatrex		S	Oral	4 Tablets /Week			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13655640	NON-EXPEDITED			US-PFIZER INC-2017261290		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13694252	EXPEDITED (15-DAY)		HO, OT	US-DRREDDYS-USA/USA/17/0091707		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered;	Valacyclovir			S	Unknown			Not Reported	
Neurotoxicity; Toxic Encephalopathy	Ceftriaxone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ampicillin			S	Unknown			Not Reported	
	Acyclovir			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13716555	NON-EXPEDITED		OT	US-AMGEN-USASP2017098352		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma; Bronchitis; Cystitis; Irritable Bowel Syndrome; Product Storage Error; Rheumatoid Arthritis; Stress	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13755278	NON-EXPEDITED			US-PFIZER INC-2017298701			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13756004	NON-EXPEDITED			US-PFIZER INC-2017300704		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Burning Sensation; Dizziness; Eye Movement Disorder; Movement Disorder	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2017	13757204	DIRECT		OT			29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Auditory; Product Label Issue; Product Tampering; Thought Broadcasting	Brexipiprazole			S	Oral	Other Strength:Mg;Quantity:1 Tablet(S);Other Route:By Mouth		Altana	
	Z-Pak			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	10364541	EXPEDITED (15-DAY)		HO	ES-CELGENEUS-144-21880-14040270		49 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Rash	Revlimid			S	Oral	20 Milligram		Celgene	
	Revlimid			S	Oral	15 Milligram		Celgene	
	Rituximab			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	10686345	NON-EXPEDITED			US-PFIZER INC-2014360873			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13758241	NON-EXPEDITED			US-PFIZER INC-2017309299		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper	Azithromycin			S	Oral	250 Mg, 1x/Day, For 4 Days		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2017	13759341	NON-EXPEDITED			US-PFIZER INC-2017298194		33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Burning Sensation; Coordination Abnormal; Dizziness	Azithromycin			S		1000 Mg, Single		Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13762940	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA100048		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition	Seebri Breezhaler			S	Respiratory (inhalation)	1 Df, Qd (Every 24 Hr)		Not Reported	
	Atorvastatine			S	Oral			Novartis	
	Apo Azithromycin			S	Oral	2 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urgency; Mobility Decreased; Product Use Issue	Alendronate	C	Unknown	Not Reported
	Calcium	C	Unknown	Not Reported
	Dexilant	C	Unknown	Not Reported
	Montelukast	C	Unknown	Not Reported
	Pulmicort	C	Unknown	Not Reported
	Qvar	C	Unknown	Not Reported
	Remicade	C	Unknown	Not Reported
	Salbutamol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13763162	DIRECT		DS				Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Azithromycin 250mg Tab Z-Pak			S	Oral	2-1st Day & 1 Daily After		Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13763484	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017302018		65 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Iga Nephropathy	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	L-Thyroxine /00068001/			C		75 Ug, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13763843	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2017261603		39 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Neutropenia	Zithromac 500mg			S	Intravenous drip	500 Mg, 1x/Day		Pfizer
	Ceftriaxone Na			S	Intravenous drip	1 G, 1x/Day		Not Reported
	Ceftriaxone Na			S	Intravenous drip	1 G, 2x/Day		Not Reported
	Loxoprofen Emec			C	Oral	Unk, As Needed		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13764965	NON-EXPEDITED			US-PFIZER INC-2017308306			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13765009	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2017M1041299			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Clarithromycin			S	Oral			Not Reported	
	Zithromac			S	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13765277	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2017301707		78 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Interstitial Lung Disease	Azithromycin			S	Oral	Unk		Pfizer	
	Bicalutamide Nk			S	Oral	80 Mg, 1x/Day		Not Reported	
	Betanis			S	Oral	25 Mg, 1x/Day		Not Reported	
	Salobel			C	Oral	Unk		Not Reported	
	Amlodipine Besilate			C	Oral	Unk		Not Reported	
	Clopidogrel			C	Oral	Unk		Not Reported	
	Candesartan			C	Oral	Unk		Not Reported	
	Nexium			C	Oral	Unk		Not Reported	
	Carbocysteine			C		Unk		Not Reported	
	Dexchlorpheniramine Maleate			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2017	13765830	DIRECT	Y	HO			25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Lip Swelling	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13766398	EXPEDITED (15-DAY)		DS	UA-TEVA-786295ISR		18 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Disorder	Sumamed			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13768578	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP015629		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Azithromycin			S	Unknown	Unk		Apotex	
	Albuterol Sulfate Inhalation Solution			S	Unknown	Unk		Apotex	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13769440	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION-2017SUN003152		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use	Glycopyrrolate			S	Respiratory (inhalation)	Seebri Capsule 50 Mg, 1 Df Qd		Sunovion	
	Atorvastatin			S	Oral	20 Mg, Unk		Not Reported	
	Apo Azithromycin			S	Oral	2 Df Qd		Not Reported	
	Alendronate			C				Not Reported	
	Calcium			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue	Dexilant	C	Not Reported
	Montelukast	C	Not Reported
	Pulmicort	C	Not Reported
	Qvar	C	Not Reported
	Remicade	C	Not Reported
	Salbutamol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2017	13770343	EXPEDITED (15-DAY)		OT	US-TEVA-788976USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Faeces Soft; Haematochezia	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13695212	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2017274345		27 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tongue Oedema	Azithromycin Ipso Pharma			S	Oral	1 Df, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13734527	EXPEDITED (15-DAY)		DE, HO	RS-TEVA-783527ROM		56 YR	Female	SRB

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Megacolon	Azithromycin			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Teva
	Vancomycin			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported
	Amikacin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13744549	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2017AP014541		81 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ecchymosis; Epistaxis; Haematuria; Thrombocytopenia	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13772526	EXPEDITED (15-DAY)		OT	GB-GLAXOSMITHKLINE-GB2017109573		38 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Limb Discomfort; Migraine; Paralysis; Speech Disorder	Azithromycin			S	Oral	Unk		Glaxosmithkline	
	Azithromycin			S	Oral	500 Unk, Unk		Glaxosmithkline	
	Lamictal			S	Unknown	Unk		Glaxosmithkline	
	Cetirizine			C	Unknown	Unk		Glaxosmithkline	
	Mucodyne			C	Unknown	Unk		Glaxosmithkline	
	Omeprazole			C	Unknown	Unk		Glaxosmithkline	
	Singulair			C	Unknown	Unk		Glaxosmithkline	
	Theophyllin			C	Unknown	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13775289	NON-EXPEDITED			US-MYLANLABS-2016M1050573		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Decreased	Prednisone			S		Unk		Not Reported	
	Azithromycin			S		Unk		Mylan	
	Ipratropium Bromide			S	Nasal	2 Df, Bid		Mylan	
	Sertraline			C		Unk, Qd		Mylan	
	Vitamin D /00107901/			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2017	13775686	NON-EXPEDITED			US-BAUSCH-BL-2017-003530		65 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Application Site Erythema; Application Site Irritation; Application Site Pain; Condition Aggravated; Conjunctivitis; Incorrect Dose Administered; Product Dropper Issue	Besivance (Besifloxacin Ophthalmic Suspension) 0.6%			S	Ophthalmic	In The Left Eye		Bausch And Lomb	
	Besivance (Besifloxacin Ophthalmic Suspension) 0.6%			S	Ophthalmic	In The Left Eye		Bausch And Lomb	
	Besivance (Besifloxacin Ophthalmic Suspension) 0.6%			S				Bausch And Lomb	
	Besivance (Besifloxacin Ophthalmic Suspension) 0.6%			S				Bausch And Lomb	
	Besivance (Besifloxacin Ophthalmic Suspension) 0.6% Z-Pak			S	Oral			Not Reported	
	Z-Pak			S				Not Reported	
	Z-Pak			S				Not Reported	
Z-Pak			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13676665	NON-EXPEDITED			US-PFIZER INC- 2017267809			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Drug Intolerance	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13777216	NON-EXPEDITED			US-PFIZER INC- 2017317668			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13777247	NON-EXPEDITED			US-PFIZER INC- 2017314436			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neurontin	S	Unk	Pfizer
Bactrim	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Floxin	S	Unk	Not Reported
Dhc	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13777270	NON-EXPEDITED			US-PFIZER INC-2017315403			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13777980	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2017310684		38 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Limb Discomfort; Migraine; Paralysis; Product Use Issue; Speech Disorder	Azithromycin			S	Oral	Unk		Pfizer	
	Azithromycin			S	Oral	500 Mg, 3x/Week		Pfizer	
	Lamictal			S		Unk		Not Reported	
	Cetirizine			C		Unk		Not Reported	
	Mucodyne			C		Unk		Not Reported	
	Omeprazole			C		Unk		Not Reported	
	Singulair			C		Unk		Not Reported	
	Theophyllin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13778711	NON-EXPEDITED			US-PFIZER INC-2017311894			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Bactrim	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13778714	NON-EXPEDITED			US-PFIZER INC-2017311987			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Byetta			S		Unk		Not Reported
	Victoza			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported
	Aleve			S		Unk		Not Reported
	Niacin			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported
	Sitagliptin			S		Unk		Not Reported
	Januvia			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13778738	NON-EXPEDITED			US-PFIZER INC-2017312535		15 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13779035	NON-EXPEDITED			US-PFIZER INC-2017317830		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Drug Intolerance; Palpitations		Zithromax	S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2017	13779101	NON-EXPEDITED			US-PFIZER INC- 2017314571		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Genital Blister; Rash	Zithromax			S		Unk		Pfizer	
	Revlimid			S	Oral	15 Mg, Cyclic (21 In 28 D)		Not Reported	
	Revlimid			S	Oral	10 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2017	13780929	DIRECT		OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin 250 Mg			S	Oral	Other Strength:Mg;Quantity:5 Tablet(S); Oral		Greenstone	
	Lisinopril 10 Mg			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Biotin 5000			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13721954	NON-EXPEDITED			US-PFIZER INC- 2017282435			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Levofloxacin			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13781560	DIRECT					64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Breath Sounds Abnormal; Cough; Dysuria; Pyrexia; Urine Flow Decreased	Azithromycin Tablets Usp			S	Oral	Other Strength:Mg;Quantity:6 Tablet(S);		Teva	
	Vitamin D Nos			C				Not Reported	
	Fungi Perfecty My Community Mushroom Extract			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13781744	NON-EXPEDITED			US-PFIZER INC-2017317404			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13783473	NON-EXPEDITED			US-AKORN-63468			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eyelid Margin Crusting	Azasite			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13783956	EXPEDITED (15-DAY)		OT	PHBS2017LV000449		26 YR	Female	LVA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Agitation; Diarrhoea; Hemiparesis; Vomiting	Azitromicin Sandoz			S	Oral	500 Mg, Qd		Novartis	
	Noofen			C	Oral	250 Mg, Bid		Not Reported	
	Nodryl			C	Nasal			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13783962	EXPEDITED (15-DAY)		OT	PHHY2017GR105496		61 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Disease Progression; Dyspnoea; Fatigue; Pleural Effusion; Pyrexia; Q Fever	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13783963	EXPEDITED (15-DAY)		OT	PHHY2017BR105013			Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Arrhythmia; Faeces Soft; Fatigue; Malaise; Tachycardia; Tinnitus	Azithromycin			S	Unknown	500 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13784302	EXPEDITED (15-DAY)		OT	PHFR2017GB005724		38 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Limb Discomfort; Migraine; Paralysis; Speech Disorder	Azithromycin			S	Oral			Novartis	
	Azithromycin			S	Oral	500 Mg, Qw3		Novartis	
	Lamictal			S	Unknown			Not Reported	
	Cetirizine			C	Unknown			Not Reported	
	Mucodyne			C	Unknown			Not Reported	
	Omeprazole			C	Unknown			Not Reported	
	Singulair			C	Unknown			Not Reported	
	Theophyllin			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2017	13785192	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Dispensed To Wrong Patient	Azithromycin Tab 250mg/Azithromycin Tablets 250mg Greenstone			S	Oral	Tablet Oral 250 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13354044	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2017-30942		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Azithromycin			S	Oral			Aurobindo	
Abdominal Distension;	Azithromycin			S				Aurobindo	
Abdominal Pain; Acute	Dextromethorphan			C				Not Reported	
Hepatic Failure; Burning	W/Promethazine								
Sensation; Chromaturia;	Salbutamol			C		Unk		Not Reported	
Diarrhoea; Dizziness;	Promethazine -			C	Unknown			Not Reported	
Drug-Induced Liver Injury;	Dextromethorphan								
Fall; Gingival Bleeding;									
Hepatic Steatosis; Hepato-									
Lenticular Degeneration;									
Hyperhidrosis; Jaundice;									
Nausea; Skin Laceration;									
Syncope; Tachycardia;									
Vaginal Haemorrhage;									
Vomiting									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13698442	NON-EXPEDITED			US-PFIZER INC- 2017273725		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Dizziness;	Azithromycin			S	Oral	500 Mg, First Day		Pfizer	
Eating Disorder; Feeling	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
Abnormal; Loss Of	Azithromycin			S		250 Mg, 1x/Day (1 X On		Pfizer	
Personal Independence In									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Daily Activities; Malaise;
Nausea

Days 2 And 3 Quit After
That)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13789125	NON-EXPEDITED			US-UNITED THERAPEUTICS-UNT- 2016-019613			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Dizziness; Upper Respiratory Tract Infection	Orenitram Azithromycin			S S	Oral Unknown	1 Mg, Bid Unk		United Therapeutics Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2017	13790199	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2017-10248		41 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Hyperhidrosis; Sinus Bradycardia	Azithromycin Sulfamethoxazole And Trimethoprim Cefotaxime			S S C	Intravenous (not otherwise specified)	500 Mg, Unk Unk		Aurobindo Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2017	12249190	NON-EXPEDITED		DS	US-PFIZER INC- 2016179934		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Cough	Azithromycin Azithromycin Azithromycin			S S S	Oral	2 Tablets Of The 250mg The First Day, Then 1 Tablet Of The 250mg A Day Thereafter, Total Of 6 Pills		Pfizer Pfizer Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Aleve

C

1 To 2 Dosage Forms As
Needed

Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13779995	EXPEDITED (15-DAY)		OT	US-ABBVIE-17K-163-2046326-00		65 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea; Eye Swelling; Myalgia; Tuberculosis	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S				Not Reported	
	Rifampin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Carvedilol			C				Not Reported	
	Valsartan			C				Not Reported	
	Simvastatin			C				Not Reported	
	Cyclobenzaprine			C				Not Reported	
	Ropinirole			C				Not Reported	
	Pramipexole			C				Not Reported	
	Testosterone			C				Not Reported	
	Diazepam			C				Not Reported	
	Balsalazide			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13794684	NON-EXPEDITED			US-PFIZER INC-2017321607			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Anosmia	Azithromycin			S		250 Mg, Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2017	13796214	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017313990		75 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Arthralgia; Discomfort; Fatigue; Muscle Tightness;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Zithromax			S		Unk, 2x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Pain; Paralysis		Zithromax	S		Unk, 1x/Day		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13564287	NON-EXPEDITED			US-PFIZER INC- 2017216573		98 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Malaise; Nausea; Product Preparation Issue; Vomiting	Zithromax			S		Put The Pill In Water And Drank The Water		Pfizer	
	Zithromax			S				Pfizer	
	Verapamil			C	Oral	Unk Unk, 2x/Day		Not Reported	
	Baby Aspirin			C	Oral	80 Mg, 1x/Day		Not Reported	
	Allopurinol			C	Oral	Unk Unk, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13799597	DIRECT	Y	HO, RI			27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Azithromycin			S	Oral			Not Reported	
	Dextromethorphan/Guaifenesin			S	Subcutaneous	Dose - 5-10 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2017	13801477	EXPEDITED (15-DAY)		OT	PH-PFIZER INC- 2017298875		30 YR	Male	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction; Chest Pain; Palpitations	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	12006249	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA013616			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Candida Infection; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Dyspnoea; Wheezing	Azithromycin Sandoz Alvesco Spiriva Ventoline	S C C C	Oral Unknown Unknown Unknown	250 Mg, Tiw	Novartis Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13803164	EXPEDITED (15-DAY)		HO, OT	PT-TEVA-2010R0403230		41 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Drug Interaction; Electrocardiogram Abnormal; Electrocardiogram Qt Prolonged; Hyperhidrosis; Sinus Bradycardia	Co-Trimoxazole (Sulfamethoxazole) Azithromycin Cefotaxime			S S C	Intravenous (not otherwise specified)	500 Mg Single Dose		Teva Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13803189	EXPEDITED (15-DAY)		OT	GB-TEVA-789695ACC		38 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Limb Discomfort; Migraine; Paralysis; Speech Disorder	Azithromycin Azithromycin Lamictal Cetirizine Mucodyne Omeprazole Singulair Theophyllin			S S S C C C C C	Oral Oral			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2017	13804753	NON-EXPEDITED			US-PFIZER INC-2017325174			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Fungal Infection		Zithromax		S				Unk		Pfizer
		Cleocin		S				Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Jul-2017	13804954	NON-EXPEDITED			US-PFIZER INC- 2017325066			Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Jul-2017	13807216	NON-EXPEDITED			US-PFIZER INC- 2017326398			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer		
	Ultram			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Jul-2017	13810246	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2017320190			Unknown	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Enterocolitis Haemorrhagic	Zithromac 250mg			S	Oral	Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Jul-2017	13811242	NON-EXPEDITED			US-ROCHE-1006474			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Diarrhoea; Sinusitis	Boniva			S	Unknown			Not Reported		
	Azithromycin			S				Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2017	13812654	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2017M1043751			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Limb Discomfort; Migraine; Paralysis; Speech Disorder	Azithromycin			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	500 Mg, 3xw		Not Reported	
	Lamictal			S		Unk		Mylan	
	Cetirizine			C		Unk		Mylan	
	Mucodyne			C		Unk		Mylan	
	Omeprazole			C		Unk		Mylan	
	Singulair			C		Unk		Mylan	
	Theophyllin			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2017	13814231	DIRECT		OT			42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Urticaria	Azythromycin, Zithromax			S	Oral	Quantity:3 Tablet(S);		Rite Aid	
	Vitamin D Nos			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	12941118	EXPEDITED (15-DAY)		OT	US-AMGEN-USASL2016158384		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Arrhythmia; Cardiac Disorder; Fatigue; Feeling Jittery; Musculoskeletal Disorder; Myocardial Infarction	Repatha			S	Unknown	140 Mg, Q2wk		Amgen	
	Repatha			S				Amgen	
	Repatha			S				Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13559001	EXPEDITED (15-DAY)		OT	PHEH2017US014016		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Electrocardiogram Qt Prolonged	Lamprene			S	Oral	100 Mg, Qd		Not Reported
	Lamprene			S	Oral	50 Mg, Qd		Not Reported
	Lamprene			S	Oral	100 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Imipenem			S	Unknown			Not Reported
	Isavuconazonium			C	Oral	312 Mg, Qd		Not Reported
	Carvedilol			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13814097	NON-EXPEDITED			US-PFIZER INC-2017327428		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; C-Reactive Protein Increased; Platelet Count Increased; Red Blood Cell Sedimentation Rate Increased	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2017	13814364	NON-EXPEDITED		HO, OT	US-APOTEX-2017AP016071		18 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Cefepime			S	Unknown			Apotex
	Azithromycin			S	Unknown			Apotex
	Vancomycin			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	
Prednisone	C	Unknown	Not Reported
Mycophenolate Mofetil	C	Unknown	Not Reported
Tacrolimus	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	11928169	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-000263		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Cough; Dyspnoea; Encephalitis	Ipilimumab			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk		Bristol Myers Squibb
	External-Bevacizumab			S	Intravenous (not otherwise specified)	15 Mg/Kg, Unk		Unknown
	External-Azithromycin			S	Unknown			Not Reported
	Lisinopril			C	Unknown			Not Reported
	Loratadine			C	Unknown			Not Reported
	Pseudoephedrine			C	Unknown			Not Reported
	Metformin			C	Unknown			Not Reported
	Slo-Niacin			C	Unknown			Not Reported
	Vitamin D3			C	Unknown			Not Reported
	Carvedilol			C	Unknown			Not Reported
	Sildenafil			C	Unknown			Not Reported
	Magnesium Oxide			C	Unknown			Not Reported
	Morphine			C	Unknown			Not Reported
	Melatonin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	12949400	NON-EXPEDITED			US-PFIZER INC- 2016528901			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13820739	EXPEDITED (15-DAY)		OT	PHHY2017ES110080		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gait Disturbance; Ototoxicity	Amoxicillin + Clavulanate			S	Unknown			Novartis	
	Potassium Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13822365	EXPEDITED (15-DAY)		OT	CA-AMGEN- CANSP2017112628		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Lower Respiratory Tract Infection; Mobility Decreased; Pain In Extremity	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
	Pms Azithromycin			S	Unknown	Unk		Not Reported	
	Bisoprolol			C		Unk		Not Reported	
	Dexilant			C		600 Mg, Qd		Not Reported	
	Domperidone			C		1 Df, Bid		Not Reported	
	Eltroxin			C		100 Mg, Qd		Not Reported	
	Methotrexate			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13823101	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA- 2017SE77827		22 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Inexium			S	Oral			Astrazeneca	
	Augmentin			S	Intravenous (not otherwise specified)			Not Reported	
	Augmentin			S	Oral			Not Reported	
	Zithromax			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Primperan		S	Unknown				Not Reported	
	Lovenox		S	Subcutaneous				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2017	13824675	DIRECT		OT			9 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Arthralgia; Pain In Extremity; Swelling	Azithromycin 250 Mg Tab			S	Oral	Quantity:6 Tablet(S);		Greenstone	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13825074	EXPEDITED (15-DAY)		DE	PH-PFIZER INC- 2017332367		21 YR	Unknown	PHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Unasyn			S		1.5 G, Unk		Pfizer	
	Zithromax			S	Intravenous (not otherwise specified)	500 Unknown Unit		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13825261	NON-EXPEDITED			PHEH2017US023183		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Intolerance; Nausea; Vomiting	Zometa			S	Intravenous (not otherwise specified)	4 Mg, Qw4		Not Reported	
	Hydrochlorothiazide			S	Oral	1 Df, Qd		Novartis	
	Anastrozole			S	Oral	1 Df, Qd (For 30 Days)		Not Reported	
	Docetaxel			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	1 Df, Qd		Not Reported	
	Ranitidine			S	Intravenous (not	1 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Diphenhydramine	S	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Ibrance	S	Oral	1 Df Qd (21 Days Of 28 Days)	Not Reported
Faslodex	S	Intramuscular	500 Mg, Unk	Not Reported
Aleve	S	Oral	1 Df, Qd	Not Reported
Aspirin	S	Oral	1 Df, Qd	Not Reported
Calcium & Vitamin D3	S	Unknown	1 Df, Qd	Not Reported
Potassium Chloride	S	Oral	2 Df, Tid (Controlled Release)	Not Reported
Multivitamin	S	Oral	1 Df, Qd	Not Reported
Proair Hfa	S	Respiratory (inhalation)	2 Df, Qid	Not Reported
Zyrtec Allergy	S	Oral	1 Df, Qd	Not Reported
Cathflo Activase	S	Intravenous (not otherwise specified)	2 Mg, Once/Single	Not Reported
Cleocin	S	Oral	1 Df, Qid (For 7 Days)	Not Reported
Compazine	S	Oral	Prn (Every 6 Hours)	Not Reported
Dexamethasone	S	Intravenous (not otherwise specified)	1 Df, Qd	Not Reported
Exemestane	S	Oral	1 Df, Qd (For 30 Days)	Not Reported
Metochlopramide	S	Oral	1 Df, (Tid) Prn	Not Reported
Neupogen	S	Subcutaneous	480 Ug, Qd (For 3 Days)	Not Reported
Oxycodone Hcl	S	Oral	1 Df, Prn (Every 6 Hours)	Not Reported
Paroxetine Hcl	S	Oral	1 Df, Qd (For 30 Days)	Not Reported
Tamoxifen Citrate	S	Oral	1 Df, Qd	Not Reported
Zithromax	S	Oral	Prn, As Directed	Not Reported
Vitamin D3	C	Oral	1 Df, Qd (2000 U)	Not Reported
Vitamin D3	C		2 Df, Qd (1000 U)	Not Reported
Fluzone Quadrivalent	C	Intramuscular	0.5 Ml, Once/Single	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Heparin Lock Flush	C	Intravenous (not otherwise specified)	10 MI, Once/Single	Not Reported
Influenza Virus Vaccine	C	Intramuscular	0.5 MI, Unk	Not Reported
Lortab	C	Oral	Prn (As Directed)	Not Reported
Methocarbamol	C	Oral	Prn (As Directed)	Not Reported
Normal Saline	C		20 MI, Qd	Not Reported
Af Loratadine	C	Oral	1 Df, Prn	Not Reported
Caltrate 600 + Vitamin D	C	Oral	2 Df, Qd	Not Reported
Citracal Plus	C	Oral	2 Df, Qd	Not Reported
Coumadin	C	Oral	1 Df, Qd	Not Reported
Hydrocodone/Acetaminophen	C	Oral	1 Df, Prn (Every 4 Hours)	Not Reported
Hydrocodone/Acetaminophen	C	Oral	1 Df, Prn (Every 6 Hours)	Not Reported
Prochlorperazine	C	Oral	1 Df, Prn (Qid)	Not Reported
Iron	C	Oral	1 Df, Qd	Not Reported
Arimidex	C	Oral	1 Df, Qd (For 30 Days)	Not Reported
Prednisone	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13825321	EXPEDITED (15-DAY)		HO, OT	KP-MYLANLABS-2017M1046512			Unknown	PRK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Vancomycin			S		Unk		Not Reported
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Mylan
	Oseltamivir			S		Unk		Mylan
	Ribavirin			S	Oral	2000 Mg, Unk		Mylan
	Ribavirin			S	Oral	600 Mg, Q8h		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ribavirin	S	Oral	400 Mg, Q8h	Mylan
Peginterferon Alfa-2b	S		180 Mg, Once	Mylan
Meropenem	S			Mylan
Irbesartan	C		Unk	Mylan
Atorvastatin	C		Unk	Mylan
Aspirin /00002701/	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13828994	DIRECT		OT				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Morbidity Thoughts; Suicidal Ideation	Z Pack			S	Oral	Quantity:1 Tablet(S);			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2017	13829192	DIRECT	Y	HO			87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Thrombocytopenia	Azithromycin			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13577406	NON-EXPEDITED			US-PFIZER INC- 2017228100		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Calan			S		Unk			Pfizer
	Celebrex			S		Unk			Pfizer
	Lidocaine Hcl			S		Unk			Pfizer
	Effexor			S		Unk			Pfizer
	Erythromycin			S		Unk			Pfizer
	Zithromax			S		Unk			Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ciprofloxacin	S	Unk	Unknown
Augmentin	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Benicar	S	Unk	Not Reported
Ceftin	S	Unk	Not Reported
Compazine	S	Unk	Not Reported
Entex La /00922801/	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Motrin	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Tamiflu	S	Unk	Not Reported
Tetanus Vaccines & Toxoid	S	Unk	Not Reported
Valium	S	Unk	Not Reported
Xylocaine /00033402/	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13731828	NON-EXPEDITED			US-PFIZER INC-2017294483			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Xeljanz			S		Unk		Pfizer
	Macrobid			S		Unk		Not Reported
	Benazepril			S		Unk		Not Reported
	Cefaclor			S		Unk		Not Reported
	Cipro			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13742615	NON-EXPEDITED			US-PFIZER INC-2017296442			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Humira			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13828396	NON-EXPEDITED			US-PFIZER INC-2017334367		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Motrin			S		Unk		Not Reported	
	Keflex /00145501/			S		Unk		Not Reported	
	Darvocet			S		Unk		Not Reported	
	Ultram /00599202/			S				Not Reported	
	Tylenol With Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13828797	NON-EXPEDITED		OT	PHEH2017US023879			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Cough; Diarrhoea; Diarrhoea; Ejection Fraction Decreased; Malaise; Pruritus; Vomiting	Entresto			S	Oral	2 Df (49 Mg Sacubitril/51 Mg Valsartan), Bid		Novartis	
	Amoxicillin			S	Unknown			Not Reported	
	Metoprolol Succinate			S	Unknown	100 Mg In The Morning And 50 Mg In The Evening		Not Reported	
	Metoprolol Succinate			S	Unknown	25 Mg, Qd		Not Reported	
	Z-Pak			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2017	13831575	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2017M1047197			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extravasation; Injection Site Erythema; Injection Site Pain; Injection Site Swelling	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qid		Not Reported	
	Solumedrol			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Aug-2017	13836138	NON-EXPEDITED			US-PFIZER INC-2017335130			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swelling	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2017	13837606	NON-EXPEDITED			US-009507513-1707USA013359			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event	Fosamax			S	Unknown	Unk		Merck	
	Dulera			S	Unknown	Unk		Merck	
	Zithromax			S	Unknown	Unk		Not Reported	
	Cellcept			S	Unknown	Unk		Not Reported	
	Ventolin (Albuterol)			C				Not Reported	
	Prednisone			C				Merck	
	Trazodone Hydrochloride			C				Not Reported	
	Citalopram			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13657362	NON-EXPEDITED			US-PFIZER INC-2017259140		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13828392	NON-EXPEDITED			US-PFIZER INC-2017333790			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bowel Movement Irregularity; Constipation; Dyspepsia; Dysphagia; Dyspnoea; Gastric Disorder; Gastritis; Gastroenteritis Viral; Gastrointestinal Disorder; Pain; Secretion Discharge	Zithromax			S		Two Tablets On The First Day, Then One Tablet For Four Days		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13838710	NON-EXPEDITED			US-PFIZER INC-2017333888			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2017	13838931	NON-EXPEDITED			US-PFIZER INC-2017338401			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Remicade			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	13844089	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1048377		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ototoxicity	Amoxicillin/Clavulanic Acid			S	Unknown				Not Reported
	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2017	13844120	NON-EXPEDITED			US-PFIZER INC-2017336436			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2017	13693711	NON-EXPEDITED		OT	US-PFIZER INC-2017271561		9 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Condition Aggravated; Cough; Drug Ineffective; Product Label Issue; Pyrexia; Reaction To Excipient; Respiratory Disorder; Upper Respiratory Tract Infection	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2017	13851596	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2017340731		3 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Muscle Twitching; Seizure; Somnolence; Tic	Zithromax			S	Oral	150 Mg, 1x/Day			Pfizer
	Zithromax			S	Oral	150 Mg, 1x/Day			Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	10997719	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2015117511		20 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Toxic Epidermal Necrolysis	Azithromycin			S		Unk		Pfizer	
	Ibuprofen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13815343	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017325444		76 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Face Oedema; Hypokalaemia; Hyponatraemia; Vomiting	Zitromax			S	Oral	500 Mg, Daily		Pfizer	
	Karvezide			S	Oral	1 Df, Daily		Not Reported	
	Amlodipine			C		5 Mg, Unk		Not Reported	
	Atorvastatin			C		20 Mg, Unk		Not Reported	
	Lobivon			C		5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2017	13853104	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2013-03488			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Intentional Overdose; Intentional Product Misuse; Somnolence	Ramipril Aurobindo Compresse 5mg			S	Oral	7 Df, Total,		Aurobindo	
	Levocetirizine Dihydrochloride			S	Oral	15 Df, Total,		Not Reported	
	Almotriptan			S	Oral	5 Df, Total,		Not Reported	
	Paracetamol			S	Oral	4 Df, Total,		Not Reported	
	Pursennid /00142207/			S	Oral	30 Df, Total,		Not Reported	
	Zitromax			S	Oral	3 Df, Total,		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13275373	EXPEDITED (15-DAY)		OT	CA-ROCHE-1898517		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bladder Discomfort; Blood Pressure Increased; Hot Flush; Urinary Tract Infection	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Azithromycin Sandoz			S	Unknown			Not Reported	
	Montelukast			S	Unknown			Not Reported	
	Tamsulosin Sandoz			S	Oral			Not Reported	
	Ventolin			C	Unknown	6 Df, Qd		Not Reported	
	Spiriva			C	Unknown	1 Df, Qd		Not Reported	
	Symbicort			C	Unknown	6 Df, Qd		Not Reported	
	Prednisone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13286649	EXPEDITED (15-DAY)		OT	PHHY2017CA010851		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bladder Discomfort; Blood Pressure Increased; Hot Flush; Urinary Tract Infection	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Azithromycin Sandoz			S	Unknown	250 Mg, Unk		Not Reported	
	Montelukast Sandoz			S	Unknown	1 Df, Qd		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tamsulosin Sandoz	S	Oral	1 Df, Qd	Not Reported
Ventolin	C	Unknown	6 Df, Qd	Not Reported
Spiriva	C	Unknown	1 Df, Qd	Not Reported
Symbicort	C	Unknown	6 Df, Qd	Not Reported
Prednisone	C	Oral	1 Df, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13432899	EXPEDITED (15-DAY)		OT	TH-VIIV HEALTHCARE LIMITED- TH2017GSK049438		327 DAY	Male	THA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alanine Aminotransferase Increased	Dolutegravir			S	Oral	12.8 Mg, Qd		Viiv
	Fluconazole			S	Intravenous (not otherwise specified)	Unk		Glaxosmithkline
	Fluconazole			S	Oral	Unk		Glaxosmithkline
	Zidovudine			S		Unk		Viiv
	Trimethoprim + Sulfamethoxazole			S	Oral	Unk		Glaxosmithkline
	Trimethoprim + Sulfamethoxazole			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Not Reported
	Oseltamivir			C		Unk		Not Reported
	Oseltamivir			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Cefotaxime			C		Unk		Not Reported
	Piperacillin + Tazobactam			C		Unk		Not Reported
	Piperacillin + Tazobactam			C		Unk		Not Reported
	Piperacillin + Tazobactam			C		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Ciprofloxacin			C	Oral	Unk		Not Reported
	Zinc Sulfate			C				Not Reported
	Zinc Sulfate			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Ferrous		C					Not Reported
		Blood Transfusion		C					Not Reported
		Lamivudine		C		Unk			Viiv
		Lopinavir+Ritonavir		C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2017	13861316	NON-EXPEDITED			GXBR2017US002060		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Azithromycin 250 Mg			S	Unknown	2 Today, Then 1 Qd X 4d		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	11284307	NON-EXPEDITED			US-AEGERION PHARMACEUTICAL INC.-AEGR001280			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue;	Juxtapid			S	Oral	5 Mg, Qd		Aegerion	
Myalgia; Nasal	Zithromax Z-Pack			S		2 Rounds		Not Reported	
Congestion; Sinusitis;	Crestor			C	Unknown	40 Mg, Unk		Not Reported	
Therapy Interrupted;									
Weight Decreased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13865893	NON-EXPEDITED			US-ROCHE-700367		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Parosmia;	Tamiflu			S	Oral			Not Reported	
Vomiting	Zithromax			S	Unknown			Not Reported	
	Crestor			C	Unknown	Started Years Ago		Not Reported	
	Aspirin			C	Unknown	Started Years Ago		Not Reported	
	Sertraline			C	Unknown	Started Years Ago		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2017	13879831	DIRECT		DS				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Feeling Abnormal; Hypoacusis; Tinnitus	Azithromycin			S	Oral	Quantity:8 Capsule(S); Daily Oral		Not Reported	
	Bupropion			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Liothyronine			C				Not Reported	
	Losartan			C				Not Reported	
	Mirtazapine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13801194	NON-EXPEDITED			US-PFIZER INC-2017325058			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Epinephrine			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Voltaren			S		Unk		Not Reported	
	Tylenol W/Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13868670	NON-EXPEDITED			US-PFIZER INC-2017345057		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Oxycodone Hydrochloride			S		Unk		Pfizer	
	Hydrocodone Cp			S		Unk		Not Reported	
	Hcq			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13868679	NON-EXPEDITED			US-PFIZER INC-2017347580			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zmax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13869994	NON-EXPEDITED			US-PFIZER INC-2017347653			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2017	13870274	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2017345966		15 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Zithromax			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13871075	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2017-04592		1 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bk Virus Infection; Cytomegalovirus Infection Reactivation; Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin			S	Unknown	Unk		Lupin	
	Pranlukast			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13872452	NON-EXPEDITED			US-PFIZER INC-2017347521			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Sulfamide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13872519	NON-EXPEDITED			US-PFIZER INC-2017353570		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13874126	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017351663		53 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Dizziness; Otitis Media Chronic; Tinnitus	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2017	13874133	EXPEDITED (15-DAY)		HO, OT	NL-PFIZER INC-2017347842		76 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoglobin Decreased	Azithromycin			S	Oral	250 Mg, Alternate Day		Pfizer	
	Azithromycin			S		250 Mg, 1x/Day		Pfizer	
	Colchicine			C	Oral	Start With 2 Tablets, After That 1 Tablet 2-3x/Day Until Pain Free		Not Reported	
	Clopidogrel			C	Oral	75 Mg, 1x/Day		Not Reported	
	Pantoprazol			C	Oral	40 Mg, 1x/Day		Not Reported	
	Combivent			C	Respiratory (inhalation)	1 Df, 2-4x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisolon "Dif"	C	Oral	1 G, Irregular Scheme	Not Reported
Flutiform	C	Respiratory (inhalation)	2 Df, 2x/Day	Not Reported
Amoxicilline/Clavulaanzuur	C	Oral	1 Df, Irregular Use	Not Reported
Crestor	C	Oral	10 Mg, 1x/Day	Not Reported
Bumetanide	C		2 Mg, 2x/Day	Not Reported
Spiriva	C		2 Df, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13877175	NON-EXPEDITED			US-AKORN-64799			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus; Pruritus	Azasite			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13877380	NON-EXPEDITED			US-AKORN-65171			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pain	Azasite			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13877381	NON-EXPEDITED			US-AKORN-65064			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea	Azasite			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13877393	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2017352167		27 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Arthralgia; Delirium; Mania; Off Label	Azithromycin			S	Oral	500 Mg, 2x/Day		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Use; Self-Injurious Ideation; Syncope; Tendonitis; Violence-Related Symptom	Lamotrigine	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13877761	NON-EXPEDITED			GXBR2017US001336			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Nausea; Vomiting	Methylprednisolone Tablets Usp			S	Unknown	Unk		Novartis	
	Z-Pak			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2017	13898542	DIRECT					79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Haematochezia; Muscle Spasms; Nausea; Vomiting	Azithromycin 250mg			S	Oral	6 Pills 2 First Day Then 1- For 4 Days By Mouth Expiration Day: 9-19- No Year		Greenstone	
	Norvasc			C				Not Reported	
	Atenolol			C				Not Reported	
	Centrum			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13881209	NON-EXPEDITED			US-PFIZER INC-2017353698		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2017	13881417	NON-EXPEDITED			US-PFIZER INC-2017356408		20 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Augmentin /00756801/			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2017	13883823	NON-EXPEDITED			GXBR2017US002114		31 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blister; Gait Disturbance; Pruritus; Rash Papular	Azithromycin 250 Mg			S	Oral	2 Df, Qd		Novartis	
	Azithromycin 250 Mg			S	Oral	1 Df, Qd		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2017	13883824	NON-EXPEDITED			GXBR2017US002058			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Dysgeusia; Malaise	Azithromycin 250 Mg			S	Unknown	Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2017	13886706	EXPEDITED (15-DAY)		HO, OT	PHFR2017GB006647		27 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Arrhythmia; Arthralgia; Delirium; Mania; Self- Injurious Ideation; Syncope; Tendonitis; Violence-Related Symptom	Azithromycin			S	Oral	500 Mg, Bid		Novartis	
	Lamotrigine			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2017	13850150	EXPEDITED (15-DAY)		DE	ET-PFIZER INC- 2017337881		5 YR	Female	ETH
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Aspiration; Choking	Zithromax		S	Oral	250 Mg Tablet (2), Stat (At Once)	Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13870188	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2017348276		30 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Zithromax			S	Oral	500 Mg, 2x/Day		Pfizer	
Amylase Increased;	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
Lipase Increased; Product Use Issue	Yasminelle			C	Oral	1 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13891601	EXPEDITED (15-DAY)		OT	UY-TEVA-790789ISR		36 YR	Female	URY
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parosmia; Staphylococcal Infection; Taste Disorder	Campozin			S	Oral	500 Milligram Daily;		Not Reported	
	Paracetamol			C				Not Reported	
	Zolben C			C				Not Reported	
	Biogrip			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13891916	NON-EXPEDITED			US-PFIZER INC-2017363012		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Azithromycin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Sulfasalazine			S		Unk		Pfizer	
	Xeljanz Xr			S		11 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2017	13910057	DIRECT	Y				66 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin 500mg Iv			S	Intravenous (not otherwise specified)	Q24		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13895491	NON-EXPEDITED			US-PFIZER INC-2017357440			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Duloxetine			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2017	13895654	NON-EXPEDITED			US-PFIZER INC-2017362464			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13899459	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-LUPIN PHARMACEUTICALS INC.-2017-04735		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage; Factor V Inhibition	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Lupin	
	Meropenem			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13899715	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2017-39191		27 YR	Female	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Arthralgia; Delirium; Mania; Self-Injurious Ideation; Syncope; Tendonitis; Violence-Related Symptom	Azithromycin 500 Mg			S	Oral	500 Mg, Two Times A Day		Aurobindo	
	Lamotrigine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13900039	EXPEDITED (15-DAY)		LT, OT	US-PFIZER INC-2017359315		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Voriconazole			S	Intravenous (not otherwise specified)	200 Mg, 2x/Day (Every 12 Hours)		Pfizer	
	Azithromycin			S	Oral	250 Mg, Daily		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, 1x/Day		Pfizer	
	Ciprofloxacin			S	Intravenous (not otherwise specified)	400 Mg, 3x/Day (Every 8 Hours)		Unknown	
	Rocuronium Bromide			S		Unk		Unknown	
	Etomidate			S		Unk		Unknown	
	Propofol			S		Unk		Unknown	
	Cefepime			C	Intravenous (not otherwise specified)	2 G, 2x/Day (Every 12 Hours)		Not Reported	
	Clofazimine			C	Oral	50 Mg, Daily		Not Reported	
	Cefoxitin			C	Intravenous (not otherwise specified)	2 G, 3x/Day (Every 8 Hours)		Not Reported	
	Cefoxitin			C	Intravenous (not otherwise specified)	2 G, 3x/Day (Every 8 Hours)		Not Reported	
	Tigecycline			C	Intravenous (not otherwise specified)	50 Mg, Daily		Not Reported	
	Tigecycline			C	Intravenous (not otherwise specified)	100 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aztreonam	C	Respiratory (inhalation)	75 Mg, 3x/Day (Every 8 Hours Alternating Monthly With Tobramycin Inhaled Every 12 Hours)	Not Reported
Tobramycin	C	Respiratory (inhalation)	Unk, 2x/Day (75 Mg Inhaled Every 8 Hours Alternating Monthly With Tobramycin Inhaled Every 12 Hours)	Not Reported
Amphotericin	C	Respiratory (inhalation)	20 Mg, 1x/Day	Not Reported
Ondansetron	C	Oral	8 Mg, 3x/Day, (Every 8 Hours)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13900971	EXPEDITED (15-DAY)		OT	ES-APOTEX-2017AP017264		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Ototoxicity; Vestibular Ataxia	Azitromicina Apotex Comprimidos Recubiertos Con Pelicula Efg Amoxi Clav			S	Unknown			Apotex	
				S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13903432	NON-EXPEDITED			US-PFIZER INC-2017365682			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13903634	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2017M1051158		27 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arrhythmia; Arthralgia; Delirium; Mania; Self- Injurious Ideation; Syncope; Tendonitis; Violence-Related Symptom	Azithromycin	S	Oral	500 Mg, Bid	Not Reported
	Lamotrigine	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13903688	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2017361320		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Disorder; Fatigue; Feeling Jittery; Localised Infection; Musculoskeletal Disorder; Myocardial Infarction; Palpitations	Zithromax			S		Unk		Pfizer	
	Repatha			S	Subcutaneous	140 Mg, Once In Two Weeks (Q2wk)		Not Reported	
	Repatha			S				Not Reported	
	Repatha			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2017	13903803	EXPEDITED (15-DAY)		OT	US-TEVA-798457ACC			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Azithromycin			S		Took The Product 3.5 Years Ago		Pliva	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2017	13014473	EXPEDITED (15-DAY)		DS	PT-PFIZER INC- 2016565274		29 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erectile Dysfunction; Libido Decreased	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2017	13897810	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-797651ACC		27 YR	Female	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Arthralgia; Delirium; Mania; Self- Injurious Ideation; Syncope; Tendonitis; Violence-Related Symptom	Azithromycin			S	Oral	1000 Milligram Daily;		Not Reported	
	Aps Lamotrigine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2017	13904647	NON-EXPEDITED			US-PFIZER INC- 2017365615			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Aug-2017	13906840	EXPEDITED (15-DAY)		OT	JP-MYLANLABS- 2017M1051623			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Infectious	Vancomycin			S	Oral			Not Reported	
	Zithromac			S	Oral	1 Df, Qd		Mylan	
	Ebutol /00022301/			C	Oral			Mylan	
	Adona /00056903/			C	Oral			Mylan	
	Biofermin R			C	Oral			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2017	13913896	DIRECT	Y	HO, RI			33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea Exertional; Fatigue; Haemolytic Anaemia; Pyrexia; Rash; Vitamin B12 Deficiency; White	Azithromycin			S	Oral			Not Reported	
	Topiramate			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Blood Cell Count
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	12000790	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016US-110952		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Ranbaxy	
	Azithromycin			S	Unknown	Unk		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13813865	NON-EXPEDITED			US-PFIZER INC- 2017330516		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Levothyroxine			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13909557	NON-EXPEDITED			US-PFIZER INC- 2017369128		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hallucination; Headache; Rash; Vomiting	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2017	13909619	NON-EXPEDITED			US-PFIZER INC- 2017370916			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13909633	NON-EXPEDITED			US-PFIZER INC-2017369349		72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Supraventricular Tachycardia	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Aug-2017	13911303	EXPEDITED (15-DAY)		HO	PHHY2017IT123300		19 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Diarrhoea; Dysstasia	Azithromycin			S	Oral	500 Ug, Qd		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13398360	NON-EXPEDITED		OT	US-PFIZER INC-2017135146		75 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anaphylactic Reaction; Diarrhoea; Drug Hypersensitivity	Zithromax			S	Oral	250 Mg, Unk		Pfizer	
	Zithromax			S				Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Aug-2017	13838872	NON-EXPEDITED			US-PFIZER INC-2017338948		72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ibuprofen	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Robaxin	S	Unk	Not Reported
	Tegretol	S		Not Reported
	Suprep Bowel Prep	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13864543	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-39046		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Gait Disturbance; Hyporeflexia; Ototoxicity	Amoxicillin+Clavulanic Acid			S	Unknown			Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13873200	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-797021ROM		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Neurosensory; Gait Disturbance; Hyporeflexia; Ototoxicity	Amoxicillin W/Clavulanic Acid			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13913592	EXPEDITED (15-DAY)		DE, HO, LT	US-TORRENT-00003293		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Cerebral Haemorrhage; Coagulation Factor V Level Decreased; Subdural Haematoma	Levofloxacin			S				Unknown	
	Ceftriaxone Sodium			S				Unknown	
	Azithromycin			S				Unknown	
	Meropenem Trihydrate			S				Unknown	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13917057	NON-EXPEDITED			US-AKORN-65492			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Eye Pain; Vision Blurred	Azasite (Azithromycin Ophthalmic Solution) 1%			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13917061	EXPEDITED (15-DAY)		OT	US-BAYER-2017- 162841		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Ciprofloxacin			S	Intravenous (not otherwise specified)	400 Mg, Tid		Bayer	
	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, Qid		Not Reported	
	Tacrolimus			S				Not Reported	
	Voriconazole			S		200 Mg, Bid		Not Reported	
	Cefoxitin			C	Intravenous (not otherwise specified)	2 G, Unk		Not Reported	
	Tigecycline			C	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported	
	Amphotericin			C		20 Mg, Unk		Not Reported	
	Pantoprazole Ondansetron			C C				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13917644	NON-EXPEDITED			US-AKORN-59248			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Pain	Azasite			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13918051	EXPEDITED (15-DAY)		OT	US-TEVA-800893USA		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Swelling; Speech Disorder; Swollen Tongue	Azithromycin			S	Oral	10 MI		Not Reported	
	Azithromycin			S	Oral	200 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2017	13918069	EXPEDITED (15-DAY)		OT	GXJP2017JP001351			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Anaemia; Diarrhoea; Haematochezia; Syncope	Azithromycin Tablets			S	Oral			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2017	13896725	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017360832			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blood Creatinine Increased;	Xeljanz Xr			S		11 Mg, Unk		Pfizer	
Blood Glucose Increased;	Methotrexate Sodium			S		0.8 MI (20mg), Weekly		Unknown	
Blood Pressure Increased;	Enbrel			S		Unk		Pfizer	
Blood Urea Increased;	Bumetanide			S		2 Mg		Unknown	
Bursitis; C-Reactive Protein Increased;	Medrol			S		2 Mg, Daily		Pfizer	
Depression; Ecchymosis;	Zithromax			S		250 Mg, Unk		Pfizer	
Foot Deformity; Glomerular Filtration Rate Decreased; Obesity; Oedema; Red Cell Distribution Width Increased									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2017	13923648	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2017US15070			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dyspnoea; Pleural Effusion; Therapy Non- Responder	Levofloxacin			S	Unknown	Unk		Cipla	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Cipla	
	Vancomycin			S	Unknown	Unk		Cipla	
	Tazobactam/Piperacillin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2017	13925886	EXPEDITED (15-DAY)		HO	JP-FRESENIUS KABI- FK201707271		1 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bk Virus Infection; Cytomegalovirus Infection Reactivation; Drug Hypersensitivity; Drug Reaction With Eosinophilia And Systemic Symptoms; Infection Reactivation; Product Use Issue	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Azithromycin (Manufacturer Unknown)			S				Fresenius Medical Care	
	Pranlukast			S	Unknown			Not Reported	
	Pranlukast			S				Not Reported	
	Ampicillin/Sulbactam			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13829525	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC- 2017334431		30 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumoretroperitoneum	Zithromac			S	Oral	Unk		Pfizer	
	Abilify			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13928488	EXPEDITED (15-DAY)		DS	US-ROCHE-1968367		62 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia; Arthralgia; Cognitive Disorder; Depression; Fatigue; Gait Inability; Headache; Myalgia; Pain; Tinnitus; Unevaluable Event	Pegasys			S	Unknown			Not Reported
	Azithromycin			S	Oral			Not Reported
	Macrobid (United States)			C	Unknown			Not Reported
	Acyclovir			C	Unknown			Not Reported
	Alprazolam			C	Unknown			Not Reported
	Estring			C	Unknown			Not Reported
	Flexeril (Cefixime)			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13928652	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-148695			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental			Sun
	Gentamicin			S	Transplacental			Not Reported
	Ampicillin			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13928662	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-148672		34 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amniotic Cavity Infection; Amniotic Cavity Infection; Drug Ineffective; Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Intravenous (not otherwise specified)			Sun
	Gentamicin			S	Intravenous (not otherwise specified)			Not Reported
	Ampicillin			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13929105	NON-EXPEDITED		OT	US-APOTEX-2017AP017629		35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Levofloxacin Tablets			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Amoxicillin And Clavulanate Potassium			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13929702	EXPEDITED (15-DAY)		HO, OT	US-GLENMARK PHARMACEUTICALS-2017GMK028669		9 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Eosinophilic Pneumonia; Pneumomediastinum; Pneumopericardium; Pneumothorax	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Glenmark	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoxicillin			C	Unknown	Unk		Not Reported	
	Hydrocortisone			C	Topical	Unk		Not Reported	
	Diphenhydramine			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2017	13934906	DIRECT	Y				56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Inversion; Palpitations	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13931696	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2017US15484			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Herniation; Cerebral Haemorrhage; Condition Aggravated; Subdural Haematoma	Levofloxacin			S	Unknown	Unk		Cipla	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Cipla	
	Meropenem			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13932107	NON-EXPEDITED			US-PFIZER INC-2017377544			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13932920	EXPEDITED (15-DAY)		OT	MX-PFIZER INC-2017377730		17 YR	Male	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne Fulminans	Azitrocin			S		500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13933113	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2017374734		27 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Chest Discomfort; Palpitations; Tachypnoea	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Sodium Chloride			C	Intravenous drip	250 MI, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2017	13935952	DIRECT					29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence; Somnolence	Azithromycin	Y		S	Oral	As Needed Oral		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13925733	EXPEDITED (15-DAY)			CH-PFIZER INC-2017329558		32 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Zithromax			S	Oral	500 Mg (1 Tablet), Twice A Day - In The Morning And Evening		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2017	13936868	NON-EXPEDITED			US-PFIZER INC-2017380740			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Skin Disorder	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	11215103	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-99137		9 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Amoxicillin			S	Unknown	Unk		Sun	
Condition Aggravated;	Azithromycin			S	Unknown	Unk		Sun	
Drug Hypersensitivity;	Co-Trimoxazole			S	Unknown	Unk		Mutual	
Eosinophilic Pneumonia;	Co-Trimoxazole			S	Unknown	Unk		Mutual	
Nausea;	Prednisone			S	Oral	60 Mg, Daily		Mutual	
Pneumomediastinum;	Levofloxacin			S	Unknown	Unk		Ranbaxy	
Pneumopericardium;	Diphenhydramine			C	Oral	Unk		Not Reported	
Pneumothorax; Pulmonary Embolism; Vomiting	Hydrocortisone			C	Topical	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13750292	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017299421		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Sebaceous Carcinoma	Novatrex			S	Oral	7.5 Mg, Once Weekly		Pfizer	
	Roactemra			S	Intravenous (not otherwise specified)	280 Mg, Every 15 Days		Not Reported	
	Speciafoldine			C		Unk		Not Reported	
	Fosavance			C		Unk		Not Reported	
	Orocal /00944201/			C		Unk		Not Reported	
	Avodart			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13936039	EXPEDITED (15-DAY)		HO	NL-PFIZER INC-2017374778		74 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticonvulsant Drug Level Decreased; Drug Interaction; Epilepsy	Azithromycin Teva			S	Oral	1 Df, 1x/Day (Finished Treatment)		Not Reported	
	Diphantoine-Z 25 Tablet 23mg			S	Oral	Unk		Not Reported	
	Losartan/Hydrochloorthiazide			C	Oral	50/12.5 Mg		Not Reported	
	Ferrofumaraat			C	Oral	200 Mg, Unk		Not Reported	
	Fluticasonpropionaat			C	Nasal	Unk		Not Reported	
	Prednisolon /00016201/			C	Oral	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13938887	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2017US16113			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchopulmonary Aspergillosis Allergic; Cystic Fibrosis; Drug	Levofloxacin			S	Unknown	Unk		Cipla	
	Levofloxacin			S				Cipla	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective	Levofloxacin	S						Cipla
	Azithromycin	S	Unknown	Unk				Cipla
	Azithromycin	S						Cipla
	Azithromycin	S						Cipla
	Amoxicillin/Clavulanic Acid	S	Unknown	Unk				Not Reported
	Amoxicillin/Clavulanic Acid	S						Not Reported
	Amoxicillin/Clavulanic Acid	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939150	EXPEDITED (15-DAY)		OT	BR-009507513-1709BRA001238		4 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Delirium; Ear Disorder; Hypothermia; Hypothermia; Pharyngeal Disorder	Nasonex			S	Nasal	2 Df, Hs		Merck	
	Nasonex			S				Merck	
	Amoxicillin			S		Unk		Not Reported	
	Amoxicillin			S				Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939476	NON-EXPEDITED			US-PFIZER INC-2017380451			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Erythromycin Base			S		Unk		Not Reported	
	Toradol			S		Unk		Not Reported	
	Chlorhexidine			S		Unk		Not Reported	
	Allegra D 12 Hour Allergy And Congestion			S		Unk		Not Reported	
	Reglan			S		Unk		Not Reported	
	Claforan			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939979	EXPEDITED (15-DAY)		OT	PHHY2017ES130258		20 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Oligohydramnios; Premature Delivery; Preterm Premature Rupture Of Membranes; Product Use In Unapproved Indication	Ciclosporin			S	Unknown	4 Mg/Kg, Qd		Novartis
	Ampicillin			S	Intravenous (not otherwise specified)	1 G, Q6h		Not Reported
	Gentamicin			S	Intravenous (not otherwise specified)	240 Mg, Qd		Not Reported
	Clindamycin			S	Intravenous (not otherwise specified)	600 Mg, Q8h		Not Reported
	Betamethasone			S	Intramuscular	12 Mg, Unk		Not Reported
	Betamethasone			S	Intramuscular	12 Mg, Unk		Not Reported
	Etoposide			S	Intravenous (not otherwise specified)	150 Mg/M2, Qw2		Not Reported
	Piperacillin, Tazobactam			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported
	Pyrazinamide Sandoz			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Rifampicin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Amoxicillin			S	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported
	Erythromycin			S	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported
	Immunoglobulin (Ivig)			S	Unknown	1 G/Kg, Once/Single		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13939982	EXPEDITED (15-DAY)		CA, OT	PHHY2017ES130257			Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Tuberculosis; Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby; Testicular Torsion	Ciclosporin			S	Transplacental	Maternal Dose: 4 Mg/Kg, Qd		Novartis	
	Ampicillin			S	Transplacental	Maternal Dose: 1 G, Q6h		Not Reported	
	Gentamicin			S	Transplacental	Maternal Dose: 240 Mg, Qd		Not Reported	
	Clindamycin			S	Transplacental	Maternal Dose: 600 Mg, Q8h		Not Reported	
	Betamethasone			S	Transplacental	Maternal Dose: 12 Mg		Not Reported	
	Etoposide			S	Transplacental	Maternal Dose: 150 Mg/M2, Qw2		Not Reported	
	Piperacillin, Tazobactam			S	Transplacental			Not Reported	
	Meropenem			S	Transplacental			Not Reported	
	Isoniazid			S	Transplacental			Not Reported	
	Pyrazinamide Sandoz			S	Transplacental			Not Reported	
	Ethambutol			S	Transplacental			Not Reported	
	Rifampicin			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental			Not Reported	
	Amoxicillin			S	Transplacental	Maternal Dose: 500 Mg, Q8h		Not Reported	
	Erythromycin			S	Transplacental	Maternal Dose: 500 Mg, Q8h		Not Reported	
	Immune Globulin Iv			S	Transplacental	Maternal Dose: 1 G/Kg, Once/Single		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2017	13941742	NON-EXPEDITED			US-PFIZER INC- 2017382815		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Trimethoprim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	12854110	NON-EXPEDITED			US-PFIZER INC-2016481711		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Augmentin /00756801/			S		Unk		Not Reported	
	Augmentin /00756801/			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13932079	NON-EXPEDITED			US-PFIZER INC-2017380011			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13942043	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017379309			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterocolitis Haemorrhagic	Zithromac 250mg			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13942415	EXPEDITED (15-DAY)		DE	HR-PFIZER INC-2017376042		75 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchoalveolar Lavage Abnormal; Drug Ineffective; Hypogammaglobulinaemia ; Pleural Effusion; Pneumonia; Respiratory Failure	Azithromycin			S		500 Mg, Daily		Pfizer	
	Piperacillin/Tazobactam			S		Unk		Unknown	
	Amoxicillin Clavulanic Acid			S		Unk		Not Reported	
	Amoxicillin Clavulanic Acid			S				Not Reported	
	Cyclophosphamide			C		Unk, Cyclic		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Vincristine	C	Unk, Cyclic	Not Reported
Doxorubicin	C	Unk, Cyclic	Not Reported
Methylprednisolone	C	Unk, Cyclic	Not Reported
Methylprednisolone	C	Unk, 1 Mg/Kg Body Weight	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13942577	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1055007		22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Rocuronium			S	Unknown			Not Reported
	Etomidate			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Intravenous (not otherwise specified)	400 Mg, Q8h		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	200 Mg, Unk		Not Reported
	Azithromycin			S	Oral	250mg Daily		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, Qd		Not Reported
	Propofol			S	Unknown	Unk		Not Reported
	Tigecycline			C	Intravenous (not otherwise specified)	100 Mg Daily		Mylan
	Cefepime			C	Intravenous (not otherwise specified)	2 G, Unk		Mylan
	Cefoxitin			C	Intravenous (not otherwise specified)	2 G, Q8h		Mylan
	Amphotericin B			C	Respiratory (inhalation)	20 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13943366	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2017US125072		22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Electrocardiogram Qt Prolonged	Rocuronium Bromide	S	Unknown		Novartis
	Voriconazole	S	Intravenous (not otherwise specified)	200 Mg, Q12h	Not Reported
	Etomidate	S	Unknown		Not Reported
	Propofol	S	Unknown		Not Reported
	Ciprofloxacin	S	Intravenous (not otherwise specified)	400 Mg, Q8h	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	250 Mg, Qd	Not Reported
	Cefoxitin	C	Intravenous (not otherwise specified)	400 Mg, Q8h	Not Reported
	Tigecycline	C	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
	Cefepime	C	Intravenous (not otherwise specified)	2 G, Q12h	Not Reported
	Amphotericin	C	Respiratory (inhalation)	20 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13945331	NON-EXPEDITED			US-PFIZER INC- 2017386399			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Fatigue; Product Use Issue; Reflexes Abnormal; Weight Increased	Zithromax			S		Unk (3x A Week Until 6 Months)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13945464	NON-EXPEDITED			US-PFIZER INC- 2017383494			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Biaxin			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13945521	NON-EXPEDITED			US-PFIZER INC-2017384864			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13946769	NON-EXPEDITED			PHEH2017US028080			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhinorrhoea	Azithromycin 250 Mg			S	Oral	4 Df, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2017	13947226	EXPEDITED (15-DAY)		HO	PHHY2017US132048		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Babesiosis; Condition Aggravated; Dyspnoea	Clindamycin			S	Intravenous (not otherwise specified)	600 Mg, Q8h		Novartis	
	Clindamycin			S	Oral	450 Mg, Q8h		Novartis	
	Quinidine			S	Unknown			Not Reported	
	Doxycycline			S	Oral	100 Mg, Bid		Not Reported	
	Doxycycline			S	Oral	100 Mg, Bid For 6 Days		Not Reported	
	Atovaquone			S	Oral	750 Mg, Qd		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	1000 Mg, Qd		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported	
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13935667	NON-EXPEDITED			US-AMGEN-USASP2017132441		61 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Endodontic Procedure; Skin Lesion; Swelling; Tooth Disorder	Enbrel			S	Unknown	25 Mg, 2 Times/Wk		Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	
	Tylenol			C		Unk		Not Reported	
	Oxycodone			C		Unk		Not Reported	
	Clindamycin			C		150 Mg, Q6h		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13947689	EXPEDITED (15-DAY)		HO	US-APOTEX- 2017AP017999		25 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective For Unapproved Indication	Azithromycin			S	Unknown			Apotex	
	Prednisone			C	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13949547	NON-EXPEDITED		OT	US-APOTEX- 2017AP018298		28 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	2 G, Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13949837	NON-EXPEDITED		OT	US-APOTEX- 2017AP018300		31 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	2 G, Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Sep-2017	13949983	NON-EXPEDITED		OT	US-APOTEX- 2017AP018301		41 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment Failure	Azithromycin	S	Unknown	2 G, Unk	Apotex				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2017	13951689	EXPEDITED (15-DAY)	OT		CA-MYLANLABS-2017M1054041		23 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Sinus Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported	
	Acetaminophen			C		Unk		Mylan	
	Ciprofloxacin			C		Unk		Mylan	
	Cyanocobalamin			C		Unk		Mylan	
	Dimenhydrinate			C		Unk		Mylan	
	Echinacea /01323501/			C		Unk		Mylan	
	Folic Acid			C		Unk		Mylan	
	Ibuprofen			C		Unk		Mylan	
	Oseltamivir			C		Unk		Mylan	
	Piperacillin / Tazobactam			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	12092177	NON-EXPEDITED			ES-LUPIN PHARMACEUTICALS INC.-2015-03915		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952583	NON-EXPEDITED			JP-LUPIN PHARMACEUTICALS INC.-2017-02630		38 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption; Vertigo	Azithromycin 250mg Tablet			S	Oral	500 Mg, Qd		Lupin	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952589	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03030			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown	1 Gm, Single		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952591	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03039			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown	1 Gm, Single		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952594	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03040			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown	1 Gm, Single		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952595	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03041			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown	1 Gm, Single		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Sep-2017	13952596	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03042			Female	AUS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea	Azithromycin		S	Unknown	1 Gm, Single			Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952600	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03043			Female	AUS
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Azithromycin				S	Unknown	1 Gm, Single		Lupin
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952601	NON-EXPEDITED			AU-LUPIN PHARMACEUTICALS INC.-2017-03044			Female	AUS
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain	Azithromycin				S	Unknown	1 Gm, Single		Lupin
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952608	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-03220		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper	Azithromycin Tablets Usp, 250 Mg				S	Oral	As Directed, Qd		Lupin
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952615	NON-EXPEDITED		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-03529		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thrombocytopenia	Azithromycin				S	Unknown	Unk		Lupin
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952617	NON-EXPEDITED		HO, OT	GB-LUPIN PHARMACEUTICALS INC.-2017-03824		69 YR	Male	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Azithromycin			S	Unknown	500 Mg, Qd		Lupin	
	Amoxicillin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13952618	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-04742		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product Packaging; No Adverse Event	Azithromycin Tablets Usp, 250 Mg			S	Oral	4 Df, Single		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13953312	EXPEDITED (15-DAY)		OT	FR-LUPIN PHARMACEUTICALS INC.-2017-05105		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Forced Expiratory Volume Decreased	Azithromycin			S	Unknown	Unk		Lupin	
	Montelukast			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13953315	EXPEDITED (15-DAY)		OT	US-ZYDUS-016539		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Etomidate			S	Unknown			Zydus Pharm	
	Voriconazole			S	Intravenous (not otherwise specified)			Zydus Pharm	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Ciprofloxacin/Ciprofloxacin Hydrochloride/Ciprofloxacin Lactate			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Propofol	S	Unknown	Not Reported
	Rocuronium/Rocuronium Bromide	S	Unknown	Not Reported
	Clofazimine	C	Oral	Not Reported
	Cefoxitin	C	Intravenous (not otherwise specified)	Not Reported
	Tigecycline	C	Intravenous (not otherwise specified)	Not Reported
	Tigecycline	C	Intravenous (not otherwise specified)	Not Reported
	Aztreonam	C	Respiratory (inhalation)	Not Reported
	Tobramycin	C	Respiratory (inhalation)	Not Reported
	Ondansetron	C	Oral	Not Reported
	Cefepime/Cefepime Hydrochloride	C	Intravenous (not otherwise specified)	Not Reported
	Amphotericin B	C	Respiratory (inhalation)	Not Reported
	Azithromycin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13954024	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP018099		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Azithromycin			S	Unknown			Apotex	
Drug Ineffective; Exposure	Ceftriaxone			S	Unknown			Not Reported	
During Pregnancy; Foetal	Hydralazine			S	Unknown			Not Reported	
Death; Premature Delivery									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2017	13956531	EXPEDITED (15-DAY)		OT	IT-TEVA-803916ACC		55 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper; Diarrhoea Haemorrhagic	Azitromicina Teva Italia - Teva Italia S.R.L.		S			500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13891181	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2017359606		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ototoxicity	Azithromycin			S		Unk		Pfizer	
	Amoxicillin, Clavulanic Acid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13959286	DIRECT					5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Taste Abnormal; Vomiting	Azithromycin			S	Oral	Quantity:1 Teaspoon(S);		Teva	
	Zyrtec			C				Not Reported	
	Tylenol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13961594	NON-EXPEDITED			US-PFIZER INC- 2017391811			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2017	13961902	EXPEDITED (15-DAY)		HO	US-TEVA-804672USA		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Propofol			S	Unknown			Actavis	
	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	
	Azithromycin			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Rocuronium Bromide	S	Unknown		Not Reported
Etomidate	S	Unknown		Not Reported
Ciprofloxacin	S	Intravenous (not otherwise specified)		Not Reported
Voriconazole	S	Intravenous (not otherwise specified)		Not Reported
Cefoxitin	C	Intravenous (not otherwise specified)		Not Reported
Tigecycline	C	Intravenous (not otherwise specified)	100 Mg Daily	Not Reported
Cefepime	C	Intravenous (not otherwise specified)		Not Reported
Amphotericin B	C	Respiratory (inhalation)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13965511	EXPEDITED (15-DAY)		OT	US-TEVA-805695USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Insomnia; Loss Of Consciousness; Muscle Spasms; Pain; Walking Aid User	Azithromycin			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Augmentin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2017	13966818	DIRECT		HO, LT, OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Hot; Feeling Jittery; Heart Rate Irregular; Hypertension; Impaired Work Ability; Panic Reaction	Z Pack	Y		S	Oral	Quantity:1 Tablet(S);		Unknown
	Multi Vitamin B12			C				Not Reported
	B Complex			C				Not Reported
	Dha/Epa			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13967239	EXPEDITED (15-DAY)		LT, OT	US-IBIGEN-2017.02994		66 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Decadron			S	Intravenous (not otherwise specified)			Not Reported	
	Bactrim			S				Not Reported	
	Piperacillin/Tazobactam			S				Not Reported	
	Vancomycin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Furosemide			S				Not Reported	
	Levetiracetam			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13969886	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017393606			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anxiety; Insomnia; Loss Of Consciousness; Muscle Tightness; Pain; Walking Aid User	Azithromycin			S		Unk		Pfizer	
	Levofloxacin			S		500 Mg, Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2017	13972637	NON-EXPEDITED			US-ASTELLAS-2016US049573		78 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nasopharyngitis; Vomiting	Xtandi			S	Oral			Astellas	
	Z-Pak			S	Unknown	Unk, Unknown Freq.		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
15-Sep-2017	11087172	NON-EXPEDITED			US-PFIZER INC-2015146170			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Demerol	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	11754997	EXPEDITED (15-DAY)		LT, OT	US-TEVA-610432USA		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Respiratory Failure	Azithromycin			S	Oral			Not Reported
	Suboxone			S	Sublingual			Not Reported
	Lorazepam			S				Not Reported
	Cocaine			C				Not Reported
	Tramadol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13735428	NON-EXPEDITED			US-PFIZER INC- 2017294632			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Percocet			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13818741	EXPEDITED (15-DAY)		HO, LT, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-146193		1 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bk Virus Infection; Cardiac Hypertrophy; Cytomegalovirus Infection Reactivation; Drug Hypersensitivity; Drug Reaction With Eosinophilia And Systemic Symptoms;	Azithromycin			S	Unknown	Unk		Sun
	Pranlukast			S	Unknown	Unk		Not Reported
	Ampicillin, Sulbactam			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Multiple Organ
Dysfunction Syndrome;
Pneumonia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13882365	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2017AP016997		41 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Cytomegalovirus Infection; Drug Ineffective	Mycophenolate Mofetil			S	Unknown	1000 Mg, Bid		Apotex
	Mycophenolate Mofetil			S	Unknown	500 Mg, Bid		Apotex
	Azithromycin			S	Oral			Apotex
	Levofloxacin Tablets			S	Unknown			Apotex
	Tacrolimus			S	Unknown	2 Mg, Bid		Not Reported
	Valganciclovir			C	Unknown	225 Mg, Qd		Not Reported
	Valganciclovir			C	Unknown	900 Mg, Bid		Not Reported
	Sulfamethizole W/Trimethoprim			C	Unknown	Unk, Single-Strength Every Monday, Wednesday, And Friday, For 1 Month		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13973521	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2013-09817			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Moxifloxacin			S	Unknown	400 Mg, Once A Day,		Aurobindo
	Azithromycin			S	Unknown	1 G, Once A Day,		Aurobindo
	Azithromycin			S	Unknown	.5 G, Once A Day,		Aurobindo
	Doxycycline			S	Unknown	200 Mg, Once A Day,		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13975469	NON-EXPEDITED			US-PFIZER INC- 2017398887		62 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Drug Ineffective	Zithromax			S		Unk		Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13976854	EXPEDITED (15-DAY)		OT	ES-APOTEX-2017AP018622		20 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Foetal Growth Restriction; Oligohydramnios; Premature Delivery	Azitromicina Apotex			S	Unknown			Apotex
	Comprimidos Recubiertos Con Pelicula Efg							
	Ampicillin			S	Unknown	1 G, Every 6 Hour		Not Reported
	Gentamicin			S	Unknown	240 Mg, Every 24 Hour		Not Reported
	Clindamycin			S	Intravenous (not otherwise specified)	600 Mg, For Every 8 Hour		Not Reported
	Betamethasone			S	Intramuscular	12 Mg, Repeated After 24 H		Not Reported
	Cyclosporine			S	Unknown	4 Mg/Kg, Qd		Not Reported
	Etoposide			S	Intravenous (not otherwise specified)	150 Mg/M2, Twice A Week		Not Reported
	Piperacillin & Tazobactam			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Ethambutol			S	Unknown			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Erythromycin			S	Intravenous (not otherwise specified)	500 Mg, Every 8 Hour		Not Reported
	Amoxicillin /00249602/			S	Unknown	500 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13976917	EXPEDITED (15-DAY)		OT	PHEH2017US029412			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Insomnia; Loss Of Consciousness; Muscle Tightness; Pain	Azithromycin 250 Mg			S	Unknown	250 Unk, Unk		Novartis	
	Levofloxacin			S	Unknown	Unk		Not Reported	
	Augmentin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2017	13976944	EXPEDITED (15-DAY)		HO	JP-TEVA-805079ROM		1 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bk Virus Infection; Cytomegalovirus Infection Reactivation; Drug Reaction With Eosinophilia And Systemic Symptoms; Infection Reactivation; Multiple Organ Dysfunction Syndrome	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Pranlukast			S	Unknown			Not Reported	
	Pranlukast			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13831006	EXPEDITED (15-DAY)		DE, HO, OT	US-EXELIXIS-CABO-17009961		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Campylobacter Infection; Cardiac Amyloidosis; Cardiac Tamponade; Diarrhoea; Haematocrit Increased; Haemoglobin Increased; Hypotension; Malignant Neoplasm Progression; Pericarditis; Ventricular Tachycardia	Cabometyx			S	Oral	60 Mg, Qd		Exelixis	
	Cabometyx			S	Oral	40 Mg, Qd		Exelixis	
	Azithromycin			S				Not Reported	
	L-Thyroxine			C				Not Reported	
	Amlodipine			C				Not Reported	
	Metoprolol Tartrate			C				Not Reported	
	Phos-Flur			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13868719	NON-EXPEDITED			US-PFIZER INC-2017349690		57 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13980462	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ACCORD-058449		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Drug Ineffective; Left Ventricular Hypertrophy; Lymphopenia; Off Label Use; Pneumocystis Jirovecii Pneumonia; Respiratory Failure; Sepsis; Urinary Tract Infection	Temozolomide			S	Oral	Dose: 150 Mg/M2/Day Po On Days 7-11		Accord	
	Furosemide			S				Accord	
	Dexamethasone			S	Oral	Dose: 4 Mg Four Times A Day, Tapering Dose		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Dose: 375 Mg/ M2 Iv Days (3,10,17,24)		Not Reported	
	Decadron			S				Not Reported	
	Bactrim			S	Intravenous (not otherwise specified)			Not Reported	
	Piperacillin/Tazobactam			S				Not Reported	
	Vancomycin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Levetiracetam			C				Not Reported	
	Methotrexate			C	Intravenous (not otherwise specified)	Dose: 8 Mg/M2 Iv On Day 1 And 15		Not Reported	
	Folinic Acid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2017	13984456	EXPEDITED (15-DAY)		HO, OT	US-AKORN-68092		29 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Herpangina; Pharyngitis; Viral Infection	Azasite (Azithromycin Ophthalmic Solution)			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	10429761	EXPEDITED (15-DAY)		CA	DE-PFIZER INC-2014240983			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Pfizer
	Levofloxacin			S	Transplacental	Unk		Pfizer
	Ceftazidime			S	Transplacental	Unk		Unknown
	Meropenem			S	Transplacental	Unk		Pfizer
	Ciprofloxacin			S	Transplacental	500 Mg, 2x/Day		Not Reported
	Aztreonam			S	Transplacental	Unk		Not Reported
	Insulin			S	Transplacental	Unk		Not Reported
	Salbutamol			S	Transplacental	Unk		Not Reported
	Ipratropium			S	Transplacental	Unk		Not Reported
	Colistin			S	Transplacental	Unk		Not Reported
	Fenoterol			S	Transplacental	Unk		Not Reported
	Pancreatin			S	Transplacental	Unk		Not Reported
	Vitamin K /00032401/			S	Transplacental	Unk		Not Reported
	Ivacaftor			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13920959	EXPEDITED (15-DAY)		HO	JP-TEVA-2017-JP-002776J		6 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azithromycin Tablet 250mg Teva			S	Unknown	10 Mg/Kg Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13985486	EXPEDITED (15-DAY)		LT, OT	US-AUROBINDO-AUR-APL-2017-40417		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Piperacillin+Tazobactam	S				Aurobindo
	Vancomycin	S				Aurobindo
	Azithromycin	S				Aurobindo
	Furosemide	S				Not Reported
	Decadron /00016001/	S	Oral	4 Mg, Four Times/Day		Not Reported
	Bactrim	S	Intravenous (not otherwise specified)			Not Reported
	Levetiracetam	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13986393	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/17/0093349		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anxiety; Arthralgia; Back Pain; Balance Disorder; Contusion; Drug Ineffective; Dyspnoea; Emotional Disorder; Erythema; Fatigue; Feeling Abnormal; Gait Disturbance; Insomnia; Loss Of Consciousness; Muscle Spasms; Muscle Tightness; Neuropathy Peripheral; Nightmare; Pain; Product Complaint; Pruritus; Restlessness; Skin Swelling; Temperature Intolerance; Tendon Discomfort	Augmentin			S	Unknown			Not Reported
	Levofloxacin			S	Oral			Not Reported
	Levofloxacin			S				Not Reported
	Z Pack			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2017	13988248	EXPEDITED (15-DAY)		OT	US-CELGENEUS-USA-20170902512			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Hypersensitivity; Peripheral Swelling; Sinus	Revlimid			S	Oral	25 Milligram		Celgene

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congestion	Revlimid	S	Oral	15 Milligram	Celgene
	Zithromax	S	Unknown		Not Reported
	Augmentin	C	Unknown		Not Reported
	Acyclovir	C	Unknown		Not Reported
	Albuterol Sulfate	C	Unknown		Not Reported
	Nasonex	C	Unknown		Not Reported
	Lasix	C	Unknown		Not Reported
	Ondansetron Hcl	C	Unknown		Not Reported
	Famotidine	C	Unknown		Not Reported
	Singulair	C	Unknown		Not Reported
	Tylenol	C	Unknown		Not Reported
	Calcium Citrate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13895655	NON-EXPEDITED			US-PFIZER INC-2017361509		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13919292	EXPEDITED (15-DAY)		OT	US-009507513-1708USA012322		29 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Proventil			S	Respiratory (inhalation)	Unk		Merck
	Proventil			S				Merck
	Azithromycin			S		Unk, Chronic		Not Reported
	Azithromycin			S				Not Reported
	Budesonide (+) Formoterol Fumarate			S	Respiratory (inhalation)	Unk		Not Reported
	Budesonide (+) Formoterol			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fumarate Sodium Chloride	S	Respiratory (inhalation)	Nebulized Hypertonic Saline	Not Reported
Sodium Chloride	S			Not Reported
Zemaira	S		Unk	Not Reported
Zemaira	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13951012	EXPEDITED (15-DAY)		HO	US-FRESENIUS KABI- FK201707522		22 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Propofol (Manufacturer Unknown)			S	Unknown			Not Reported
	Rocuronium (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Ciprofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Etomidate			S				Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Cefoxitin			C				Not Reported
	Tigecycline			C				Not Reported
	Cefepime			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13989674	NON-EXPEDITED			US-AMGEN- USASP2017140299			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atypical Pneumonia; Incorrect Dose	Enbrel			S	Unknown	50 Mg, Unk		Amgen
Administered; Injection	Enbrel			S				Amgen
Site Reaction; Injury	Enbrel			S				Amgen
Associated With Device;	Prednisone			S	Unknown	Unk		Not Reported
Off Label Use; Therapy	Azithromycin			S	Unknown	250 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Non-Responder; Weight Increased; Wrong Technique In Product Usage Process	Methotrexate	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2017	13990537	NON-EXPEDITED			US-PFIZER INC-2017401733		45 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Rash; Vomiting	Azithromycin			S	Oral	500 Mg, Single (2 Tablets The First Day)		Pfizer
	Azithromycin			S	Oral	250 Mg, 1x/Day (1 Tablet Daily Prescribed For 4 Days)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13834321	EXPEDITED (15-DAY)		DS, HO	AU-ROCHE-1971951		1 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Test Positive; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Viral Infection	Pulmozyme			S	Respiratory (inhalation)			Not Reported
	Azithromycin			S	Unknown	Most Recent Dose Before The Dose Was 100 Mg		Not Reported
	Biotin			C				Not Reported
	Calcium Pantothenate			C				Not Reported
	Ascorbic Acid			C	Unknown			Not Reported
	Colecalciferol			C	Unknown			Not Reported
	Cyanocobalamin			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Nicotinamide			C	Unknown			Not Reported
	Phytomenadione			C	Unknown			Not Reported
	Pyridoxine Hydrochloride			C	Unknown			Not Reported
	Retinol Palmitate			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Riboflavin	C	Unknown	Not Reported
Thiamine Hydrochloride	C	Unknown	Not Reported
Tocopheryl Acid Succinate	C	Unknown	Not Reported
Ergocalciferol	C	Unknown	Not Reported
Panthenol	C	Unknown	Not Reported
Pancrelipase	C	Unknown	Not Reported
Sodium Chloride	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13995528	EXPEDITED (15-DAY)		OT	US-TORRENT-00003406		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Diarrhoea; Nausea; Off Label Use; Optic Neuritis; Visual Impairment; Weight Decreased	Azithromycin			S				Unknown
	Moxifloxacin			S				Unknown
	Ethambutol			S				Unknown
	Tacrolimus			C				Unknown
	Prednisone			C				Unknown
	Atorvastatin			C				Unknown
	Filgrastim			C				Unknown
	Pentamidine			C				Unknown
	Rifampin			C				Unknown
	Levemir			C				Unknown
	Insulin Aspart			C				Unknown
	Acetylsalicylic Acid			C				Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13995599	NON-EXPEDITED			US-PFIZER INC-2017403759		42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13997268	EXPEDITED (15-DAY)		HO	US-TEVA-795307USA		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dispensing Error;	Clozapine			S	Oral			Ivax	
Psychotic Disorder; Road	Azithromycin			S	Unknown			Teva	
Traffic Accident									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2017	13997783	NON-EXPEDITED			US-PFIZER INC-2017404793			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Reaction To Excipient	Azithromycin			S		Unk		Pfizer	
	Azithromycin Teva			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13988127	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2009151051		34 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; C-	Azithromycin			S		Unk		Pfizer	
Reactive Protein	Clarithromycin			S	Oral	Unk		Pfizer	
Increased; Clostridium	Clarithromycin			S				Pfizer	
Difficile Colitis;	Meropenem			S	Intravenous (not	Unk		Pfizer	
Dehydration; Diarrhoea;					otherwise specified)				
Hypotension; Nausea;	Minocycline			S		Unk		Not Reported	
Pseudomembranous	Minocycline			S				Not Reported	
Colitis; Pyrexia;	Ciprofloxacin			S	Oral			Not Reported	
Tachycardia	Tobi			S	Respiratory	Unk		Not Reported	
					(inhalation)				
	Tobi			S				Not Reported	
	Interferon Gamma			S	Subcutaneous	Unk		Not Reported	
	Interferon Gamma			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Colomycin (Colistin)	S	Intravenous (not otherwise specified)	Not Reported
Colomycin (Colistin)	S		Not Reported
Omeprazole	C	Oral Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	13999842	EXPEDITED (15-DAY)		OT	US-BAYER-2017-178245		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Diarrhoea; Nausea; Optic Neuritis; Visual Impairment; Weight Decreased	Moxifloxacin Oral			S		400 Mg, Qd		Bayer
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Ethambutol			S		15 Mg/Kg, Qd		Not Reported
	Tacrolimus			C		5 Mg, 12 Hours		Not Reported
	Tacrolimus			C				Not Reported
	Tacrolimus			C		10 Mg, Qd		Not Reported
	Tacrolimus			C	Respiratory (inhalation)			Not Reported
	Tacrolimus			C				Not Reported
	Tacrolimus			C	Subcutaneous	4 lu, Unk		Not Reported
	Tacrolimus			C				Not Reported
	Filgrastim			C	Subcutaneous			Not Reported
	Levemir			C	Subcutaneous	12 lu, Qd		Not Reported
	Aspirin			C		162 Mg, Qd		Not Reported
	Prednisone			C		5 Mg, Qd		Not Reported
	Atorvastatin			C		10 Mg, Qd		Not Reported
	Pentamidine			C		300 Mg, Q1mon		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2017	14005367	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2017406636		52 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Erythema; Feeling Hot; Hypersensitivity	Zithromax		S	Oral	Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	6738550	EXPEDITED (15-DAY)		LT	GB-PFIZER INC-2008069235		27 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Rash; Sensation Of Foreign Body	Azithromycin			S	Oral			Pfizer	
	Misoprostol			S	Vaginal	800 Ug, Unk		Pfizer	
	Buccastem			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	13724499	EXPEDITED (15-DAY)			IT-PFIZER INC-2017282947		66 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vulvovaginal Pruritus	Azithromycin			S	Oral	500 Mg, As Needed		Pfizer	
	Ramipril Teva			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	14006993	NON-EXPEDITED			US-PFIZER INC-2017413456		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Acetaminophen			S		Unk		Not Reported	
	Aspartame			S		Unk		Not Reported	
	Saccharin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	14007017	NON-EXPEDITED			US-PFIZER INC-2017413514		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Morphine Sulfate	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2017	14007465	DIRECT					16 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Back Pain; Headache; Neck Pain	Zithromax, Azithromycin			S	Oral	Quantity:2 Capsule(S);		Not Reported	
	Antibiotics			C				Not Reported	
	Penicillin			C				Not Reported	
	Multi Vitamins			C				Not Reported	
	Paracetamol			C				Not Reported	
	Ibuprofen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	13567909	EXPEDITED (15-DAY)		DE	US-009507513- 1705USA009560		3 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Dexamethasone Sodium Phosphate			S	Intravenous (not otherwise specified)	0.6 Mg/Kg (10.4 Mg), Qd		Merck	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rifampin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Amphotericin B			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Fluconazole			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Miltefosine			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Levetiracetam			C		30 Mg/Kg, Unk		Not Reported	
	Lorazepam			C	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Fosphenytoin Sodium	C	otherwise specified)	Intravenous (not otherwise specified)	Unk			Not Reported
		Pentobarbital	C	Intravenous drip	30 Mg/Kg, Unk				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	13961986	EXPEDITED (15-DAY)		DE, OT	ET-PFIZER INC-2017387919		56 YR	Male	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Zithromax			S	Oral	4 Df, Single Dose		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14010310	NON-EXPEDITED			US-SHIRE-US201719116			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Cuvitru			S	Unknown			Shire	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14011061	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-05581			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Insomnia; Loss Of Consciousness; Muscle Tightness; Pain	Levofloxacin			S	Unknown	500 Mg, Unk		Lupin	
	Zithromax Z-Pack			S	Unknown	Unk		Not Reported	
	Augmentin /00756801/			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14011636	DIRECT		OT			85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Hypersensitivity	Azithromycin	S	Oral	Quantity:1 Tablet(S);				Teva	
	Glyberide	C						Not Reported	
	Montelukast	C						Not Reported	
	Prednisone	C						Not Reported	
	Hydrochlorothiazide	C						Not Reported	
	Cyanocobalamin	C						Not Reported	
	Vitamin D Nos	C						Not Reported	
	Robitussin Dm	C						Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14012489	EXPEDITED (15-DAY)		DE, DS, HO, OT	JP-PFIZER INC-2017409644		72 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Interstitial Lung Disease; Sepsis	Zithromac 250mg			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14013023	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017408051			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atypical Pneumonia; Incorrect Dose Administered; Injection Site Reaction; Injury Associated With Device; Therapy Non-Responder; Weight Increased; Wrong Technique In Device Usage Process	Enbrel Enbrel Enbrel Azithromycin Prednisone Methotrexate			S S S S S C		50 Mg, Unk 250 Mg, Unk Unk Unk		Unknown Unknown Unknown Pfizer Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2017	14013104	NON-EXPEDITED			US-PFIZER INC-2017411963			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Codeine			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Sep-2017	13853417	EXPEDITED (15-DAY)			IT-AUROBINDO-AUR-APL-2017-36807		66 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Vulvovaginal Pruritus	Azithromycin			S	Oral	500 Mg, Unk		Aurobindo		
	Ramipril Teva			C	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Sep-2017	13998951	EXPEDITED (15-DAY)		HO	PHHY2017IT137198		55 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Mechanical Urticaria; Rash; Urticaria	Azithromycin			S	Oral	500 Mg, Qd		Novartis		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Sep-2017	14009824	EXPEDITED (15-DAY)		OT	PHHY2017ES139409		63 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Blepharitis Allergic; Conjunctival Hyperaemia; Erythema Of Eyelid; Eyelid Oedema	Tropicamide			S	Ophthalmic	Unk		Not Reported		
	Povidone-Iodine			S	Ophthalmic	Unk		Not Reported		
	Azydrop			S	Ophthalmic	Unk		Not Reported		
	Moxifloxacin			C	Ophthalmic	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
28-Sep-2017	14020593	NON-EXPEDITED			US-PFIZER INC-2017413143			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Bladder Pain; Renal Pain	Azithromycin			S		Unk		Pfizer		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	13905967	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-03			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Feeling Abnormal; Hysterectomy; Migraine; Nausea; Sleep Apnoea Syndrome; Vomiting	Vancomycin			S	Unknown			Westward
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Xyrem			S	Oral			Not Reported
	Topamax			S	Unknown			Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Cephalosporin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14024590	EXPEDITED (15-DAY)		HO	PHHY2017IT141131		71 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Cordarone			S	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14025655	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2017GSK148284			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Depression; Drug Ineffective; Fatigue; Fear; Hypervigilance; Impaired	Nucala Powder For Injection			S		Unk		Glaxosmithkline
	Serevent			S		Unk		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quality Of Life; Lung	Pulmicort	S	Unk	Glaxosmithkline
Disorder; Peak Expiratory	Azithromycin	S	Unk	Glaxosmithkline
Flow Rate Decreased;	Albuterol	S	Unk	Glaxosmithkline
Therapeutic Product Effect	Zafirlukast	S	Unk	Not Reported
Incomplete; Therapeutic	Qvar	S	Unk	Not Reported
Response Unexpected	Spiriva	S	Unk	Not Reported
	Duoneb	S	Unk	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2017	14025798	NON-EXPEDITED			US-PFIZER INC-2017419686			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lexapro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14032111	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2017414155		33 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis;	Zithromax			S	Oral	500 Mg, Daily		Pfizer	
Hepatocellular Injury;	Zithromax			S				Pfizer	
Product Use In	Amoxicillin			S	Oral	2 G, Daily		Not Reported	
Unapproved Indication;	Augmentin /00852501/			S	Oral	2 G, Daily		Not Reported	
Transaminases Increased	Paroxetine			C		20 Mg, 1x/Day (In The Evening)		Not Reported	
	Lysanxia			C		5.5 Mg, 1x/Day (11 Drops In The Evening)		Not Reported	
	Inipomp			C		40 Mg, 1x/Day(In The Evening)		Not Reported	
	Tobradex			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Rifampicin		C		Unk			Not Reported	
	Rifampicin		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2017	14033403	DIRECT		OT			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Scar; Eye Irritation	Azasite			S	Ophthalmic	Quantity:1 Drop(S);		Akorn	
	Repatha			C				Not Reported	
	Aspirin			C				Not Reported	
	Lovaza			C				Not Reported	
	Multivitamin			C				Not Reported	
	Coq10			C				Not Reported	
	Magnesium B6			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	13948828	EXPEDITED (15-DAY)		LT	US-009507513-1709USA002134		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Furosemide			S		Unk		Merck	
	Decadron			S	Oral	4 Mg, Four Times A Day		Merck	
	Decadron			S	Oral	Unk, Tapering Dose		Merck	
	Decadron			S	Oral	4 Mg, Twice Daily		Merck	
	Bactrim			S	Intravenous (not otherwise specified)			Not Reported	
	Vancomycin			S		Unk		Not Reported	
	Piperacillin Sodium (+) Tazobactam Sodium			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Levetiracetam			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14023746	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2017414351		71 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Electrocardiogram Qt Prolonged	Cordarone			S	Oral	200 Mg, Daily		Pfizer	
	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14033164	NON-EXPEDITED			US-PFIZER INC- 2017417269			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14033373	EXPEDITED (15-DAY)		HO, OT	US-APOTEX- 2017AP019442		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Levofloxacin Tablets			S	Unknown			Apotex	
	Levofloxacin Tablets			S				Apotex	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14034565	NON-EXPEDITED			US-PFIZER INC- 2017424180			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14035341	EXPEDITED (15-DAY)		OT	PHHY2017KR140508			Unknown	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged	Clofazimine	S	Unknown	Novartis
	Azithromycin	S	Unknown	Not Reported
	Moxifloxacin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14035398	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2017M1061969		51 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pathogen Resistance	Azithromycin			S	Unknown	Single Dose Regimen		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2017	14036007	EXPEDITED (15-DAY)		OT	US-TEVA-811169USA		87 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Choking; Drug Ineffective; Dyspnoea; Dyspnoea Exertional	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported
	Norco			C		2.5 Mg; Splits In Half		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	13333824	EXPEDITED (15-DAY)		HO, OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17-00		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Blood Pressure Increased; Decreased Appetite; Headache; Lethargy; Malaise; Transient Ischaemic Attack; Tremor	Doxycycline Hyc			S	Oral			Hikma
	Doxycycline Hyc			S				Hikma
	Zithromax			S	Oral			Not Reported
	Amlodipine			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Atorvastatin			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2017	14038806	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017420253		44 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia	Zithromax			S	Oral	250 Mg, 2x/Day		Pfizer
	Bactrim			S	Oral	Unk		Not Reported
	Rovalcyte			S	Oral	900 Mg, 2x/Day		Not Reported
	Neoral			S	Oral	180 Mg, 2x/Day		Not Reported
	Zarzio			S	Subcutaneous	30 Mg, 2x/Week		Not Reported
	Zopiclone			C	Oral	7.5 Mg, 1x/Day		Not Reported
	Doliprane			C	Oral	1 G, As Needed		Not Reported
	Folinoral			C	Oral	25 Mg, 3x/Week (On Monday, Wednesday And Friday)		Not Reported
	Ursolvan			C	Oral	Unk		Not Reported
	Cerazette (Desogestrel)			C	Oral	Unk		Not Reported
	Amlor			C	Oral	10 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14011852	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-DRREDDYS-USA/USA/17/0093555		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Diabetes Mellitus; Dialysis Related Complication; Diarrhoea; End Stage Renal Disease; Mycobacterium Avium Complex Infection; Nausea; Optic Neuritis; Visual Impairment; Weight Decreased	Tacrolimus			S	Unknown			Not Reported
	Moxifloxacin			S	Unknown			Not Reported
	Ramipril			S	Unknown			Not Reported
	Atorvastatin			S	Unknown	At Night		Not Reported
	Prednisone			S	Unknown			Not Reported
	Azithromycin			S				Not Reported
	Ethambutol			S	Unknown			Not Reported
	Levemir			C	Subcutaneous	Every Morning		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Filgrastim	C	Subcutaneous		Not Reported
	Pentamidine	C	Respiratory (inhalation)		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Insulin Aspart	C	Subcutaneous	With Meals	Not Reported
	Rifampin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14045600	EXPEDITED (15-DAY)		LT, OT	US-009507513-1710USA001510		5 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Methotrexate			S		20 Mg/M2, Qw		Not Reported
	Dexamethasone			S		9 MI, Qd		Merck
	Azithromycin			S		5 Mg/Kg, Monday, Wednesday, And Friday		Not Reported
	Mercaptopurine			S		75 Mg/M2, Qd		Not Reported
	Vincristine			S		1 Dose		Not Reported
	Globulin, Immune			S	Intravenous (not otherwise specified)	1000 Mg/Kg; 2 Doses		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2017	14045664	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP019109			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Insomnia; Loss Of Consciousness; Muscle Tightness; Pain; Walking Aid User	Levofloxacin Tablets			S	Unknown	500 Mg, Unk		Apotex
	Azithromycin			S	Unknown	Unk		Apotex
	Augmentin /00756801/			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14052164	NON-EXPEDITED			US-PFIZER INC-2017428392			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14056868	EXPEDITED (15-DAY)		HO	PHHY2017FR145361		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Zarzio			S	Subcutaneous	30 Mg, Biw		Not Reported	
	Neoral			S	Oral	2 Unk, Unk		Novartis	
	Zithromax			S	Oral	One Tablet In Morning And One Tablet In Evening, Bid		Not Reported	
	Bactrim			S	Unknown	Unk		Not Reported	
	Rovalcyte			S	Oral	2 Df, Bid		Not Reported	
	Doliprane			C	Oral	1 G, Unk		Not Reported	
	Folic Acid			C	Unknown	3 Df, Qw		Not Reported	
	Ursolvan			C	Oral	Unk		Not Reported	
	Cerazette (Desogestrel)			C	Oral			Not Reported	
	Amlor			C	Unknown	1 Df, Unk		Not Reported	
	Zopiclone			C	Oral	1 Df, In Evening		Not Reported	
	Aerius (Desloratadine)			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057048	EXPEDITED (15-DAY)		HO	PHHY2017FR143694		44 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Neoral			S	Oral	180 Mg, Bid		Novartis	
	Zarzio			S	Subcutaneous	1 Df, Biw		Not Reported	
	Zithromax			S	Oral	2 Df, Qd		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
	Rovalcyte			S	Oral	2 Df, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Doliprane	C	Oral	1 G, Prn	Not Reported
	Folinoral	C	Oral	1 Df, Tiw	Not Reported
	Ursolvan	C	Oral	200 Mg, Unk	Not Reported
	Cerazette (Desogestrel)	C	Oral	0.075 Mg, Unk	Not Reported
	Amlor	C	Oral	10 Mg, Qd	Not Reported
	Zopiclone	C	Oral	7.5 Mg, Qd	Not Reported
	Aerius (Desloratadine)	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057354	NON-EXPEDITED			US-PFIZER INC-2017426482			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pharyngeal Swelling	Tetracycline Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057367	NON-EXPEDITED			US-PFIZER INC-2017428323			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Oct-2017	14057881	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2017M1061269		71 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
	Cordarone			S	Oral	200 Mg, Qd		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	10428584	NON-EXPEDITED			US-PFIZER INC-2014241606		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	11639862	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-104615		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	Unk		Sun	
	Doxycycline			S	Oral	Unk Unk, Daily		Sun	
	Doxycycline			S				Sun	
	Levofloxacin			S	Oral	Unk		Ranbaxy	
	Linezolid			S	Unknown			Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Minocycline			S	Unknown	Unk		Ranbaxy	
	Minocycline			S				Ranbaxy	
	Tigecycline			S				Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14061984	NON-EXPEDITED			US-PFIZER INC-2017430524			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Azithromycin			S				Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14064073	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-17- 03		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cystitis; Fungal Infection; Hypersensitivity; Leukopenia; Rash; Stomatitis	Methotrexate			S	Unknown			Westward
	Flagyl			S	Unknown			Not Reported
	Penicillin (Benzylpenicillin)			S	Unknown			Not Reported
	Cytosan			S	Unknown			Not Reported
	Augmentin			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported
	Cleocin			S	Unknown			Not Reported
	Sulfa			S	Unknown			Not Reported
	Lyrica			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Klor-Con			C	Unknown			Not Reported
	Restasis Emul			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Oral			Not Reported
	Ventolin Hfa			C	Unknown			Not Reported
	Biotene Dry Mouth Liquid			C	Unknown			Not Reported
	Vitamin D3			C	Oral			Not Reported
	Triamcinolone			C	Unknown			Not Reported
	Vitamin C			C	Unknown			Not Reported
	Actemra			C	Unknown			Not Reported
	Crestor			C	Oral			Not Reported
	Reclast			C	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexilant	C	Unknown		Not Reported
Hydrocortisone-Acetaminophen	C	Oral	5-326 Mg; 1-2 Twice A Day	Not Reported
Ibuprofen	C	Oral		Not Reported
Valsartan	C	Oral		Not Reported
Symbicort	C	Unknown		Not Reported
Aspirin	C	Oral		Not Reported
Gas-X Extra	C	Oral		Not Reported
Cvs Melatonin	C	Oral		Not Reported
Tylenol	C	Oral		Not Reported
Fluticasone	C	Nasal		Not Reported
Cetirizine	C	Oral		Not Reported
Acetaminophen	C	Unknown		Not Reported
Fluorometholone	C	Unknown		Not Reported
Benadryl	C	Unknown		Not Reported
Dexilant	C	Unknown		Not Reported
Flaxseed	C	Unknown		Not Reported
Iron	C	Unknown		Not Reported
Melatonin	C	Unknown		Not Reported
Actemera	C	Intravenous drip		Not Reported
Miconazole	C	Oral		Not Reported
Remicade	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14067392	NON-EXPEDITED			US-PFIZER INC-2017434696			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Baclofen			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Claritin	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported
	Prozac	S	Unk	Not Reported
	Macrobid	S	Unk	Not Reported
	Benicar	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2017	14067432	NON-EXPEDITED		OT	US-PFIZER INC-2017430442		79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Zithromax			S		500 Mg, Single		Pfizer	
	Zithromax			S		250 Mg, Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2017	14074267	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017431266		43 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ischaemic Stroke	Zithromax			S	Oral	Unk		Pfizer	
	Cimzia			S	Subcutaneous	200 Mg, 2x/Month (Every 15 Days)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	13989051	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-150140		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Sun	
	Bactrim			S	Intravenous (not otherwise specified)	Unk		Mutual	
	Furosemide			S	Unknown	Unk		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Piperacillin/Tazobactam	S	Unknown	Unk	Not Reported
Vancomycin	S	Unknown	Unk	Not Reported
Decadron	S	Unknown	4 Mg, Bid	Not Reported
Levetiracetam	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14071640	EXPEDITED (15-DAY)		LT, OT	US-AUROBINDO-AUR-APL-2017-41474		5 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Dexamethasone			S	Unknown	3 Mg/M2, Two Times A Day		Aurobindo
	Azithromycin			S		Monday, Wednesday, And Friday		Aurobindo
	Methotrexate			S		20 Mg/M2, Every Week		Not Reported
	Mercaptopurine			S	Unknown	75 Mg/M2, Daily		Not Reported
	Vincristine			S	Unknown	1 Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2017	14075736	NON-EXPEDITED			US-PFIZER INC-2017430786			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	12010104	EXPEDITED (15-DAY)		OT	CA-SA-2016SA015969		21 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Blood Lactic Acid Increased; Maternal Exposure During Pregnancy	Cefotaxime			S	Transplacental			Not Reported
	Abacavir			S	Transplacental			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amlodipine Besilate	S	Transplacental	Not Reported
Azithromycin	S	Transplacental	Not Reported
Intelence	S	Transplacental	Not Reported
Monopril	S	Transplacental	Not Reported
Prezista	S	Transplacental	Not Reported
Ritonavir	S	Transplacental	Not Reported
Tenofovir	S	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	13794426	NON-EXPEDITED			US-PFIZER INC-2017320056			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14038990	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017420021		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioimmunoblastic T-Cell Lymphoma	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Synthroid			C		Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Digoxin			C		Unk		Not Reported
	Plavix			C		Unk		Not Reported
	Cardizem			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14078332	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dose Calculation Error; Incorrect Dose Administered; Product Dispensing Error	Azithromycin	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14078482	NON-EXPEDITED			US-PFIZER INC- 2017357561		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14079944	EXPEDITED (15-DAY)		HO	PHHY2017ZA149829			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Disorder	Theophylline Sandoz			S	Oral	200 Mg, Unk		Not Reported	
	Azithromycin Dihydrate Sandoz			S	Oral	500 Mg, Unk		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14080288	EXPEDITED (15-DAY)		HO	PHHY2017AU146733		4 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Hypothermia	Azithromycin			S	Intravenous (not otherwise specified)	85 Mg, (5 Mg/Kg) Qd		Novartis	
	Azithromycin			S				Novartis	
	Piperacilin/Tazobactam			C	Intravenous (not otherwise specified)	1.7 G Intravenous Piperacillin (100 Mg/Kg) Plus Tazobactam Every 6 Hours		Not Reported	
	Piperacilin/Tazobactam			C	Unknown	Unk		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	850 Mg, Qd		Not Reported	
	Amikacin			C	Intravenous (not	380 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amphotericin B, Liposome	C	otherwise specified) Intravenous (not otherwise specified)	60 Mg, Qd	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	310 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14080633	EXPEDITED (15-DAY)		DE, LT, OT	JP-BRISTOL-MYERS SQUIBB COMPANY- 12181145		53 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysgeusia; Pancytopenia	Efavirenz			S	Oral	600 Mg, Unk		Bristol Myers Squibb
	Efavirenz			S	Unknown			Bristol Myers Squibb
	Zerit			S	Oral	Interrupted From 21-Sep-2002 To 05-Nov-2002		Bristol Myers Squibb
	Zerit			S	Unknown			Bristol Myers Squibb
	Epivir			S	Oral	Interrupted From 21-Sep-2002 To 05-Nov-2002		Not Reported
	Epivir			S	Unknown			Not Reported
	Kaletra			S	Oral	3 Df, Bid		Not Reported
	Kaletra			S	Unknown			Not Reported
	Cravit			S	Oral	300 Mg, Qd		Not Reported
	Zithromac			S	Oral	1.2 G, Qd		Not Reported
	Sulpiride			S	Unknown	50 Mg, Tid		Not Reported
	Prednisolone			C	Oral	10 Mg, Unk		Not Reported
	Pirenzepine Hcl			C	Unknown	40 Mg, Qd		Not Reported
	Pirenzepine Hcl			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2017	14082009	EXPEDITED (15-DAY)			US-MYLANLABS- 2017M1047634			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Epinephrine	S	Unk	Not Reported
	Zithromax	S	Unk	Mylan
	Erythromycin	S	Unk	Mylan
	Voltaren /00372301/	S	Unk	Mylan
	Tylenol With Codein /00116401/	S	Unk	Mylan
	Nickel	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14071555	EXPEDITED (15-DAY)		LT, OT	US-DRREDDYS-USA/USA/17/0093923		5 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Mercaptopurine			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Monday, Wednesday, And Friday		Not Reported
	Dexamethasone			S	Unknown			Not Reported
	Vincristine			S	Unknown	1 Dose		Not Reported
	Immunoglobulin (Ivig)			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14082083	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2016VAL001873		21 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Blood Lactic Acid Increased; Maternal Exposure During Pregnancy	Cefotaxime Sodium			S	Transplacental	Unk		Validus
	Abacavir			S	Transplacental	Unk, Bid		Not Reported
	Amlodipine			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Mg, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Monopril	S	Transplacental	Unk	Not Reported
Prezista	S	Transplacental	600 Mg, Bid	Not Reported
Ritonavir	S	Transplacental	100 Mg, Bid	Not Reported
Tenofovir	S	Transplacental	300 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14082469	EXPEDITED (15-DAY)	HO		AU-FRESENIUS KABI-FK201708557		4 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Hypothermia; Product Use Issue; Unmasking Of Previously Unidentified Disease	Azithromycin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
	Azithromycin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14082850	EXPEDITED (15-DAY)	HO, OT		CA-APOTEX-2017AP019532		27 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; C-Reactive Protein Decreased; Cholelithiasis; Cough; Crepitations; Forced Expiratory Volume Decreased; Gallbladder Disorder; H1n1 Influenza; Hypoventilation; Increased Viscosity Of Bronchial Secretion; Insomnia; Liver Function Test Increased; Malaise; Nasal Polyps; Neutrophil Count Increased; Pancreatic Failure; Pulmonary Function Test Abnormal; Pulmonary Function Test Decreased; Red Blood	Apo-Tobramycin			S	Unknown	160 Mg, Unk		Apotex	
	Tobi /00304201/			S	Other	Unk		Not Reported	
	Calcium			C	Unknown	600 Mg, Unk		Not Reported	
	Cotazym Ecs /00150201/			C	Unknown			Not Reported	
	Nasonex			C	Unknown			Not Reported	
	Omeprazole Magnesium			C	Unknown	20 Mg, Unk		Not Reported	
	Pancreatin			C	Unknown			Not Reported	
	Pms Azithromycin			S	Unknown	500 Mg, Unk		Not Reported	
	Pulmicort			C	Unknown	400 Mg, Unk		Not Reported	
	Ranitidine			C	Unknown	150 Mg, Unk		Not Reported	
	Salbutamol Sulfate			S	Unknown	100 Mg, Unk		Not Reported	
	Salbutamol Sulfate			S	Unknown	5 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cell Sedimentation Rate	Sodium Chloride	C	Unknown		Not Reported
Decreased; Respiratory	Symbicort Tu	C	Unknown	200 Mg, Unk	Not Reported
Tract Congestion; Sputum	Valproate Semisodium	C	Unknown	500 Mg, Unk	Not Reported
Discoloured; Therapeutic					
Response Decreased;					
Viral Upper Respiratory					
Tract Infection; White					
Blood Cell Count					
Abnormal					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14084664	EXPEDITED (15-DAY)		HO, OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-151989		4 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic	Azithromycin			S	Intravenous (not	5 Mg/Kg		Sun	
Decreased; Bradycardia;	Azithromycin			S	Intravenous (not	10 Mg/Kg		Sun	
Hypothermia	Amikacin			C	Intravenous (not	380 Mg, Daily		Not Reported	
	Amphotericin B			C	Intravenous (not	60 Mg, Daily		Not Reported	
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14085276	NON-EXPEDITED			US-PFIZER INC- 2017438686			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Zithromax			S		Unk		Pfizer	
Anxiety; Cyst; Decreased									
Appetite; Hepatic									
Steatosis; Weight									
Decreased									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Oct-2017	14086832	EXPEDITED (15-DAY)		OT	IT-TEVA-809884ACC		340 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia; Pharyngeal Erythema; Rash	Azithromycin Cardioaspirina Iron			S C C	Oral			Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	13698773	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2017271952		28 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14093193	NON-EXPEDITED			US-PFIZER INC- 2017441830			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Dyspepsia; Hepatic Cyst; Hepatic Steatosis	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14094628	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2017M1060083		340 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia; Pharyngeal Erythema; Rash	Azithromycin Iron Cardioaspirina			S C C	Oral	Unk Unk Unk		Not Reported Mylan Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2017	14094893	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017439225		4 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatic Enzyme Increased; Hepatic Function Abnormal	Zithromax			S	Intravenous drip	0.2 G, 1x/Day		Pfizer	
	Diflucan			S	Intravenous drip	0.1 G, 1x/Day		Pfizer	
	Mepem			S	Intravenous drip	0.4 G, 3x/Day (Every 8 Hours)		Pfizer	
	Sodium Chloride			C	Intravenous drip	100 MI, 3x/Day		Not Reported	
	Glucose			C	Intravenous drip	250 MI, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	13963753	EXPEDITED (15-DAY)		OT	US-009507513-1709USA002358		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Zemuron			S		Unk		Merck	
	Etomidate			S		Unk		Not Reported	
	Propofol			S		Unk		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	200 Mg, Q12h		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, Qd		Not Reported	
	Ciprofloxacin			S	Intravenous (not otherwise specified)	400 Mg, Q8h		Not Reported	
	Tacrolimus			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14095394	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-152478		22 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Enteritis; Leukocytosis; Sensory Level Abnormal; Vomiting	Azithromycin	S	Oral	On The First Day 500mg, Then 250mg Pro	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14095528	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-152237		5 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Monday, Wednesday, And Friday		Sun
	Dexamethasone			S	Unknown	3 Mg/M2, Bid		Sun
	Methotrexate			S	Unknown	20 Mg/M2, 1/Week		Not Reported
	Vincristine			S	Unknown	1 Dose		Not Reported
	Immunglobulin Iv			S	Intravenous (not otherwise specified)	2 Doses		Not Reported
	Mercaptopurine			S	Unknown	75 Mg/M2, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14096796	NON-EXPEDITED			US-PFIZER INC- 2017441674		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Xanax			S		Unk		Pfizer
	Effexor			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Loperamide Hcl			S		Unk		Not Reported
	Buspar			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Luvox	S	Unk	Not Reported
	Prednisone	S	Unk	Not Reported
	Lithium	S	Unk	Not Reported
	Zofran	S	Unk	Not Reported
	Amoxicillin	S	Unk	Not Reported
	Aspirin	S	Unk	Not Reported
	Benadryl	S	Unk	Not Reported
	Duloxetine	S	Unk	Not Reported
	Ambien	S	Unk	Not Reported
	Wellbutrin	S	Unk	Not Reported
	Zyprexa	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14098090	EXPEDITED (15-DAY)		HO, LT, OT	US-STRIDES ARCOLAB LIMITED- 2017SP013454			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acinetobacter Infection;	Vancomycin			S	Unknown	Unk		Strides
Condition Aggravated;	Azithromycin			S	Unknown	Unk		Not Reported
Delirium; Drug Ineffective;	Rifampicin			S	Unknown	Unk		Not Reported
Hepatic Function	Meropenem			S	Unknown	Unk		Not Reported
Abnormal; Hypotension;	Colistin			S	Unknown	Unk		Not Reported
Off Label Use; Renal	Tigecycline			S	Unknown	Unk		Not Reported
Impairment; Respiratory	Fluconazole			C	Unknown	Unk		Not Reported
Failure; Unresponsive To								
Stimuli								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14099596	NON-EXPEDITED			US-AKORN-70767			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Hypersensitivity; Ocular	Azasite			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperaemia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14100001	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017394284		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anxiety; Dyspnoea; Fatigue; Infection; Joint Effusion; Pain In Extremity; Palpitations; Vascular Rupture	Novatrex			S		12.5 Mg, Weekly (Wednesday)		Pfizer	
	Cystine B6			C		Unk		Not Reported	
	Lexomil			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14100577	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1064106		4 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Conduction Disorder; Hypothermia; Unmasking Of Previously Unidentified Disease	Azithromycin			S	Intravenous (not otherwise specified)	170mg(10mg/Kg) Then, 85mg (5mg/Kg) Daily		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	85mg (5mg/Kg) Daily		Not Reported	
	Adzopip			C	Unknown	Unk		Mylan	
	Amikacin			C	Intravenous (not otherwise specified)			Mylan	
	Amphotericin B Lipid Complex			C	Intravenous (not otherwise specified)	60 Mg		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2017	14100954	DIRECT		DS			84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Muscle Spasms	Azithromycin			S	Oral	2 - 1st Day 1- After That		Teva	
	1 A Day Vitamin			C				Not Reported	
	Vitamin E			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Baby Aspirin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	13752035	NON-EXPEDITED			US-PFIZER INC-2017298992			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swollen Tongue	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14101402	NON-EXPEDITED		OT	US-PFIZER INC-2017443828			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14101621	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201708674		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Nausea; Optic Neuritis; Visual Impairment; Weight Decreased	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Moxifloxacin (Manufacturer Unknown)			S	Unknown			Not Reported	
	Ethambutol			S				Not Reported	
	Tacrolimus			C				Not Reported	
	Prednisone			C				Not Reported	
	Aspirin			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Filgrastim			C	Subcutaneous			Not Reported	
	Levemir			C	Subcutaneous			Not Reported	
	Aspart			C	Subcutaneous			Not Reported	
	Pentamidine			C	Respiratory (inhalation)			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14102338	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2017444065		89 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cheilitis; Diarrhoea	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14103584	EXPEDITED (15-DAY)		OT	ES-TEVA-815231ISR		52 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Headache; Insomnia; Laryngeal Pain; Nervousness; Oral Candidiasis; Stomatitis	Azitromicina Teva 500 Mg Comprimidos Recubiertos Con Pelicula			S	Oral	500 Milligram Daily; 500 Mg Every Day, 3 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14104035	NON-EXPEDITED		HO, OT	US-APOTEX-2017AP020292		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Fluconazole Tablets			S	Unknown	Unk		Apotex	
	Colistin			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Tigecycline			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14105466	EXPEDITED (15-DAY)		OT	IN-PFIZER INC-2017442974			Unknown	IND

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Oedema; Shock	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14105502	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2017446177		23 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis; Liver Function Test Abnormal; Rash	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
	Tylenol			C	Oral	1 Df, 1x/Day		Not Reported	
	Tylenol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2017	14106291	NON-EXPEDITED			US-AMGEN- USASP2001000014			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Diarrhoea; Drug Intolerance; Myalgia; Nausea; Vomiting	Prolia			S	Subcutaneous	60 Mg/ML, Q6mo		Amgen	
	Lyrica			S	Oral	50 Mg, Bid		Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Alprazolam			C		0.25 Mg, Unk		Not Reported	
	Amlodipine Besylate			C		10 Mg, Unk		Not Reported	
	Vitamin B12			C		100 Mug, Unk		Not Reported	
	Acetaminophen W/Hydrocodone			C		10 To 325 Mg		Not Reported	
	Pantoprazole Sodium			C	Oral	40 Mg, Qd		Not Reported	
	Simvastatin			C		40 Mg, Qd		Not Reported	
	Vitamin D2			C		50000 Unit, Qwk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14048807	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2017-US- 012980		37 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeling Abnormal; Pneumonia	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustment		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Z-Pak			S				Not Reported
	Adderall			C		Unk		Not Reported
	Chlorthalidone			C		Unk		Not Reported
	Depo-Testosterone			C		Unk		Not Reported
	Losartan Potassium			C		Unk		Not Reported
	Nuvigil			C		Unk		Not Reported
	Viagra			C		Unk		Not Reported
	Vitamin D /00107901/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14106573	NON-EXPEDITED			US-PFIZER INC- 2017450685			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Piroxicam			S		Unk		Pfizer
	Mobic			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14106705	NON-EXPEDITED			US-PFIZER INC- 2017450229			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Flector			S		Unk		Pfizer
	Zithromycin			S		Unk		Not Reported
	Metformin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Phenergan /00033001/	S	Unk	Not Reported
Adderall	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14106755	NON-EXPEDITED			US-PFIZER INC-2017450171			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2017	14109437	EXPEDITED (15-DAY)		DE, HO, OT	US-MYLANLABS-2017M1065477		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Kidney Disease;	Tacrolimus			S	Unknown	5 Mg, Unk		Not Reported
Decreased Appetite;	Prednisone			S	Unknown	5 Mg Daily		Not Reported
Diarrhoea; Mycobacterium	Azithromycin			S	Unknown	250 Mg Daily		Not Reported
Avium Complex Infection;	Moxifloxacin Mylan			S	Unknown	400 Mg Daily		Mylan
Nausea; Optic Neuritis;	Ethambutol			S	Unknown	15 Mg/Kg Per Day		Mylan
Visual Impairment; Weight	Filgrastim			C	Subcutaneous	300 Mg, Qw		Mylan
Decreased	Ramipril			C	Unknown	1.25 Mg Daily		Mylan
	Aspirin /00002701/			C	Unknown	162 Mg Daily		Mylan
	Atorvastatin			C	Unknown	10 Mg Nightly		Mylan
	Pentamidine			C	Respiratory (inhalation)	300 Mg, Monthly		Mylan
	Levemir			C	Subcutaneous	12 Units Every Morning		Mylan
	Insulin Aspart			C	Subcutaneous	4 Units With Meals		Mylan
	Rifampicin			C	Unknown	600 Mg Daily		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	13725866	EXPEDITED (15-DAY)		OT	PHHY2016CA130427		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Coccydynia; Contusion; Crying; Discomfort; Dizziness Exertional; Dry Skin; Dyspnoea;	Xolair			S	Subcutaneous	Unk		Not Reported
Dyspnoea Exertional; Ear Pain; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Headache;	Xolair			S	Subcutaneous	Unk		Not Reported
Headache; Headache; Heart Rate Increased; Myalgia; Nausea; Oxygen Saturation Decreased;	Xolair			S	Subcutaneous	Unk		Not Reported
Pain In Extremity; Respiratory Rate Increased; Scratch; Vision Blurred	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous		Not Reported
Atorvastatin Sandoz	S	Unknown		Not Reported
Azithromycin Sandoz	S	Unknown		Novartis
Montelukast Sandoz	S	Unknown		Not Reported
Pantoprazole Sandoz	S	Unknown		Not Reported
Fentanyl Sandoz	S	Unknown		Not Reported
Ventolin	C	Unknown	Unk	Not Reported
Advair	C	Unknown	Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
Spiriva	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14110111	EXPEDITED (15-DAY)		OT	US-ROCHE-2010524			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pulmonary Congestion; Pulmonary Embolism	Xolair			S	Subcutaneous			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Warfarin			C				Not Reported
	Dulera			C				Not Reported
	Symbicort			C				Not Reported
	Budesonide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14110549	EXPEDITED (15-DAY)		OT	AU-009507513-1710AUS009080		48 YR	Male	AUS

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumothorax	Montelukast Sodium			S		Dose Unspec		Merck	
	Azithromycin			S		Dose Unspec		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14112220	NON-EXPEDITED		HO, OT	US-APOTEX-2017AP019963		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral			Apotex	
	Divalproex Sodium			C	Unknown			Not Reported	
	Clozapine			C	Unknown			Not Reported	
	Zolpidem			C	Unknown			Not Reported	
	Albuterol /00139501/			C	Unknown			Not Reported	
	Fluticasone			C	Unknown			Not Reported	
	Vancomycin			C	Unknown			Not Reported	
	Piperacillin & Tazobactam			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2017	14123725	EXPEDITED (15-DAY)	Y	HO	2017-001379		33 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Comminuted Fracture; Fall; Radius Fracture; Ulna Fracture	Azithromycin (Azithromycin) Suspension, 40mg/ML			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	12477076	EXPEDITED (15-DAY)		OT	PHHY2016US080839		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Drug Interaction;	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged; Intentional Product Misuse; Loss Of Consciousness; Medication Error; Product Use In Unapproved Indication; Pulse Absent; Torsade De Pointes; Ventricular Tachycardia	Sertraline	S	Unknown	Unk	Not Reported
	Ondansetron Hydrochloride	S	Unknown	Unk	Not Reported
	Diphenhydramine	S	Unknown	Unk	Not Reported
	Fluoxetine	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	13941739	NON-EXPEDITED			US-PFIZER INC-2017382484		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoacusis; Paraesthesia; Product Use In Unapproved Indication	Azithromycin			S		500 Mg, 1x/Day		Pfizer
	Azithromycin			S		250 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Levoxyl			C		Unk		Not Reported
	Buspirone Hcl			C		Unk		Not Reported
	Lamictal			C		Unk		Not Reported
	Allegra			C		Unk		Not Reported
	Gabapentin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	13998728	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK143716		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Neck Pain; Weight Increased	Nucala Powder For Injection			S	Intravenous (not otherwise specified)	100 Mg, Cyc		Glaxosmithkline
	Azithromycin			S		Unk		Not Reported
	Methylprednisolone			S		Unk		Not Reported
	Montelukast			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	14114382	NON-EXPEDITED			US-PFIZER INC-2017454494			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycoplasma Infection	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	14114499	NON-EXPEDITED			US-PFIZER INC-2017454579			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2017	14114502	NON-EXPEDITED			US-PFIZER INC-2017454619			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Imuran			S		Unk		Not Reported	
	Cellcept			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	11227141	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2015-043763			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Abilify			S	Unknown			Bristol Myers Squibb	
	Geodon /01487002/			S	Unknown			Not Reported	
	Tegretol			S	Unknown			Not Reported	
	Lyrica			S	Oral	150 Mg, Tid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lyrica	S	Oral	1 Df, Bid	Not Reported
Chantix	S	Unknown		Not Reported
Celebrex	S	Unknown		Not Reported
Zithromax	S	Unknown		Not Reported
Montelukast	C	Unknown		Not Reported
Norco	C	Unknown		Not Reported
Nasonex	C	Unknown		Not Reported
Ventolin /00139501/	C	Unknown		Not Reported
Metoclopramide	C	Unknown		Not Reported
Tramadol	C	Unknown		Not Reported
Flexeril /00428402/	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Topamax	C	Unknown		Not Reported
Levothyroxine	C	Unknown		Not Reported
Zyrtec /00884302/	C	Unknown		Not Reported
Methylprednisolone	C	Unknown		Not Reported
Verapamil	C	Unknown		Not Reported
Prozac	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14018322	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-150871		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite;	Azithromycin			S	Unknown	250 Mg, Daily		Sun	
Diarrhoea; Nausea; Optic	Moxifloxacin			S	Unknown	400 Mg, Daily		Not Reported	
Neuritis; Visual	Ethambutol			S	Unknown	15 Mg/Kg, Daily		Not Reported	
Impairment; Weight	Acetylsalicylic Acid			C	Unknown	162 Mg, Daily		Not Reported	
Decreased	Atorvastatin			C	Unknown	At Night		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Filgrastim	C	Subcutaneous	300 Mg, 1/Week	Not Reported
	Insulin Aspart	C	Subcutaneous	With Meals	Not Reported
	Levemir	C	Subcutaneous	Every Morning	Not Reported
	Pentamidine	C	Respiratory (inhalation)	300 Mg, Monthly	Not Reported
	Prednisone	C	Unknown	5 Mg, Daily	Not Reported
	Rifampin	C	Unknown	600 Mg, Daily	Not Reported
	Tacrolimus	C	Unknown	5 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14051793	NON-EXPEDITED			US-PFIZER INC-2017427673		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer	
	Zithromax			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14119450	EXPEDITED (15-DAY)		LT, OT	US-AUROBINDO-AUR-APL-2017-41991		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		On Day 36		Aurobindo	
	Meropenem			S		Unk		Aurobindo	
	Vancomycin			S				Aurobindo	
	Colistin			S		On Day 36		Not Reported	
	Rifampicin			S				Not Reported	
	Tigecycline			S				Not Reported	
	Fluconazole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14119690	EXPEDITED (15-DAY)		LT, OT	US-AXELLIA-001184		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Azithromycin	S	On Day 36	Not Reported
	Colistin	S		Xellia Pharmaceuticals
	Rifampicin	S		Not Reported
	Meropenem	S		Not Reported
	Fluconazole	C		Not Reported
	Vancomycin	S		Xellia Pharmaceuticals
	Tigecycline	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14120853	EXPEDITED (15-DAY)		DE, HO, OT	US-TEVA-817602USA		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Kidney Disease;	Azithromycin			S	Unknown	250 Mg Daily		Not Reported
Decreased Appetite;	Ethambutol			S	Unknown	15 Mg/Kg Per Day		Barr
Decreased Appetite;	Prednisone			S	Unknown	5 Mg Daily		Actavis
Diarrhoea; Mycobacterium	Moxifloxacin			S	Unknown	400 Mg Daily		Teva
Avium Complex Infection;	Tacrolimus			S	Unknown			Not Reported
Nausea; Optic Neuritis;	Filgrastim			C	Subcutaneous			Not Reported
Visual Impairment; Weight	Ramipril			C	Unknown	1.25 Mg Daily		Not Reported
Decreased	Aspirin			C	Unknown	162 Mg Daily		Not Reported
	Atorvastatin			C	Unknown	10 Mg Nightly		Not Reported
	Pentamidine			C	Respiratory (inhalation)			Not Reported
	Levemir			C	Subcutaneous	12 Units Every Morning		Not Reported
	Insulin Aspart			C	Subcutaneous	4 Units With Meals		Not Reported
	Rifampicin			C	Unknown	600 Mg Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2017	14121174	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2017458742			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Rash	Zithromax			S		Unk; In A 5-Day Blister		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax			S			Pack			Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
24-Oct-2017	14122513	DIRECT					41 YR	Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Burning Mouth Syndrome; Diarrhoea; Drug Hypersensitivity; Rash	Azithromycin			S	Oral	500 Mg Day 2 Pills Day 1 Lunch By Mouth	1 DAY	Pfizer			
					Oral		4 DAY				
	Xanax			C				Not Reported			
	Zolpidem			C				Not Reported			
	Essential Oils			C				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
24-Oct-2017	14122534	DIRECT	Y	RI			24 YR	Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Incorrect Route Of Product Administration	Zithromax			S				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
25-Oct-2017	11031303	NON-EXPEDITED			US-PFIZER INC-2015126365			Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Diarrhoea; Drug Hypersensitivity; Drug Intolerance; Nausea; Palpitations	Cleocin			S		Unk		Pfizer			
	Morphine Sulfate			S		Unk		Unknown			
	Tessalon			S		Unk		Pfizer			
	Zithromax			S		Unk		Pfizer			
	Avelox			S		Unk		Not Reported			
	Darvocet			S		Unk		Not Reported			
	Demerol			S		Unk		Not Reported			

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quinidine	S	Unk	Not Reported
Reglan	S	Unk	Not Reported
Tussionex Pennkinetic	S	Unk	Not Reported
Quinine Sulfate	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14082227	EXPEDITED (15-DAY)		OT	CN- GLAXOSMITHKLINE- CN2017GSK154208		1 YR	Unknown	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adenoidal Hypertrophy; Drug Ineffective; Dyspnoea; Nasopharyngitis; Off Label Use; Overdose; Peritonsillar Abscess; Product Administered To Patient Of Inappropriate Age; Product Use In Unapproved Indication; Rash; Rhinitis; Sneezing; Snoring; Suffocation Feeling; Wheezing	Ventolin Aerosol			S	Respiratory (inhalation)	Unk		Glaxosmithkline
	Ventolin Aerosol			S	Respiratory (inhalation)	2 Df, Bid		Glaxosmithkline
	Flixotide			S	Respiratory (inhalation)	2 Unk, Bid		Glaxosmithkline
	Flixotide			S	Respiratory (inhalation)	2 Df, Bid		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Penicillin (Benzylpenicillin)			S		Unk		Not Reported
	Singulair			C	Oral	Unk Unk, Tid		Glaxosmithkline
	Cefaclor			C	Oral	Unk Unk, Tid		Not Reported
	Paracetamol Pediatric			C	Oral	Unk Unk, Tid		Not Reported
	Paracetamol Pediatric			C				Not Reported
	Paracetamol Pediatric			C				Not Reported
	Houttuynia Cordata			C	Oral	Unk		Not Reported
	Houttuynia Cordata			C				Not Reported
	Houttuynia Cordata			C				Not Reported
	Singulair			C	Oral	Unk		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14123738	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered; Product Dispensing Error; Transcription Medication Error	Azithromycin			S		Suspension		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14124262	EXPEDITED (15-DAY)		OT	PHHY2017US155037			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pulmonary Congestion; Pulmonary Embolism	Xolair			S	Subcutaneous	300 Mg, Qmo		Not Reported	
	Azithromycin			S	Unknown			Novartis	
	Warfarin			C	Unknown			Not Reported	
	Dulera			C	Unknown			Not Reported	
	Symbicort			C	Unknown			Not Reported	
	Budesonide			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14124680	NON-EXPEDITED			US-PFIZER INC-2017459068			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14125378	EXPEDITED (15-DAY)		OT	ES-VIIV HEALTHCARE LIMITED-ES2017160768		57 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Lactic Acidosis	Tivicay	S	Oral	1c/D	Viiv
	Theo-Dur	S	Oral	1c/12h	Glaxosmithkline
	Azitromicina	S	Oral	1c/D	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14126696	EXPEDITED (15-DAY)		OT	BR-009507513-1710BRA011696		58 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Underdose	Nasonex			S	Nasal	One Spray In Each Nostril, Qam		Merck
	Bromopride			S		10 Mg, Bid		Not Reported
	Pantoprazole			S		40 Mg, Unk		Not Reported
	Cholecalciferol			S	Oral	Twice A Week		Not Reported
	Azithromycin			S		500 Mg, One Day Yes, One Day No		Not Reported
	Relvar			S		Unk, Qam		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2017	14128795	DIRECT		DS, OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Zithromycin			S	Oral	5 Each		Pliva
	Multi Vitamin			C				Not Reported
	Vit E			C				Not Reported
	Fish Oil			C				Not Reported
	Flaxseed Oil			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	13713307	EXPEDITED (15-DAY)		OT	CA-ROCHE-1957733		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back	Xolair			S	Subcutaneous			Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

[illegible]

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xolair	S	Subcutaneous						Not Reported
	Atorvastatin	S	Unknown						Not Reported
	Azithromycin Sandoz	S	Unknown						Not Reported
	Montelukast	S	Unknown						Not Reported
	Pantoprazole	S	Unknown						Not Reported
	Fentanyl	S	Unknown						Not Reported
	Ventolin	C	Unknown		Unk				Not Reported
	Advair	C	Unknown		Unk				Not Reported
	Prednisone	C	Unknown		Unk				Not Reported
	Reactine (Canada)	C	Unknown		Unk				Not Reported
	Spiriva	C	Unknown		Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	13965844	NON-EXPEDITED			US-PFIZER INC-2017391366			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ulcer	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14125620	EXPEDITED (15-DAY)		OT	PHHY2017GR155971			Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Diclofenac			S	Transplacental	Maternal Dose: 50 Mg, Every 12 Hours		Novartis	
	Metronidazole			S	Transplacental	Maternal Dose: 1g, Qd		Not Reported	
	Betamethasone			S	Transplacental	Maternal Dose: Two Doses Of 12 Mg With A 24?Hour Interval		Not Reported	
	Azithromycin			S	Transplacental	Unk		Not Reported	
	Atosiban			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14127295	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-153189		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	On Day 36		Sun	
	Meropenem			S	Unknown	Unk		Not Reported	
	Tigecycline			S	Unknown			Not Reported	
	Vancomycin Hydrochloride			S	Unknown			Not Reported	
	Colistin			S	Unknown	On Day 36		Not Reported	
	Rifampicin			S	Unknown			Not Reported	
	Fluconazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14127332	EXPEDITED (15-DAY)		OT	FR-ROCHE-2013186		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Erythema; Headache; Nausea; Pruritus; Urticaria	Rocephine			S	Unknown			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Polygynax (France)			C	Unknown	For 15 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14128912	NON-EXPEDITED			US-PFIZER INC- 2017447901		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Circumstance Or Information Capable Of Leading To Medication Error	Azithromycin			S	Oral	12.5 MI As Single Dose		Pfizer	
	Azithromycin			S		6.5 MI For 4 Days		Pfizer	
	Azithromycin			S				Pfizer	
	Novolog			C				Not Reported	
	Synthroid			C		200 Ug, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Claritin		C			10 Mg, Unk			Not Reported
	Mucinex Dm		C						Not Reported
	Ibuprofen		C			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14128914	NON-EXPEDITED			US-PFIZER INC-2017459006		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased; Nausea	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14129646	EXPEDITED (15-DAY)		OT	US-BAYER-2017-200059		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pathogen Resistance; Product Use In Unapproved Indication	Ciprofloxacin			S		500 Mg, Qd		Bayer	
	Azithromycin			S		250 Mg, Qd		Not Reported	
	Rifabutin			S		300 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2017	14134018	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-013955		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Sinusitis	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S		3 G, Bid		Jazz	
	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Z-Pak			S				Not Reported	
	Norco			C		Unk		Not Reported	
	Azithromycin			C		Unk		Not Reported	
	Fluoxetine Hcl			C		Unk		Not Reported	
	Lamictal			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novolog	C	Unk	Not Reported
Novolog	C	Unk	Not Reported
Marinol /00003301/	C	Unk	Not Reported
Humalog	C	Unk	Not Reported
Maxalt Mlt	C	Unk	Not Reported
Maxalt Mlt	C	Unk	Not Reported
Fiorinal With Codeine	C	Unk	Not Reported
Abilify Maintena	C	Unk	Not Reported
Apidra	C	Unk	Not Reported
Atenolol	C	Unk	Not Reported
Atorvastatin	C		Not Reported
Cymbalta	C	Unk	Not Reported
Ibuprofen /00109205/	C		Not Reported
Klonopin	C		Not Reported
Lexapro	C	Unk	Not Reported
Lorazepam	C	Unk	Not Reported
Lortab /00607101/	C	Unk	Not Reported
Neurontin	C		Not Reported
Promethazine	C		Not Reported
Protonix /00661201/	C	Unk	Not Reported
Provigil /01265601/	C		Not Reported
Tylenol Arthritis	C		Not Reported
Zovia	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14065140	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2017426590		33 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Asthenia; Autonomic Neuropathy; Back Pain; Chest Discomfort; Cold Sweat; Dizziness; Hyperhidrosis;	Zithromac 250mg			S	Oral	500 Mg, Daily		Pfizer
	Adoair			S	Respiratory (inhalation)	Unk		Not Reported
	Rize			S		1 Df, As Needed		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Malaise; Muscular
Weakness; Palpitations;
Peripheral Coldness;
Pollakiuria;
Rhabdomyolysis; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14133832	NON-EXPEDITED			US-PFIZER INC- 2017463869		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Darvocet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14137332	NON-EXPEDITED			US-PFIZER INC- 2017465294			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14137415	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2017459901			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Haematochezia; Vomiting	Zithromac 250mg			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14137599	EXPEDITED (15-DAY)		OT	RU-TEVA-818860ISR		2 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Rheumatoid Arthritis	Sumamed			S		140 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2017	14140599	DIRECT		OT			11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Hypersensitivity; Rash	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14141698	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2017GSK165788			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cardiac Failure; Emphysema	Salbutamol Sulphate			S		Unk, Prn		Glaxosmithkline	
	Flovent Inhaler			S		2 Puff(S), Bid		Glaxosmithkline	
	Azithromycin			S				Not Reported	
	Rabeprazole			S				Glaxosmithkline	
	Inspiolto			C	Respiratory (inhalation)	2 Puff(S), 1d		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14141805	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2017455551		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Erythema; Headache; Nausea; Pruritus; Urticaria	Zithromax			S	Oral	2 Df, Single		Pfizer	
	Rocephin			S		Unk Unk, Single		Not Reported	
	Polygynax			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2017	14145348	DIRECT	Y	HO			88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Irregular;	Azithromycin			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Torsade De Pointes

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	12723804	EXPEDITED (15-DAY)		OT	IE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2016RR-122521		14 YR	Male	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Drug Resistance; Myalgia	Meropenem			S	Intravenous (not otherwise specified)	40 Mg Per Kg Per Dose [To A Maximum Of 2 G Per Dose]		Not Reported	
	Tobramycin			S	Unknown	300 Mg, Bid		Not Reported	
	Colistin			S	Unknown	Two Mega-Units Twice Daily		Not Reported	
	Aztreonam			S	Unknown	75 Mg, Tid		Not Reported	
	Azithromycin			S	Oral	250 Mg, Daily		Sun	
	Ceftazidime			C	Intravenous (not otherwise specified)	50 Mg/Kg, Tid		Not Reported	
	Ciprofloxacin			C	Oral	15 Mg/Kg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	13982850	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2017GSK143774			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Chest Discomfort; Drug Ineffective; Malaise; Product Complaint; Wheezing	Advair Diskus Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Azithromycin			S				Glaxosmithkline	
	Lipitor			C				Not Reported	
	Plavix			C				Not Reported	
	Prednisone			C				Not Reported	
	Verapamil			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2017	14015186	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-40791		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Nausea; Optic Neuritis; Visual Impairment; Weight Decreased	Azithromycin			S				Aurobindo	
	Moxifloxacin			S				Aurobindo	
	Ethambutol			S				Not Reported	
	Tacrolimus			C				Not Reported	
	Prednisone			C				Not Reported	
	Atorvastatin			C		At Night		Not Reported	
	Filgrastim			C	Subcutaneous			Not Reported	
	Pentamidine			C	Respiratory (inhalation)			Not Reported	
	Rifampin			C				Not Reported	
	Levemir			C	Subcutaneous	Every Morning		Not Reported	
	Insulin Aspart			C	Subcutaneous	With Meals		Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2017	13720497	EXPEDITED (15-DAY)		HO, LT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-144362		20 YR	Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Posterior Reversible Encephalopathy Syndrome	Aciclovir			S	Unknown			Sun	
	Azithromycin			S	Unknown			Sun	
	Tacrolimus			S	Unknown			Not Reported	
	Posaconazole			S	Unknown			Not Reported	
	Vancomycin			C	Unknown			Not Reported	
	Vancomycin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	13611323	NON-EXPEDITED			US-PFIZER INC-2017241582		83 YR	Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Heparin Sodium			S		Unk		Unknown
	Hydroxyzine Pamoate			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Cardizem			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Motrin			S		Unk		Not Reported
	Potassium			S		Unk		Not Reported
	Hctz			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Hydralazine			S		Unk		Not Reported
	Sulfur			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2017	14154292	EXPEDITED (15-DAY)		HO, OT	GR-PFIZER INC-2017464239			Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intestinal Perforation; Maternal Exposure During Pregnancy; Necrotising Enterocolitis Neonatal	Azithromycin			S	Transplacental	Unk		Pfizer
	Atosiban			S	Transplacental	Unk		Not Reported
	Diclofenac			S	Transplacental	50 Mg, Every 12 Hours		Not Reported
	Metronidazole			S	Transplacental	1 G, Daily		Not Reported
	Betamethasone			S	Transplacental	24 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2017	13720240	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2017-36388		27 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tongue Oedema	Azithromycin 500mg Film-Coated Tablet			S	Oral	1 Df, Daily		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155884	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2016569522		61 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Haematuria; Renal Cyst; Renal Disorder; Transitional Cell Carcinoma Urethra	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Novatrex			S	Oral	7.5 Mg, Weekly		Pfizer	
	Folic Acid			S	Oral	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14155985	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017474273		35 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Oculomucocutaneous Syndrome	Zithromac 250mg			S	Oral	Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156369	NON-EXPEDITED			US-PFIZER INC-2017473327		50 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S				Pfizer	
	Keflex			S				Not Reported	
	Dilaudid			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Nov-2017	14156407	NON-EXPEDITED			US-PFIZER INC-2017472525			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	14159668	NON-EXPEDITED			US-PFIZER INC-2017475616			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swelling	Zithromax			S		Unk		Pfizer	
	Effexor			S		Unk		Pfizer	
	Wellbutrin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	14162278	NON-EXPEDITED			US-PFIZER INC-2017477854			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2017	14162928	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017471514		69 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epilepsy	Zithromac Sr 2g			S	Oral	2 G, Daily		Pfizer	
	Phenobal			C				Not Reported	
	Depakene			C				Not Reported	
	Thyradin			C				Not Reported	
	Talion (Bepotastine Besylate)			C				Not Reported	
	Xarelto			C				Not Reported	
	Spirolactone			C				Not Reported	
	Dogmatyl			C				Not Reported	
	Pyrethia			C				Not Reported	
	Rabeprazole			C				Not Reported	
	Gaslon			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	13907074	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017361629		74 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Atrioventricular Block; Myalgia	Zithromax			S		2 Pills On The First Day		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Zocor			C		20 Mg, Unk		Not Reported	
	Glucophage			C		500 Mg, 2x/Day		Not Reported	
	Valsartan			C		20 Mg, Unk		Not Reported	
	Prilosec			C		40 Mg, Unk		Not Reported	
	Amlodipine			C		10 Mg, Unk		Not Reported	
	Viagra			C		50 Mg, As Needed (On Occasion)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14163934	NON-EXPEDITED			US-TEVA-759761ACC			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Interaction; Nausea; Vomiting	Methylprednisolone			S				Actavis	
	Zpak			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14165200	EXPEDITED (15-DAY)		OT	PHHY2017US161272			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Product Use In Unapproved Indication	Clofazimine			S	Unknown			Not Reported	
	Moxifloxacin			S	Unknown			Not Reported	
	Voriconazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14166583	NON-EXPEDITED			US-PFIZER INC-2017477565		79 YR	Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin Hcl			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14166860	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017473510		53 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Chills; Cyanosis; Dyspnoea; Heart Rate Increased; Hyperpyrexia; Oxygen Saturation Decreased; Seizure; Tachypnoea	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	A Le Xin			S	Intravenous drip	6 G, 2x/Day		Not Reported	
	Ambroxol Hydrochloride			S	Intravenous drip	45 Mg, 2x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2017	14166869	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017470184			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking	Zithromac Sr 2g			S	Oral			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2017	14169520	NON-EXPEDITED			US-PFIZER INC-2017475795			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	13939572	NON-EXPEDITED			US-PFIZER INC-2017382680			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity; Urticaria		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2017	14174955	EXPEDITED (15-DAY)		OT	US-TEVA-824446USA		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported	
	Azithromycin			S	Unknown	1000 Milligram Daily;		Not Reported	
	Rituximab			S	Unknown	Weekly		Not Reported	
	Atovaquone			S	Unknown			Not Reported	
	Atovaquone			S	Unknown	1750 Milligram Daily;		Not Reported	
	Immune Globulin Nos			C	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			C	Unknown	Weekly		Not Reported	
	Proguanil			C	Unknown	400 Milligram Daily;		Not Reported	
	Doxycycline			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2017	14180004	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2017477865		80 YR	Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Chills; Hypoaesthesia; Malaise; Nausea	Zithromac 250mg			S	Oral	500 Mg, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2017	14178722	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US19722			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Ineffective;	Tacrolimus			S	Unknown	Unk		Cipla	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metastases To Lung; Metastatic Squamous Cell Carcinoma; Pneumonitis; Pruritus	Mycophenolate Mofetil	S	Unknown	Unk	Cipla
	Fluorouracil	S	Topical	Unk	Not Reported
	Capecitabine	S	Unknown	Unk	Not Reported
	Erlotinib	S	Unknown	Unk	Cipla
	Azithromycin	S	Unknown	Unk	Cipla
	Levofloxacin	S	Unknown	Unk	Cipla
	Thymoglobulin	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	5 Mg, Daily	Not Reported
	Prednisone	S	Unknown	High Dose, Unk	Not Reported
	Sirolimus	S	Unknown	Unk	Not Reported
	Cetuximab	S	Unknown	Unk	Not Reported
	Cetuximab	S			Not Reported
	Interferon	S	Unknown	Unk	Not Reported
	Palbociclib	S	Unknown	Unk	Not Reported
	Nivolumab	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2017	14180623	EXPEDITED (15-DAY)		HO	HR-TEVA-824682ROM		69 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Choking; Cough; Rash; Swelling	Sumamed			S	Oral	500 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2017	14181152	EXPEDITED (15-DAY)		OT	US-TEVA-825444ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea Haemorrhagic; Extra Dose Administered; Muscle Spasms; Nausea; Vertigo	Azithromycin			S		65-150		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14182493	NON-EXPEDITED			US-PFIZER INC-2017484200			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance	Pneumococcal 13-Val Conj Vac (Dipht Crm197 Protein)			S		Single Dose		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Metformin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14182546	NON-EXPEDITED			US-PFIZER INC-2017483884		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S				Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Esomeprazole Magnesium			S				Unknown	
	Nalidixic Acid			S		Unk		Not Reported	
	Rabeprazole			S		Unk		Not Reported	
	Montelukast			S		Unk		Not Reported	
	Zegerid			S		Unk		Not Reported	
	Nitrofurantoin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14183591	EXPEDITED (15-DAY)		HO, OT	KZ-TEVA-824797ISR		4 YR	Unknown	KAZ
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhagic Vasculitis; Product Administered To Patient Of Inappropriate Age	Sumamed			S	Oral	250 Milligram Daily; 2 Tablets (Per 125 Mg) Once A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2017	14185614	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2017US19845			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukocytosis; Pyrexia; Respiratory Distress; Septic Shock	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Tigecycline			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14185652	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.- 2017US19846			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Death; Drug Ineffective	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Tigecycline			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14185669	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.- 2017US19849			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Death; Drug Ineffective; Electrocardiogram Qt Prolonged; Multiple Organ Dysfunction Syndrome	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Tigecycline			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14186436	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.- 2017US19847			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Levofloxacin			S	Unknown	Unk		Cipla	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pyrexia; White Blood Cell Count Decreased	Azithromycin	S	Unknown	Unk				Cipla
	Tigecycline	S	Unknown	Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14186437	EXPEDITED (15-DAY)		HO	US-CIPLA LTD.-2017US19848			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; White Blood Cell Count Decreased	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Tigecycline			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14186630	EXPEDITED (15-DAY)		DE, HO	US-CIPLA LTD.-2017US19844			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Death; Drug Ineffective; Septic Shock	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Cipla	
	Tigecycline			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2017	14187001	NON-EXPEDITED			US-PFIZER INC-2017484128		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Arthrotec			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2017	14193456	NON-EXPEDITED			US-BAUSCH-BL-2016-031596		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Agitation; Dyskinesia; Fatigue; Off Label Use	Xenazine	S	Oral		Not Reported
	Xenazine	S	Oral		Not Reported
	Rifampin	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2017	14194389	DIRECT		OT				Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematuria	Azithromycin 500 Mg			S	Oral	Quantity:5 Tablet(S);		Unknown
	Crestor			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	12887375	NON-EXPEDITED			US-PFIZER INC- 2016495762			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Rifampin			S		Unk		Not Reported
	Levaquin			S		750 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14068065	EXPEDITED (15-DAY)		OT	JP-ROCHE-1991698		32 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Eosinophilia; Hepatic Function Abnormal; Hypersensitivity; Nasal Congestion; Pyrexia	Rocephin			S	Intravenous drip			Not Reported
	Voltaren			S	Oral			Not Reported
	Zithromac			S	Oral			Not Reported
	Calonal			S	Oral			Not Reported
	Onon			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mucodyne			C		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14196153	NON-EXPEDITED			US-PFIZER INC-2017492855			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Medrol			S		Unk		Pfizer	
	Skelaxin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2017	14196160	NON-EXPEDITED			US-PFIZER INC-2017492920			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
	Toradol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14198761	NON-EXPEDITED			US-PFIZER INC-2017490115			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Limb Discomfort; Nausea; Pain; Pain	Zithromax			S	Intravenous drip	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14198778	NON-EXPEDITED			US-PFIZER INC-2017490342			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14199346	NON-EXPEDITED			US-ASTRAZENECA-2017SF15843		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Esomeprazole Magnesium			S	Oral	Unknown Dose		Astrazeneca	
	Nalidixic Acid			S	Unknown	Unknown Dose		Not Reported	
	Azithromycin			S	Unknown	Unknown Dose		Not Reported	
	Ciprofloxacin			S	Unknown	Unknown Dose		Not Reported	
	Rabeprazole			S	Unknown	Unknown Dose		Not Reported	
	Montelukast			S	Unknown	Unknown Dose		Not Reported	
	Zegerid			S	Unknown	Unknown Dose		Not Reported	
	Nitrofurantoin			S	Unknown	Unknown Dose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2017	14200076	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00003945		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Toxicity To Various Agents	Oxycodone			S		Inhalation And Ingestion		Unknown	
	Cyclobenzaprine Hydrochloride			S		Inhalation And Ingestion		Unknown	
	Metoprolol			S		Inhalation And Ingestion		Unknown	
	Clonidine			S		Inhalation And Ingestion		Unknown	
	Glyceryl Trinitrate			S		Inhalation And Ingestion		Unknown	
	Lisinopril			S	Oral	Inhalation And Ingestion		Unknown	
	Escitalopram Oxalate			S		Inhalation And Ingestion		Unknown	
	Ibuprofen			S	Oral	Inhalation And Ingestion		Unknown	
	Diclofenac			S		Inhalation And Ingestion		Unknown	
	Azithromycin			S		Inhalation And Ingestion		Unknown	
	Cefalexin			S		Inhalation And Ingestion		Unknown	
	Doxycycline			S		Inhalation And Ingestion		Unknown	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methylprednisolone			S		Inhalation And Ingestion			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2017	14204987	DIRECT		HO, OT			69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident	Azithromycin Tablets Usp 250mg			S	Oral	Quantity:2 Tablet(S);Other Frequency:2 Tab To Start,;		Teva	
	Estrodial			C				Not Reported	
	Zoloft Generic			C				Not Reported	
	Senior Adult Multi Vitamin			C				Not Reported	
	Coq10			C				Not Reported	
	Vitamins B12 And D			C				Not Reported	
	Stool Softener			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	12689111	EXPEDITED (15-DAY)		OT	JP-009507513-1308JPN007810		58 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Renal Impairment	Isentress Tablets 400mg			S	Oral	800 Mg, Unk		Merck	
	Epivir			S	Oral	Unk		Not Reported	
	Epivir			S	Oral	150 Mg, Unk		Not Reported	
	Epzicom			S	Oral	1 Df, Unk		Not Reported	
	Ziagen			S	Oral	300 Mg, Bid		Not Reported	
	Valixa			S	Oral	450 Mg, Qd		Not Reported	
	Baktar			S	Oral	1 Df, Bid		Not Reported	
	Benambax			S	Unknown	300 Mg, Qm		Not Reported	
	Zithromac			S	Unknown	1200 Mg, Qw		Not Reported	
	Tivicay			S	Oral	50 Mg, Unk		Not Reported	
	Clarith			C	Unknown	400 Mg, Bid		Not Reported	
	Takepron			C	Unknown	15 Mg, Qd		Not Reported	
	Allelock			C	Oral	5 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	14194455	NON-EXPEDITED			US-PFIZER INC-2017494767		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swelling; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	14203865	NON-EXPEDITED			US-PFIZER INC-2017495810			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ampicillin Sodium			S		Unk		Unknown	
	Phenoxymethylpenicillin			S		Unk		Pfizer	
	Potassium Percodan			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2017	14205475	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017493563		82 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Purpura	Novatrex			S	Oral	2.5 Mg, Weekly		Pfizer	
	Kardegic			C		Unk		Not Reported	
	Diffu K			C		Unk		Not Reported	
	Uvedose			C		Unk		Not Reported	
	Cacit Vitamine D3			C		Unk		Not Reported	
	Actonel			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	12655803	NON-EXPEDITED			US-PFIZER INC-2016267297		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	14207123	EXPEDITED (15-DAY)		HO	AU-BAXTER-2017BAX036989		15 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Function Test Increased; Pyrexia; Rash	Baxter Water For Injections 1000ml Injection Bp Bag Ahb0304			S	Intravenous (not otherwise specified)	Compounded With Cefoxitin		Baxter	
	Baxter Water For Injections 1000ml Injection Bp Bag Ahb0304			S	Intravenous (not otherwise specified)	Compounded With Cefoxitin		Baxter	
	Cefoxitin			S	Intravenous (not otherwise specified)	Frequency: Qds		Not Reported	
	Cefoxitin			S	Intravenous (not otherwise specified)	Tds, Compounded With Water For Injection		Not Reported	
	Cefoxitin			S	Intravenous (not otherwise specified)	Compounded With Water For Injection		Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Clofazimine			S	Oral			Not Reported	
	Vitabdeck			C	Oral	2 Tablets Daily, On Long Term Use		Not Reported	
	Creon			C	Oral	Creon 10000, Varies (Discrepantly Reported As Various) With Food, Long Term Use		Not Reported	
	Seretide			C	Respiratory	Dose: 2 Puffs, On Long		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nasonex	C	(inhalation) Nasal	Term Use On Long Term Use, Intranasal	Not Reported
Pulmozyme	C	Respiratory (inhalation)	On Long Term Use	Not Reported
Hypertonic Saline	C	Respiratory (inhalation)	Bd, On Long Term Use	Not Reported
Salt	C	Oral	Tablets, Daily In The Afternoon, On Long Term Use	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	14209807	NON-EXPEDITED			US-PFIZER INC- 2017499499			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	14210726	NON-EXPEDITED			US-AKORN-68487			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pain	Azasite 1% Ophthalmic Solution			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2017	14211319	NON-EXPEDITED		HO	US-AKORN-73343		71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation; Eye Irritation; Ocular Hyperaemia	Azasite (Azithromycin Ophthalmic Solution)			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Nov-2017	14211354	NON-EXPEDITED			US-AKORN-73309			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Swelling; Ocular Hyperaemia; Vision Blurred	Azasite			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	11361083	NON-EXPEDITED		OT	US-PFIZER INC-2015259792		19 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Stevens-Johnson Syndrome	Zithromax			S	Oral	Unk, As Directed		Pfizer	
	Azithromycin			S	Oral	Unk, As Directed		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	13763947	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017302041		41 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea	Zitromax			S	Oral	1 Df, Total		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2017	14213249	EXPEDITED (15-DAY)		HO	CO-PFIZER INC-2017496767			Female	COL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Lower; Chills; Dysuria; Tachycardia; Vaginal Haemorrhage; Vaginal Ulceration	Zitromax			S	Oral	Unk		Pfizer	
	Zitromax			S				Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14214364	NON-EXPEDITED			US-PFIZER INC-2017495423			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14214434	NON-EXPEDITED			US-PFIZER INC-2017499485			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gemfibrozil			S		Unk		Pfizer	
	Omnicef			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14215736	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171125535			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14215762	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171125555			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14215772	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171125545			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown	Unknown Dose		Not Reported	
	Cetirizine Hydrochloride			S	Unknown	Unknown Dose		Not Reported	
	Azithromycin			S	Unknown	Unknown Dose		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14215928	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171125565			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14215980	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171125603			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14216276	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171126432			Unknown	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cetirizine Hydrochloride	S	Unknown	Not Reported
Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14216307	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171126433			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2017	14216308	EXPEDITED (15-DAY)		OT	IN-JNJFOC-20171126434			Unknown	IND

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Off Label Use	Cetirizine Hydrochloride		Y	S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	14121462	NON-EXPEDITED			US-PFIZER INC-2017458719			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	14213693	NON-EXPEDITED		OT	US-APOTEX-2017AP021857		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dermatitis Bullous; Hypersensitivity		Azithromycin		S	Unknown	Unk	Apotex		
		Penicillin /00000901/		S	Unknown	Unk	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2017	14217614	NON-EXPEDITED			US-PFIZER INC- 2017497050			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Vomiting	Zithromax			S		Unk		Pfizer	
	Cipro			S		20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2017	14221235	NON-EXPEDITED			US-PFIZER INC- 2017505474		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2017	14221544	EXPEDITED (15-DAY)		OT	PHHY2017US173210			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Prochlorperazine			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Quizartinib			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	6937650	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2009177895		48 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic	Azithromycin			S		Unk(First Dose)		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Symptoms; Hypersensitivity Myocarditis	Azithromycin		S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14133970	NON-EXPEDITED			US-PFIZER INC- 2017464935			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash; Vomiting	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14224782	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-06793		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous	Azithromycin			S	Unknown	Unk		Lupin	
	Penicillin /00000901/			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14225299	NON-EXPEDITED			US-PFIZER INC- 2017504055			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14225391	NON-EXPEDITED			US-PFIZER INC- 2017505429		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Demerol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abraxane			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14225904	EXPEDITED (15-DAY)		OT	US-TEVA-2017-US-827032			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Haemorrhage; Hepatic Function Abnormal; Hypersensitivity; Lung Disorder; Rash; Renal Failure; Tongue Discolouration	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2017	14226478	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2017501481		8 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Ototoxicity; Pyrexia; Weight Decreased	Amikacin Sulfate			S		Unk			Unknown
	Azithromycin			S		Unk			Pfizer
	Minocycline Hcl			S		Unk			Unknown
	Moxifloxacin			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	13645986	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-35168		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Resistance; Treatment Failure	Azithromycin 500 Mg			S	Unknown	500 Mg, Daily			Aurobindo
	Atovaquone			S	Unknown	750 Mg, Two Times A Day			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	14017419	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2017GSK148723		82 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Back Pain; Bronchospasm; Chapped Lips; Cough; Erythema; Feeding Disorder; Glossodynia; Hypersensitivity; Hypotension; Insomnia; Malaise; Product Use In Unapproved Indication; Productive Cough; Pruritus; Purpura; Rash; Rash Pruritic; Speech Disorder; Stomatitis; Swollen Tongue; Tongue Biting; Tongue Discolouration; Tongue Disorder; Tongue Eruption; Tongue Erythema; Urticaria; White Blood Cell Count Increased	Ventolin Hfa Inhalation Powder			S	Respiratory (inhalation)	2 Puff(S), 6d		Glaxosmithkline
	Prevacid			S				Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Albuterol Nebulizer			C				Not Reported
	Prednisone			C				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14227100	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2017504228			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Haematochezia; Haemorrhage	Zithromac 250mg			S	Oral	1000 Mg, 1x/Day		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Nov-2017	14229351	NON-EXPEDITED			US-PFIZER INC- 2017510763		73 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Peripheral Swelling; Rash;	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Urticaria

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	14232165	NON-EXPEDITED			US-PFIZER INC-2017509095			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Augmentin			S		Unk		Not Reported	
	Clonazepam			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Zestril			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2017	14232400	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2017M1074271		26 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Paracetamol			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Tranexamic Acid			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2017	14235785	NON-EXPEDITED		OT	US-AMGEN-USASP2017176648		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Congestive; Transaminases Increased	Enbrel			S	Unknown	Unk		Amgen	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Aza (Azithromycin Dihydrate)			S	Unknown	Unk		Not Reported	
	Remicade			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz			C		Oral		5 Mg, Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-Nov-2017	14236513	NON-EXPEDITED			US-PFIZER INC-2017510986			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Nov-2017	12919710	NON-EXPEDITED			US-PFIZER INC-2016514679			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Pruritus; Swelling	Zithromax			S		Unk		Pfizer		
	Biaxin			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
01-Dec-2017	14243765	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2017508116		62 YR	Female	AUT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Blood Pressure Increased; Blood Pressure Increased; Dizziness; Ear Discomfort; Feeling Of Body Temperature Change; Paraesthesia; Product Use In Unapproved Indication; Restlessness; Swollen Tongue; Tendon Pain; Tension Headache; Tongue Erythema	Azithromycin			S		Unk		Pfizer		
	Concor			C		0.5 Df, 1x/Day (1/2-0-0)		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
02-Dec-2017	13967065	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-		56 YR	Male	USA	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2017US-149805

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Electrocardiogram Qt Prolonged	Quinidine			S	Unknown	Unk		Mutual
	Azithromycin			S	Intravenous (not otherwise specified)	1000 Mg, Daily		Sun
	Doxycycline			S	Oral	100 Mg, Bid		Sun
	Doxycycline			S				Sun
	Atovaquone			S	Oral	750 Mg, Daily		Not Reported
	Atovaquone			S	Unknown	750 Mg, Bid		Not Reported
	Atovaquone			S		Unk		Not Reported
	Clindamycin			S	Intravenous (not otherwise specified)	600 Mg, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	13752833	NON-EXPEDITED			US-PFIZER INC- 2017300790		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ciprofloxacin Hcl			S		Unk		Unknown
	Flagyl			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14056124	EXPEDITED (15-DAY)		HO, LT, OT	PHHO2017US013497		13 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Acidosis; Acute Kidney Injury; Back Pain; Cytokine Release Syndrome; Cytokine	Kymriah			S	Intravenous (not otherwise specified)	0.9084x10^8 Transduced Viable T Cells (Total Dose 0.3 X 10^9 Total Viable Cells)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Release Syndrome; Cytokine Release Syndrome; Delirium; Disseminated	Olanzapine	S	Oral	2.5 Mg, Q12h	Novartis
Intravascular Coagulation; Ecchymosis; Febrile Neutropenia; Febrile Neutropenia; Febrile Neutropenia; Hypotension; Pancytopenia; Physical Deconditioning; Pulmonary Oedema; Respiratory Failure; Seizure; Tumour Lysis Syndrome; Ventricular Tachycardia	Azithromycin	S	Intravenous (not otherwise specified)	1200 Mg, Q12h	Not Reported
	Keppra	S	Unknown		Not Reported
	Dexmedetomidine	S	Unknown		Not Reported
	Hydromorphone	S	Unknown		Not Reported
	Precedex	S	Unknown		Not Reported
	Fentanyl	S	Unknown		Not Reported
	Zofran	S	Oral	4 Mg, Q8h, Prn	Not Reported
	Epinephrine	S	Intravenous (not otherwise specified)	0-0.1 Mcg/Kg/Min	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14246130	EXPEDITED (15-DAY)		OT	AT-MYLANLABS- 2017M1075067		62 YR	Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Blood Pressure Increased; Chills; Dizziness; Ear Discomfort; Paraesthesia; Restlessness; Swollen Tongue; Tendon Pain; Tension Headache	Azithromycin			S		Unk		Not Reported
	Concor			C		1/2-0-0		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14246718	NON-EXPEDITED			US-PFIZER INC- 2017514458			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Pruritus	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14246915	NON-EXPEDITED			US-PFIZER INC-2017516950			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Calan Sr			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14249216	EXPEDITED (15-DAY)		OT	PHHY2017AT174400		62 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Blood Pressure Increased; Chills; Dizziness; Ear Discomfort; Paraesthesia; Restlessness; Swollen Tongue; Tendon Pain; Tension Headache	Azithromycin			S	Unknown			Novartis	
	Concor			C	Unknown	0.5 Df, Qd (1/2-0-0)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2017	14249499	NON-EXPEDITED			US-AMGEN-USASP2017178823			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nonspecific Reaction	Enbrel			S	Unknown	Unk		Amgen	
	Mtx			S	Unknown	Unk		Not Reported	
	Effexor			S	Unknown	Unk		Not Reported	
	Advil			S	Unknown	Unk		Not Reported	
	Zithromax			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine			S	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	13042262	EXPEDITED (15-DAY)		OT	US-JNJFOC-20161212022			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dislocation Of Vertebra; Drug Dependence; Drug Ineffective For Unapproved Indication; Erythema; Lymphoedema; Off Label Use; Overdose; Product Prescribing Error; Product Use In Unapproved Indication; Skin Fissures	Levaquin			S	Oral	3 Tablets Of 500 Mg		Not Reported	
	Levaquin			S	Oral			Not Reported	
	Levaquin			S	Oral	Dose: 250 Mg And 500 Mg		Not Reported	
	Levaquin			S	Oral			Not Reported	
	Azithromycin			S	Unknown	For 3 Days		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	3 Of 500 Mg Up To 40 Days		Not Reported	
	Tetracycline			S	Unknown			Not Reported	
	Doxycycline			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14241128	NON-EXPEDITED			US-PFIZER INC-2017512167		86 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amlodipine Besilate			S				Pfizer	
	Zithromax			S				Pfizer	
	Lisinopril			S				Not Reported	
	Septra			S				Pfizer	
	Eliquis			S		Unk		Not Reported	
	Propafenone			S				Not Reported	
	Entresto			S				Not Reported	
	Sulfadiazine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14250525	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2017-44140		48 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Oral	1 Df In Total		Aurobindo	
	Omeprazole			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2017	14252560	EXPEDITED (15-DAY)		OT	AT-TEVA-2017-AT-828762		62 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Blood Pressure Increased; Chills; Dizziness; Ear Discomfort; Paraesthesia; Restlessness; Swollen Tongue; Tendon Pain; Tension Headache	Azithromycin			S		1/2-0-0		Not Reported	
	Concor 5 Mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2017	14255256	EXPEDITED (15-DAY)		DE	US-TORRENT-00004586		15 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Completed Suicide; Toxicity To Various Agents	Amlodipine			S	Oral			Unknown	
	Clonazepam			S	Oral			Unknown	
	Tadalafil			S	Oral			Unknown	
	Acetaminophen W/Diphenhydramine Hydrochloride			S	Oral			Unknown	
	Azithromycin			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	11861010	NON-EXPEDITED			US-PFIZER INC-2015427384			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Urticaria	Azithromycin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14240614	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2017506564		70 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Overdose;	Novatrex			S		5 Mg, Weekly		Pfizer
Agranulocytosis;	Novatrex			S		4 Df, Daily (Were Found In The Patient'S Pill Organizer)		Pfizer
Stomatitis	Tahor			C		10 Mg, 1x/Day		Not Reported
	Atenolol			C		50 Mg, 1x/Day		Not Reported
	Axeler			C		1 Df, 1x/Day		Not Reported
	Kaleorid Lp			C		600 Mg, 3x/Day		Not Reported
	Hepsera			C		10 Mg, Alternate Day		Not Reported
	Zeffix			C		100 Mg, 1x/Day		Not Reported
	Speciafoldine			C		5 Mg, 1x/Day		Not Reported
	Clobex /00337102/			C		1 Df, Weekly		Not Reported
	Diclofenac			C		Unk Unk, As Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2017	14258317	EXPEDITED (15-DAY)		DE, HO, OT	US-APOTEX- 2017AP022520		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy;	Azithromycin			S	Unknown	Unk		Apotex
Hypotension; Respiratory	Ceftriaxone For Injection, Usp			S	Unknown	Unk		Apotex
Failure; Respiratory	Piperacillin And Tazobactam For			S	Unknown	Unk		Hospira
Failure; Respiratory	Injection							
Failure	Vancomycin			S	Unknown	Unk		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14205505	NON-EXPEDITED			US-PFIZER INC-2017494453			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Reaction To Excipient	Azithromycin			S		250 Mg, Unk		Pfizer	
	Tylenol			S		Unk		Not Reported	
	Gluten			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14261341	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP022143		23 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Sinus Tachycardia	Azithromycin For Injection			S	Intravenous (not otherwise specified)	500 Mg, Qd		Apotex	
	Acetaminophen			C	Unknown	Unk		Not Reported	
	Ciprofloxacin			C	Unknown	Unk		Not Reported	
	Cyanocobalamin			C	Unknown	Unk		Not Reported	
	Dimenhydrinate			C	Unknown	Unk		Not Reported	
	Echinacea /01323501/			C	Unknown	Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
	Ibuprofen			C	Unknown	Unk		Not Reported	
	Oseltamivir			C	Unknown	Unk		Not Reported	
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14262542	NON-EXPEDITED			US-PFIZER INC-2017487513			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Administration Error;	Azithromycin			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Storage Error

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14263144	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-07033		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Failure To Thrive; Mycobacterium Abscessus Infection; Weight Decreased	Ethambutol			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14264183	EXPEDITED (15-DAY)		OT	PHHY2017TW180587		29 YR	Male	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Pain In Extremity; Progressive Multifocal	Levofloxacin			S	Unknown			Novartis	
	Clarithromycin			S	Unknown			Not Reported	
Leukoencephalopathy; Seizure; Speech Disorder; Vision Blurred	Rifabutin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Nevirapine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2017	14267237	DIRECT	Y	HO			14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Zithromax Z-Pak			S			1 DAY	Not Reported	
	Brompheniramine- Pseudoephedrine			C				Not Reported	
	Motrin			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	12101071	NON-EXPEDITED			US-PFIZER INC-2015380183			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14143260	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017434305		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Enbrel			S	Unknown	50 Mg, Qwk		Pfizer	
Asthenia; Bradyphrenia;	Enbrel			S	Unknown	50 Mg, Weekly		Pfizer	
Chronic Kidney Disease;	Enbrel			S	Unknown	50 Mg, Qwk		Unknown	
Chronic Obstructive	Zithromax			S	Unknown	Unk		Pfizer	
Pulmonary Disease;	Azulfidine			S	Oral	500 Mg, Qd		Pfizer	
Contusion; Decreased	Azulfidine			S	Oral	500 Mg, Bid		Pfizer	
Appetite; Drug	Amoxicillin			S	Unknown	Unk		Not Reported	
Hypersensitivity; Fatigue;	Percocet			S	Unknown	Unk		Not Reported	
Frustration Tolerance	Welchol			S	Unknown	Unk		Not Reported	
Decreased; Full Blood	Baclofen			S	Unknown	Unk		Not Reported	
Count Decreased;	Fosamax			S	Unknown	Unk		Not Reported	
Hypoaesthesia; Joint	Celebrex			C	Oral	200 Mg, Bid		Not Reported	
Injury; Liposarcoma;	Hcq			C		100 Mg, Unk		Not Reported	
Lumbar Spinal Stenosis;	Hcq			C		200 Mg, Unk		Not Reported	
Mobility Decreased;	Orencia			C	Subcutaneous	125 Mg/MI, Qwk		Not Reported	
Nausea; Nerve Injury;	Albuterol Sulfate And			C	Nasal	Unk (0.5-2.5 Mg/MI)		Not Reported	
Neuropathy Peripheral;	Ipratropium Bromide								
Osteochondrosis;									
Paraesthesia; Peroneal									
Nerve Injury; Pneumonia;									
Post Procedural									
Complication; Pruritus;									
Rheumatoid Arthritis;									
Sciatica; Skin Papilloma;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Soft Tissue Sarcoma; Spinal Fracture; Spinal Osteoarthritis; Swelling; Thoracic Vertebral Fracture; Wheezing; Wrong Technique In Product Usage Process	Xanax	C	Oral	2 Mg, Unk (4 Times Daily)	Not Reported
	Norvasc	C	Oral	2.5 Mg, Qd	Not Reported
	Symbicort	C	Nasal	Unk Unk, Bid (160-4.5 Mcg/Act Inhaler)	Not Reported
	Wellbutrin	C	Oral	150 Mg, Bid	Not Reported
	Cholecalciferol	C	Oral	1000 Unit, Qd	Not Reported
	Colace	C	Oral	100 Mg, Bid	Not Reported
	Allegra D 24 Hour	C	Oral	Unk Unk, Qd (180-240 Mg)	Not Reported
	Flonase	C	Nasal	50 Mug, Qd	Not Reported
	Lasix	C	Oral	20 Mg, Qd	Not Reported
	Norco	C	Oral	Unk Unk, Q4h (10-325 Mg) As Needed	Not Reported
	Nexium	C	Oral	40 Mg, Qd	Not Reported
	Mycostatin	C	Oral	Unk Unk, Q4h (100000 MI/Unit Take 5 MI)	Not Reported
	Singulair	C	Oral	10 Mg, Unk (Nightly)	Not Reported
	Vitamin D3	C		Unk	Not Reported
	Caltrate	C		Unk Unk, Qd	Not Reported
	Caltrate	C		Unk (Per Three Day)	Not Reported
	Reclast	C	Unknown	Unk	Not Reported
	Ambien	C	Oral	10 Mg, Unk (Nightly As Needed)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14244008	EXPEDITED (15-DAY)		HO, OT	US-SA-2017SA236247		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Failure To Thrive;	Azithromycin			S	Unknown			Not Reported
Mycobacterium Abscessus	Ethambutol			S	Unknown			Not Reported
Infection; Respiratory	Rifampicin			S	Unknown			Not Reported
Failure; Superinfection;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14266967	NON-EXPEDITED			ES-LUPIN PHARMACEUTICALS INC.-2017-05043		1 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Decreased	Azithromycin			S	Unknown	Unk		Lupin	
	Sirolimus			S	Unknown	0.8 Mg/M2, Every 12 Hrs		Not Reported	
	Sirolimus			S	Unknown	0.4 Mg/M2, Every 12 Hrs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14266978	NON-EXPEDITED			IN-LUPIN PHARMACEUTICALS INC.-2017-06463		73 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia	Aziswift Film C. Tabs 500 Mg			S	Oral	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14266979	NON-EXPEDITED			ES-LUPIN PHARMACEUTICALS INC.-2017-05659		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blepharitis Allergic	Azithromycin			S	Topical	Unk		Lupin	
	Tropicamide			S	Topical	Unk		Not Reported	
	Povidone Iodine			S	Topical	Unk		Not Reported	
	Vigamox			C	Topical	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14266994	EXPEDITED (15-DAY)		CA, DS, HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-156685		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dermatitis Bullous; Drug Eruption; Leukaemic Infiltration		Azithromycin		S		Unknown		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14267115	NON-EXPEDITED			US-PFIZER INC-2017524627		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2017	14271361	NON-EXPEDITED			US-PFIZER INC-2017527938		2 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S		9.2 MI For First Dose, Then 2.3ml Once Daily For 4 Days		Pfizer	
	Azithromycin			S		9.2 MI For First Dose, Then 2.3ml Once Daily For 4 Days		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14272081	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2017-45057		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Drug Eruption; Leukaemic Infiltration	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14276174	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2017529950		82 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hypotension; Rash; Stridor		Azithromycin		S	Intravenous (not otherwise specified)		500 Mg / 24h		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14277486	EXPEDITED (15-DAY)		DE	PHHY2017US177936			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby Death	Ceftriaxone			S	Transplacental			Novartis	
	Azithromycin			S	Transplacental			Not Reported	
	Zosyn			S	Transplacental			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14278063	NON-EXPEDITED			US-PFIZER INC-2017527647		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Macrodantin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14278494	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1076886		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14278790	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1076911		17 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Haematuria; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14278800	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2017M1076908		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2017	14279956	EXPEDITED (15-DAY)		OT	PHHY2017US177950		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Zosyn			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	11229096	NON-EXPEDITED			US-PFIZER INC-2015213308			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Doxepin Hcl			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Hydroxyzine Pamoate			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Skelaxin	S	Unk	Pfizer
Fentanyl Citrate	S	Unk	Unknown
Celebrex	S	Unk	Pfizer
Naproxen	S	Unk	Not Reported
Methadone	S	Unk	Not Reported
Amitiptyline	S	Unk	Not Reported
Bupropion	S	Unk	Not Reported
Citalopram	S	Unk	Not Reported
Toradol	S	Unk	Not Reported
Robaxin	S	Unk	Not Reported
Zocor	S	Unk	Not Reported
Valium	S	Unk	Not Reported
Zanaflex	S	Unk	Not Reported
Topamax	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Darvon	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported
Demerol	S	Unk	Not Reported
Talwin	S	Unk	Not Reported
Paxil	S	Unk	Not Reported
Norflex	S	Unk	Not Reported
Albuterol	S	Unk	Not Reported
Propacet	S	Unk	Not Reported
Tamiflu	S	Unk	Not Reported
Tylenol With Codeine	S	Unk	Not Reported
Vioxx	S	Unk	Not Reported
Ultracet	S	Unk	Not Reported
Darvocet A500	S	Unk	Not Reported
Clonazepam	S	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tramadol	S	Unk	Not Reported
Trazodone	S	Unk	Not Reported
Prozac	S	Unk	Not Reported
Seroquel	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14279247	EXPEDITED (15-DAY)		HO, OT	US-VISTAPHARM, INC.- VER201712-001293		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Drug Interaction; Electrocardiogram Qt Prolonged; Hyperhidrosis; Palpitations	Methadone Azithromycin Azithromycin			S S S				Vistapharm Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14279438	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-156809		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mycobacterium Abscessus Infection	Azithromycin Ethambutol Rifampin			S S S	Unknown Unknown	Unk Unk		Sun Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2017	14279442	EXPEDITED (15-DAY)		LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-156813			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin Cyclophosphamide			S S	Unknown	Unk		Sun Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281752	NON-EXPEDITED			US-PFIZER INC-2017530986		76 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281768	NON-EXPEDITED			US-PFIZER INC-2017531151			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14281846	NON-EXPEDITED			US-PFIZER INC-2017530693		77 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Skelaxin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Atorvastatin			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282052	NON-EXPEDITED			US-PFIZER INC-2017528172			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Food Allergy; Milk Allergy	Azithromycin			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14282163	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2017525595		80 YR	Male	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tendon Rupture	Zithromax			S		500 Mg, Daily		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14283668	DIRECT	Y	OT			42 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Haemorrhage; Pruritus; Rash; Rash	Azithromycin 250mg Teva			S	Oral	250mg 2 Tabs Day 1 Then 1 Tab Daily, Oral		Teva	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2017	14284020	DIRECT					60 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin Tablets Usp			S	Oral	Quantity:6 Tablet(S);		Pliva	
	Cpap			C				Not Reported	
	Trazodone			C				Not Reported	
	Travatan			C				Not Reported	
	Tinfoil			C				Not Reported	
	Xarelto			C				Not Reported	
	Gabapentin			C				Not Reported	
	Mirlax			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Similasan			C				Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Dec-2017	14149104	EXPEDITED (15-DAY)		OT	ZW-PFIZER INC-2017442302		24 YR	Female	ZWE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Rash	Zithromax	S	Oral	500 Mg, 1x/Day	Pfizer
Erythematous; Rash	Zithromax	S			Pfizer
Pruritic; Tongue Eruption	Cetirizine	S	Oral	10 Mg, 1x/Day	Not Reported
	Cetirizine	S			Not Reported
	Myprodol	C	Oral	1 Df (Capsule), 3x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14283555	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2017AP022812		83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Type I Hypersensitivity; Urticaria	Levofloxacin			S	Unknown	Unk		Apotex
	Azithromycin			S	Unknown	Unk		Apotex
	Ceftriaxone			S	Unknown	Unk		Apotex
	Ampicillin And Sulbactam			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14284206	NON-EXPEDITED			PHEH2017US039108			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Nausea	Azithromycin			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14285695	EXPEDITED (15-DAY)		OT	US-APOTEX-2017AP022811			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction	Azithromycin			S	Unknown			Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14286444	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-07139		57 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	500 Mg, Single		Lupin	
	Methadone			S	Unknown	60 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14288057	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2017528934		5 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Pharyngeal Swelling; Pyrexia; Rhinorrhoea; Tracheal Oedema	Zithromax			S	Oral	200 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	100 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2017	14289310	NON-EXPEDITED			US-PFIZER INC- 2017532854			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	14287956	EXPEDITED (15-DAY)		DE	ES-CIPLA LTD.- 2017ES22937			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neoplasm Progression	Levofloxacin			S	Unknown	Unk		Cipla	
	Ethambutol			S	Unknown	600 Mg, Unk, Continued For 10 Months		Cipla	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Daily, Continued For 10 Months		Not Reported	
	Rifampicin			S	Unknown	600 Mg, Unk, Continued For 10 Months		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxone			C		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14288939	EXPEDITED (15-DAY)		LT, OT	US-AUROBINDO-AUR-APL-2017-45370			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin				S	Unknown	()		Aurobindo	
	Cyclophosphamide				S	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14289120	NON-EXPEDITED			US-PFIZER INC-2017534824			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14289216	NON-EXPEDITED			US-PFIZER INC-2017533371			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Dec-2017	14289239	NON-EXPEDITED			US-PFIZER INC-2017536321			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Diflucan				S		Unk		Pfizer	
	Azithromycin				S		Unk		Pfizer	
	Benzylpenicillin Potassium				S		Unk		Pfizer	
	Amlodipine Besilate				S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2017	14296492	DIRECT		OT			27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Acne; Eructation; Nausea; Pruritus; Sensory Disturbance	Macrozit Azitromicina, Na Mg			S	Oral	Quantity:500 Tablet(S);		Laboratorios Liomont	
	Vagilen			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Panadol			C				Not Reported	
	Iron			C				Not Reported	
	One A Day For Women			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2017	14298995	DIRECT		OT			18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Pressure Decreased; Dizziness; Hyperhidrosis; Loss Of Consciousness	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Teva	
	Duac (Generic)			C				Not Reported	
	Dextromethorphan Hbr			C				Not Reported	
	Dimetapp			C				Not Reported	
	Emergen C			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2017	13269725	EXPEDITED (15-DAY)		OT	PT-PFIZER INC- 2017075380		88 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Amoxicillin Trihydrate/Clavulanic Acid			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Bisoprolol			C				Not Reported	
	Bromazepam			C				Not Reported	
	Pentoxifylline			C				Not Reported	
	Triflusal			C				Not Reported	
	Furosemide			C				Not Reported	
	Cyamemazine			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14295431	NON-EXPEDITED			US-PFIZER INC-2017536822			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14297073	EXPEDITED (15-DAY)		HO	PHHY2017ES187680		82 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypotension; Rash; Stridor	Azitromicina			S	Intravenous (not otherwise specified)	500 Mg, Qd (Every 24 Hous)		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2017	14297784	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2017M1079058		82 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypotension; Rash; Stridor	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg / 24 H		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	11772189	NON-EXPEDITED		OT	US-TEVA-385814USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Event; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	13023077	NON-EXPEDITED			US-TEVA-708963USA		43 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Headache; Product Formulation Issue		Azithromycin		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	13023078	NON-EXPEDITED			US-TEVA-706559USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Taste Disorder	Azithromycin			S				Not Reported	
	Amlodipine			C				Not Reported	
	Asa			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Cartia Xt			C				Not Reported	
	Escitalopram			C				Not Reported	
	Lactobacillus			C				Not Reported	
	Levothyroxine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	13023081	NON-EXPEDITED			US-TEVA-700356USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Product Physical Issue; Weight Decreased	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	13023084	NON-EXPEDITED			US-TEVA-692762USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	13023086	NON-EXPEDITED			US-TEVA-696379USA		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dizziness	Azithromycin	S	Oral						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	13023136	NON-EXPEDITED			US-TEVA-678789USA			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Product Taste Abnormal; Vomiting	Azithromycin			S	Unknown	200mg/5ml			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	13858259	NON-EXPEDITED			US-TEVA-795174ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Of Eyelid	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14009264	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017407265		73 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Infusion Site Extravasation; Skin Necrosis; Skin Ulcer	Zithromac			S	Intravenous drip	Unk			Pfizer
	Bfluid			S		Unk			Not Reported
	Nyrozin			C		Unk Unk, Single			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300170	NON-EXPEDITED			US-TEVA-712894USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Diarrhoea	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300171	NON-EXPEDITED			US-TEVA-760379ACC			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Diarrhoea; Frequent Bowel Movements	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300172	NON-EXPEDITED			US-TEVA-821121ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin Azithromycin			S S				Not Reported Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300173	NON-EXPEDITED			US-TEVA-795381ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300174	NON-EXPEDITED			US-TEVA-724570ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Abnormal	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300175	NON-EXPEDITED			US-TEVA-754388ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Hot; Myalgia	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300176	NON-EXPEDITED			US-TEVA-800634ACC		76 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Eye Pruritus	Azithromycin Azithromycin			S S				Not Reported Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300177	NON-EXPEDITED			US-TEVA-795205ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Overdose; Product Prescribing Error	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300178	NON-EXPEDITED		OT	US-TEVA-812968USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Respiratory Tract Infection	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300179	NON-EXPEDITED			US-TEVA-741304USA			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin			S	Unknown	200 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300180	NON-EXPEDITED			US-TEVA-762634ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin			S		Two 250 Mg Doses On Thursday And One 250 Mg Dose On Friday		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300181	NON-EXPEDITED			US-TEVA-726583ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Product Substitution Issue	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300182	NON-EXPEDITED			US-TEVA-729237USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting; Wrong Product Administered	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300183	NON-EXPEDITED			US-TEVA-801776ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Urticaria	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300184	NON-EXPEDITED			US-TEVA-752008ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Abdominal Pain Upper; Irritable Bowel Syndrome; Reaction To Excipient	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300185	NON-EXPEDITED			US-TEVA-767891ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pollakiuria	Azithromycin		S						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300186	NON-EXPEDITED			US-TEVA-733670ACC		8 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Nausea	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300187	NON-EXPEDITED			US-TEVA-710852USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S					Not Reported
	Azithromycin			S		2 Tablets On First Day And 1 Every Other Day			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300188	NON-EXPEDITED			US-TEVA-753458ACC		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Eating Disorder; Insomnia; Nausea; Vomiting	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300189	NON-EXPEDITED			US-TEVA-732962USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300190	NON-EXPEDITED			US-TEVA-779774USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Ear Discomfort; Ear Pain; Feeling Abnormal; Hypoacusis; Sinus Congestion	Zpack			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300191	NON-EXPEDITED			US-TEVA-733589ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin Tablets			S				Not Reported	
	Azithromycin Tablets			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300192	NON-EXPEDITED			US-TEVA-731375USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300193	NON-EXPEDITED			US-TEVA-789018USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Heart Rate Increased; Nausea	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300194	NON-EXPEDITED			US-TEVA-794872ACC			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Anosmia; Dyschezia	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300195	NON-EXPEDITED			US-TEVA-816968ACC		20 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Urticaria	Azithromycin			S		Took Two Tablets Once		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300196	NON-EXPEDITED			US-TEVA-729482ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Poor Quality Product Administered; Vomiting	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300197	NON-EXPEDITED			US-TEVA-748253ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chills; Oropharyngeal Pain; Pyrexia	Azithromycin Tums			S C				Not Reported Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300198	NON-EXPEDITED			US-TEVA-788972ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300199	NON-EXPEDITED			US-TEVA-748824USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chills; Oropharyngeal Pain; Pyrexia	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300200	NON-EXPEDITED			US-TEVA-793739ACC		12 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S		Dose Strength: 200 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300201	NON-EXPEDITED			US-TEVA-809039ACC		78 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cough; Drug Ineffective	Azithromycin			S				Not Reported	
	Lisinopril			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300202	NON-EXPEDITED			US-TEVA-818608ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300204	NON-EXPEDITED			US-TEVA-744615ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Reaction To Colouring	Azithromycin	S	Dose Strength: 200 Mg/5 MI	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300206	NON-EXPEDITED			US-TEVA-802055USA			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Event; Feeling Abnormal	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300207	NON-EXPEDITED		OT	US-TEVA-792629USA		8 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased	Azithromycin			S	Oral	200mg/5ml		Not Reported
	Ibuprofen			C				Not Reported
	Prednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300208	NON-EXPEDITED			US-TEVA-773245ACC		6 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Feeding Disorder; Oral Discomfort; Product Taste Abnormal; Throat Irritation	Azithromycin			S	Oral	200mg/5ml		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300209	NON-EXPEDITED			US-TEVA-735340ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Abnormal Faeces; Diarrhoea	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300210	NON-EXPEDITED			US-TEVA-727383ACC		68 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chest Discomfort; Heart Rate Increased	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300211	NON-EXPEDITED			US-TEVA-772485ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dizziness; Fatigue; Pain In Extremity; Somnolence	Azithromycin			S					Not Reported
	Tramadol			C					Not Reported
	Ambien			C					Not Reported
	Klonopin			C					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300212	NON-EXPEDITED			US-TEVA-812868ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nausea	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300213	NON-EXPEDITED			US-TEVA-727835ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Diarrhoea	Z-Pak			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300214	NON-EXPEDITED			US-TEVA-741777ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Malaise	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300215	NON-EXPEDITED			US-TEVA-711561USA			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Physical Consistency Issue; Product Taste Abnormal; Vomiting	Azithromycin			S	Oral	200 Mg / 5 MI			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300216	NON-EXPEDITED			US-TEVA-727262USA			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Emotional Distress; Hypoaesthesia Oral; Product Physical Issue; Product Taste Abnormal	Azithromycin			S		200mg/5ml			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300218	NON-EXPEDITED			US-TEVA-727455ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300219	NON-EXPEDITED			US-TEVA-816556ACC		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Discomfort	Azithromycin			S					Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300220	NON-EXPEDITED			US-TEVA-810287ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cough; Oropharyngeal Pain; Vomiting	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300221	NON-EXPEDITED			US-TEVA-816051ACC		85 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Constipation; Dizziness; Dysphonia; Fatigue; Feeling Abnormal; Laryngitis	Azithromycin			S	Oral				Not Reported
	Valsartan			C					Not Reported
	Acefex			C					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300222	NON-EXPEDITED			US-TEVA-818211ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Rash	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300223	NON-EXPEDITED			US-TEVA-712514USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300224	NON-EXPEDITED			US-TEVA-809437USA		78 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cough	Azithromycin Lisinopril			S C					Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300225	NON-EXPEDITED			US-TEVA-774636ACC		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Parosmia; Taste Disorder	Azithromycin Azithromycin				S S		Dose: 5 Days		Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300226	NON-EXPEDITED			US-TEVA-731095ACC		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Migraine	Azithromycin				S	Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300227	NON-EXPEDITED			US-TEVA-729098ACC			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin				S	Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300228	NON-EXPEDITED			US-TEVA-747069ACC		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia; Nasal Congestion; Oropharyngeal Discomfort; Oropharyngeal Pain; Sneezing	Azithromycin				S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300229	NON-EXPEDITED			US-TEVA-725224ACC		22 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Back Pain; Myalgia	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300230	NON-EXPEDITED			US-TEVA-773662USA			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300232	NON-EXPEDITED			US-TEVA-750374ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Abdominal Pain Upper; Constipation; Flatulence; Therapy Cessation	Azithromycin			S	Oral				Not Reported
	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
	Vitamin D2			C	Oral				Not Reported
	Calcium			C	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300233	NON-EXPEDITED			US-TEVA-735995ACC		10 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Dysgeusia; Gingival Pain	Azithromycin			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300234	NON-EXPEDITED			US-TEVA-731092ACC			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Hyposmia	Azithromycin Tablets, Usp Azithromycin Tablets, Usp			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300236	NON-EXPEDITED			US-TEVA-809762ACC			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspepsia; Insomnia	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300237	NON-EXPEDITED			US-TEVA-727880ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin Azithromycin			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300238	NON-EXPEDITED			US-TEVA-740903ACC		80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Fatigue	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300239	NON-EXPEDITED			US-TEVA-775009ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Oral Discomfort; Product Taste Abnormal; Throat Irritation	Azithromycin			S	Oral	200mg/5ml		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300240	NON-EXPEDITED			US-TEVA-735503ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Retching	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300241	NON-EXPEDITED			US-TEVA-797942ACC		85 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300242	NON-EXPEDITED			US-TEVA-729456ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300243	NON-EXPEDITED			US-TEVA-723694ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300244	NON-EXPEDITED			US-TEVA-729070ACC		12 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chest Pain; Feeling Hot; Hypersensitivity; Nausea	Azithromycin			S		200 Mg/5 MI			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300245	NON-EXPEDITED		OT	US-TEVA-733256ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Heart Rate Increased	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300246	NON-EXPEDITED			US-TEVA-734303ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Nausea	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300247	NON-EXPEDITED			US-TEVA-734301ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300248	NON-EXPEDITED			US-TEVA-816092ACC			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Face	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300249	NON-EXPEDITED			US-TEVA-792162USA		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Pruritus; Urticaria	Azithromycin Allegra			S C				Not Reported Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Claritin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300250	NON-EXPEDITED			US-TEVA-737098ACC		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash	Azithromycin Tablets			S		250 Milligram Daily;		Not Reported	
	Azithromycin Tablets			S		250 Milligram Daily;		Not Reported	
	Azelastine Hcl Antihistamine			C		2 Dosage Forms Daily;		Not Reported	
	Fluticasone Propionate			C		2 Dosage Forms Daily;		Not Reported	
	Fluticasone Propionate			C		4 Dosage Forms Daily; Doctor Permits If Needed		Not Reported	
	Allegra Geq (Fexofenadine Hydrochloride Generic Equivalent)			C	Oral	180 Milligram Daily;		Not Reported	
	Elidel Cream			C		Seldom Used; Irregular		Not Reported	
	Betamethasone Dipropionate			C		Very Seldom		Not Reported	
	Vitamin C			C				Not Reported	
	Vitamin C			C				Not Reported	
	Coenzyme Q-10			C				Not Reported	
	Omega 3 Fish Oil			C		2400 Milligram Daily;		Not Reported	
	Selenium			C		200 Microgram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300251	NON-EXPEDITED			US-TEVA-734683ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300252	NON-EXPEDITED			US-TEVA-733029ACC		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Diarrhoea; Diarrhoea; Feeding Disorder; Weight Decreased	Azithromycin	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300253	NON-EXPEDITED		HO, OT	US-TEVA-719596USA			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Sodium Decreased;	Azithromycin			S				Not Reported
Hypersensitivity;	Vancomycin			S				Actavis
Pneumonia	Biaxin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300254	NON-EXPEDITED			US-TEVA-800383ACC		7 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Azithromycin			S	Oral	Dose Strength: 200 Mg/5 MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300255	NON-EXPEDITED			US-TEVA-734682ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300256	NON-EXPEDITED			US-TEVA-761339USA		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Dysphonia; Mouth Swelling	Azithromycin			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300257	NON-EXPEDITED			US-TEVA-731096ACC			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysgeusia; Hypoaesthesia Oral	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300259	NON-EXPEDITED			US-TEVA-781771ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Localised Infection	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300261	NON-EXPEDITED			US-TEVA-726998ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysgeusia; Oral Discomfort	Teva'S Azithromycin			S	Oral	10 MI 1st Day And 5 MI For Next 4 Days		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300263	NON-EXPEDITED			US-TEVA-798608ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300264	NON-EXPEDITED			US-TEVA-721562USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise; Oral Mucosal	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blistering

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300265	NON-EXPEDITED			US-TEVA-775011ACC			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Intentional Product Misuse; Oral Discomfort; Product Taste Abnormal; Throat Irritation	Azithromycin			S	Oral	200mg/5ml		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300266	NON-EXPEDITED			US-TEVA-718500USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysphonia; Product Physical Issue; Tongue Coated	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300267	NON-EXPEDITED			US-TEVA-821157ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Diarrhoea	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300268	NON-EXPEDITED			US-TEVA-811016USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Pressure Decreased; Product Quality Issue	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300269	NON-EXPEDITED			US-TEVA-750915ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300270	NON-EXPEDITED			US-TEVA-718603ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Feeling Hot; Infection Reactivation	Azithromycin Tablets			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300271	NON-EXPEDITED			US-TEVA-756023USA		273 DAY	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Taste Abnormal; Vomiting	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300273	NON-EXPEDITED			US-TEVA-742546ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Anosmia	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300276	NON-EXPEDITED			US-TEVA-734905ACC		68 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Anosmia	Azithromycin Prilosec			S C					Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Lantus			C					Not Reported
	Cozaar			C					Not Reported
	Glimepiride			C					Not Reported
	Imitrex			C					Not Reported
	Luxiq			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300277	NON-EXPEDITED			US-TEVA-809767ACC			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300278	NON-EXPEDITED			US-TEVA-734634ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300279	NON-EXPEDITED			US-TEVA-785949ACC		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Swelling; Urticaria	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300280	NON-EXPEDITED			US-TEVA-818061ACC			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Feeling Abnormal; Muscle Spasms	Azithromycin			S					Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300281	NON-EXPEDITED			US-TEVA-781681USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Localised Infection	Azithromycin			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300282	NON-EXPEDITED			US-TEVA-742421ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Disorientation; Dizziness; Dysstasia; Loss Of Personal Independence In Daily Activities	Azithromycin			S		Taken Two Tablets Yesterday And One Today			Not Reported
	Bayer Aspirin			C		Dose: 81 Mg			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300283	NON-EXPEDITED			US-TEVA-742587ACC			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nausea; Product Taste Abnormal	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300284	NON-EXPEDITED			US-TEVA-771617ACC			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2017	14300285	NON-EXPEDITED			US-TEVA-738340ACC		79 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300298	NON-EXPEDITED			US-PFIZER INC-2017538532			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14300418	EXPEDITED (15-DAY)		HO, OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-17-04		78 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Catheter Site Haemorrhage; Drug Ineffective; Dyspnoea; Haemoptysis; Pneumonia Pneumococcal; Productive Cough; Pulmonary Alveolar Haemorrhage; Purulent Discharge; Pyrexia; Respiratory Failure	Amiodarone			S	Unknown	100 Mg, Three Times A Week		Hikma	
	Azitromycin			S	Unknown	()		Not Reported	
	Apixaban			C	Unknown	5 Mg, Two Times A Day		Not Reported	
	Apixaban			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14301903	NON-EXPEDITED			US-AKORN-75018			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite (Azithromycin Ophthalmic Solution)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14302679	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-		81 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

APL-2017-45356

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterium Abscessus Infection	Azithromycin			S	Unknown	()		Aurobindo	
	Ethambutol			S	Unknown	()		Not Reported	
	Rifampin			S	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14303120	EXPEDITED (15-DAY)		OT	AU-BAYER-2017-236038		8 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Ototoxicity; Product Use Issue; Pyrexia; Weight Decreased	Moxifloxacin Oral			S		Unk		Bayer	
	Amikacin			S	Intravenous drip	Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Minocycline			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14304321	EXPEDITED (15-DAY)		DE, OT	US-OTSUKA-J20030836		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Death; Drug Interaction; Pneumonia; Sleep Apnoea Syndrome	Abilify 3mg			S	Oral	15 Mg, Unk		Otsuka	
	Zithromac			S	Oral	Unk		Not Reported	
	Zyprexa			C	Oral	30 Mg, Unk		Not Reported	
	Zyprexa			C	Oral	20 Mg, Unk		Not Reported	
	Synthroid			C	Unknown	Unk		Not Reported	
	Depakote			C	Unknown	Unk		Not Reported	
	Celexa			C	Unknown	Unk		Not Reported	
	Albuterol			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ibuprofen	C	Unknown	Unk	Not Reported
Ibuprofen	C	Unknown	Unk	Not Reported
Olanzapine	C	Unknown	30 Mg (Start Date Not Reported)Decreased To 20 Mg/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2017	14305716	EXPEDITED (15-DAY)		OT	PHHY2017ES185864			Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Maternal Drugs Affecting Foetus	Oxytocin Sandoz			S	Transplacental			Sandoz
	Azithromycin			S	Transplacental	1 G, Unk		Novartis
	Ampicillin			S	Transplacental	2 G (Then 1 G/6 H For 48 H)		Not Reported
	Betamethasone			S	Transplacental			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14307386	NON-EXPEDITED			US-PFIZER INC-2017536319		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer
	Diflucan			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Penicillin G			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14309917	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017535884			Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Off Label Use; Tonsillitis	Zitromax			S		1 MI, From Monday To Thursday On, From Friday		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Zitromax	S	To Sunday Off 1.5 MI, From Monday To Thursday On, From Friday To Sunday Off	Pfizer
Flixotide	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14309997	EXPEDITED (15-DAY)		HO	US-FRESENIUS KABI- FK201711064		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)			S				Fresenius Medical Care
	Methadone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14310161	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2016127889		51 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atelectasis; Condition Aggravated; Deafness Unilateral; Feeling Abnormal; Overdose; Pain In Extremity; Skin Disorder	Lyrice			S	Oral	50 Mg, 3x/Day		Pfizer
	Lyrice			S		400 Mg, 3x/Day [1200 Mg Per Day]		Pfizer
	Lipitor			S		20 Mg, 2x/Day		Pfizer
	Effexor Xr			S	Oral	75 Mg, 1x/Day [One In Am] [1 Capsule, Extended Release 24hr Every Morning, Once A Day]		Pfizer
	Zithromax			S		Unk		Pfizer
	Tessalon			S		Unk		Pfizer
	Amlodipine			C		5 Mg, 1x/Day		Not Reported
	Carvedilol			C		6.25 Mg, 2x/Day		Not Reported
	Clonidine Hcl			C		0.2 Mg, 2x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexilant	C		60 Mg, 1x/Day	Not Reported
Enalapril Maleate	C		10 Mg, 1x/Day	Not Reported
Epipen 2-Pak	C		Unk Unk, Monthly [1 Auto-Injector Once A Month]	Not Reported
Escitalopram	C		10 Mg, 1x/Day	Not Reported
Fluoxetine	C		20 Mg, 1x/Day [1 Capsule Every Morning, Once A Day]	Not Reported
Gabapentin	C		1200 Mg, 3x/Day [4 Capsule 3 Times A Day]	Not Reported
Glipizide	C		10 Mg, 2x/Day	Not Reported
Glucagon Emergency Kit	C		Unk Unk, As Needed (1 Kit)	Not Reported
Hydrochlorothiazide	C		25 Mg, 1x/Day	Not Reported
Levemir	C	Subcutaneous	100 Iu, 2x/Day [100 Unit/MI (3 MI)]	Not Reported
Lisinopril	C		20 Mg, 2x/Day	Not Reported
Metformin	C		1000 Mg, 2x/Day	Not Reported
Ondansetron Hcl	C		4 Mg, 4x/Day	Not Reported
Proair Hfa	C		180 Ug, 3x/Day [90 Mcg/Actuation Hfa Aerosol Inhaler] [2 Puffs 3 Times A Day]	Not Reported
Seroquel	C		200 Mg, 1x/Day	Not Reported
Simvastatin	C		20 Mg, 2x/Day	Not Reported
Topamax	C		50 Mg, 2x/Day	Not Reported
Trazodone	C		100 Mg, 1x/Day [2 Tablet Before Bed, Once A Day]	Not Reported
Zolpidem	C		10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14310663	EXPEDITED (15-DAY)	HO, OT		PT-MYLANLABS-2017M1079835		78 YR	Male	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Catheter Site Haemorrhage; Drug Ineffective; Dyspnoea; Haemoptysis; Pneumonia Pneumococcal; Productive Cough; Pulmonary Alveolar Haemorrhage; Purulent Discharge; Pyrexia; Respiratory Failure; Streptococcus Test Positive	Amiodarone			S	Unknown	100 Mg, Three Times A Week		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Apixaban			C		5 Mg, Two Times A Day		Mylan	
	Apixaban			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2017	14313230	DIRECT					66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dyspnoea	Azithromycin			S	Oral	Quantity:1 Tablet(S);Other Frequency:As Directed;		Pliva	
	Bomeo Powder			C				Not Reported	
	Mvi			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	11832414	NON-EXPEDITED			US-PFIZER INC- 2015404616			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Premarin			S		Unk		Pfizer	
	Lodine			S		Unk		Pfizer	
	Voltaren			S		Unk		Not Reported	
	Indocin			S		Unk		Not Reported	
	Lindane			S		Unk		Not Reported	
	Nickel			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orudis	S	Unk	Not Reported
Prozac	S	Unk	Not Reported
Seldane	S	Unk	Not Reported
Trazodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	12801729	NON-EXPEDITED			US-PFIZER INC-2016458988			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cefazolin			S		Unk		Pfizer
	Cefdinir			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Clindamycin Hcl			S		Unk		Pfizer
	Metoclopramide Hcl			S		Unk		Pfizer
	Sulfadiazine Silver			S		Unk		Pfizer
	Lincomycin Hcl			S		Unk		Pfizer
	Nitrofurantoin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	12964393	NON-EXPEDITED			US-PFIZER INC-2016540458		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Pneumovax 23			S		Unk		Not Reported
	Valium			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14241137	NON-EXPEDITED			US-PFIZER INC-2017512611			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Fluoxetine			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14300231	NON-EXPEDITED		OT	US-TEVA-767116USA			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Atrial Fibrillation	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312186	EXPEDITED (15-DAY)		HO	US-TEVA-2017-US-835236		17 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysuria; Haematuria; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312189	EXPEDITED (15-DAY)		HO	US-TEVA-2017-US-835237		14 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysuria; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2017	14312191	EXPEDITED (15-DAY)		HO	US-TEVA-2017-US-835259		17 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysuria; Stevens-Johnson	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Syndrome; Toxic
Epidermal Necrolysis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14312364	EXPEDITED (15-DAY)		OT	PHHY2017FR182356			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Delivery; Low Birth Weight Baby	Acetylsalicylic Acid			S	Transplacental	75 Mg, Qd		Not Reported
	Amoxicillin			S	Transplacental	1 G, Tid		Novartis
	Azithromycin			S	Transplacental			Not Reported
	Cefotaxime			S	Transplacental			Not Reported
	Methylprednisolone			S	Transplacental	1 Mg/Kg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14312604	NON-EXPEDITED			US-PFIZER INC-2017542784			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2017	14313835	EXPEDITED (15-DAY)		DS	JP-PFIZER INC-2017516663		4 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Abnormal Behaviour	Zithromac 10%			S	Oral	1.6 G, 1x/Day After Dinner		Pfizer
	Meptin			S	Oral	0.3 G, 3x/Day		Not Reported
	Asverin (Tipepidine Hibenzate)			S	Oral	0.4 G, 3x/Day		Not Reported
	Mucosal (Ambroxol Hydrochloride)			S	Oral	1.0 G, 3x/Day		Not Reported
	Zyrtec			S	Oral	0.4 G, 2x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14185605	NON-EXPEDITED			PHEH2017US036255			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin 250 Mg			S	Unknown			Novartis	
	Mepron			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14260203	NON-EXPEDITED			US-PFIZER INC-2017520331		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Embeda			S		Unk		Pfizer	
	Enbrel			S		Unk		Pfizer	
	Fentanyl Citrate			S		Unk		Unknown	
	Gabapentin			S		Unk		Pfizer	
	Lyrica			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Humira			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Rasuvo			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14316743	NON-EXPEDITED			US-PFIZER INC-2017544385		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea	Zithromax		S			Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14317432	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2017-46426		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Oral	1 Df, Total (1 Ug/Litre)		Aurobindo	
	Omeprazole			C	Oral	Unk ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14319295	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1080427		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Oral	1 Df, Total (1 Ug/Litre)		Not Reported	
	Omeprazole			C	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2017	14320277	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017545594		11 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Hyperhidrosis; Nausea; Peripheral Coldness; Somnolence	Azithromycin			S	Oral	10 ML, Single		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14299324	EXPEDITED (15-DAY)		DS, HO, LT, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-156961		82 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Rash; Stridor	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg / 24 H		Sun	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14321132	EXPEDITED (15-DAY)		OT	PHHY2017US184652		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Kidney Fibrosis; Renal Tubular Injury; Tubulointerstitial Nephritis	Ceftriaxone			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2017	14321562	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2017M1080828		11 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Hyperhidrosis; Nausea; Peripheral Coldness; Somnolence	Azithromycin			S	Oral	10 ML, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2017	14321746	EXPEDITED (15-DAY)		OT	PHHY2017ES192404		11 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Hyperhidrosis; Nausea; Peripheral Coldness; Somnolence	Azitromicina			S	Oral	10 ML, Total		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2017	14325493	DIRECT		OT			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin Tablets Usp 250 Mg			S	Oral	Quantity:6 Tablet(S);Other Frequency:2 On Day1.1 On 2-5; Oral		Teva	
	Prozac			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Wellbutrin	C	Not Reported
Lipitor	C	Not Reported
Lisinopril	C	Not Reported
Buspar	C	Not Reported
Centrum Silver	C	Not Reported
Vitamin D3	C	Not Reported
Astaxanthin	C	Not Reported
Biotin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	13783914	EXPEDITED (15-DAY)		HO	GXJP2017JP001208		64 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Hypersensitivity	Cefepime Dihydrochloride For Intravenous Injection			S	Intravenous (not otherwise specified)	1 G, Bid		Novartis
	Irradiated Washed Red Cells			S	Intravenous (not otherwise specified)	4 Df, Unk		Not Reported
	Irradiated Platelet Concentrate, Leukocytes R (Platelets)			S	Intravenous (not otherwise specified)	10 Df, Unk		Not Reported
	Zithromac			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14298608	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US-016632			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Sinusitis	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Xyrem			S	Oral	Dose Adjustments		Jazz
	Xyrem			S	Oral	4.5 G, Bid		Jazz
	Xyrem			S	Oral	2.25 G, Bid		Jazz
	Z-Pak			S				Not Reported
	Citalopram Hbr			C		Unk		Not Reported
	Ativan			C		Unk		Not Reported
	Promethazine			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Claritin /00413701/	C	Unk	Not Reported
Famotidine	C	Unk	Not Reported
Hydrocodone/Acetaminophen /00607101/	C	Unk	Not Reported
Nuvigil	C	Unk	Not Reported
Prilosec /00661201/	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Topamax	C	Unk	Not Reported
Tramadol Hcl	C	Unk	Not Reported
Ambien	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2017	14323134	NON-EXPEDITED			US-TEVA-2017-US-835793			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Product Odour Abnormal; Product Packaging Difficult To Open; Product Taste Abnormal	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	10550139	EXPEDITED (15-DAY)		DE, HO	JP-BAUSCH-BL-2014-007421		64 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Bradykinesia;	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	
Death; Dyskinesia;	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	
Epilepsy; Erythema;	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	
Headache; Pruritus;	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	
Pyrexia; Rash; Seizure;	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	
Skin Abrasion; Sleep Disorder; Stomatitis;	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	
Subdural Haematoma; Urinary Retention	Choreazine Tablets 12.5 Mg			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromac	S	Oral	Not Reported
Sennoside	C	Oral	Not Reported
Sennoside	C	Oral	Not Reported
Gasmotin	C	Oral	Not Reported
Maglax	C	Oral	Not Reported
Tamiflu	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14292507	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2017529545		5 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Dizziness; Excessive Eye Blinking; Photopsia; Tinnitus; Vision Blurred	Zithromax			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14326628	NON-EXPEDITED			US-TEVA-2017-US-835395			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysgeusia; Product Packaging Difficult To Open	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14326663	NON-EXPEDITED			US-TEVA-2017-US-836108			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Maternal Exposure During Pregnancy	Azithromycin			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2017	14327802	NON-EXPEDITED			US-PFIZER INC-2017546968		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332230	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR-APL-2017-47604		88 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S		Unk		Aurobindo	
	Amoxicillin+Clavulanic Acid			S		Unk		Aurobindo	
	Furosemide			C				Not Reported	
	Pentoxifylline			C				Not Reported	
	Bisoprolol			C				Not Reported	
	Bromazepam			C				Not Reported	
	Cyamemazine			C				Not Reported	
	Triflusal			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332477	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2017M1079712		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Methadone			S	Unknown	60mg Daily		Not Reported	
	Azithromycin			S	Unknown	Single Dose Of 500 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2017	14332886	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2017-47387		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Cavity Infection; Exposure During	Azithromycin			S	Oral	1 G ()		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Live Birth; Pathogen Resistance	Betamethasone	S	Unknown	500 Mg Every 8 H ()	Not Reported
	Ampicillin	S	Unknown	2 G Ampicillin Then 1 G/6 H For 48 H ()	Not Reported
	Oxytocin	S	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333040	EXPEDITED (15-DAY)		OT	PHHY2017US189019		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Genital Lesion; Penile Erythema; Scab	Azithromycin			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333044	EXPEDITED (15-DAY)		HO	PHHY2017US189026		14 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Genital Lesion	Azithromycin			S	Unknown	Unk		Novartis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14333620	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2017548069		40 YR	Male	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Coagulation Factor Deficiency; Haemoptysis	Zithromax			S	Oral	250 Mg, Unk		Pfizer
	Nebcine			S		450 Mg, Unk		Not Reported
	Piperacilline / Tazobactam Mylan			S	Intravenous drip	12 G, Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14334383	EXPEDITED (15-DAY)		HO	PHHY2017US189031		17 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dysuria; Genital Lesion;	Azithromycin			S	Unknown	Unk		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haematuria; Scrotal
Swelling; Urethral Meatus
Stenosis

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14337025	DIRECT	Y	OT			71 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Rash	Azithromycin Solu-Medrol	Y		S C	Intravenous drip	Other Frequency:Once;	5 MIN	Auromedics Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Dec-2017	14337104	DIRECT					36 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Diarrhoea; Rash	Azithromycin			S	Oral			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14336998	EXPEDITED (15-DAY)		OT	ES-TEVA-2017-ES- 837685		11 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Hyperhidrosis; Nausea; Peripheral Coldness; Somnolence	Azitromicina			S	Oral			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-Dec-2017	14338199	NON-EXPEDITED			US-TEVA-2017-US- 826718			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Chest Pain; Malaise; Muscle Spasms; Muscle	Azithromycin			S	Unknown	Dose Strength: 65-150		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasms

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2017	14338612	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017550381		47 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Zithromac 250mg			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2017	14339931	NON-EXPEDITED			US-TEVA-2017-US-833199			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Incorrect Dose Administered	Azithromycin			S		Taking Two Tablets In A Single Dose At 19:30		Not Reported	
	Azithromycin			S		One Tablet At 19:30		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14338201	EXPEDITED (15-DAY)		LT, OT	CN-PFIZER INC-2017555134		365 DAY	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Apnoea; Pallor	Zithromax			S	Intravenous drip	90 Mg, Unk		Pfizer	
	Sulperazon			C	Intravenous drip	35 Mg, 2x/Day		Not Reported	
	Mucosolvan			C	Intravenous drip	15 Mg, Unk		Not Reported	
	Mucosolvan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14341996	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2017M1082011		1 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute;	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pneumonia Legionella; Product Contamination Microbial				Weeks	
	Azithromycin	S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks	Not Reported
	Azithromycin	S			Not Reported
	Levofloxacin	S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days	Not Reported
	Levofloxacin	S			Not Reported
	Levofloxacin	S			Not Reported
	Sodium Chloride	S	Nasal	0.9% Nose Spray	Not Reported
	Voriconazole	S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily	Not Reported
	Voriconazole	S	Other	8 Mg/Kg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Dexamethasone	S	Unknown	10 Mg/M2 For 21 Days Then Tapering	Not Reported
	Pegaspargase	S	Unknown	Unk	Mylan
	Amphotericin B Lipid Complex	S	Unknown	4 Mg/Kg/Day	Mylan
	Amphotericin B Lipid Complex	S			Mylan
	Amphotericin B Lipid Complex	S			Mylan
	Daunorubicin	C	Unknown	Unk	Mylan
	Methotrexate	C	Intrathecal	Unk	Mylan
	Vincristine	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14343629	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2017M1083565		40 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulation Factor Deficiency; Haemoptysis	Piperacillin/Tazobactam Mylan			S	Intravenous drip	12 G, Unk		Mylan	
	Nebcine			S		450 Mg, Unk		Mylan	
	Zithromax			S	Oral	250 Mg, Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14343814	NON-EXPEDITED			US-PFIZER INC-2018000215		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Pregabalin			C		300 Mg, Unk		Not Reported	
	Glipizide			C		Unk		Not Reported	
	Liraglutide			C		18 Mg, Unk		Not Reported	
	Triamcinolone			C		Unk		Not Reported	
	Atorvastatin			C		20 Mg, Unk		Not Reported	
	Lisinopril			C		2.5 Mg, Unk		Not Reported	
	Duloxetine			C		60 Mg, Unk		Not Reported	
	Levothyroxine			C		125 Ug, Unk		Not Reported	
	Omeprazole			C		20 Mg, Unk		Not Reported	
	Metformin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2018	14344570	NON-EXPEDITED			US-TEVA-2017-US-833709		5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Oral	Dose Strength: 200 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14342433	EXPEDITED (15-DAY)			BR-GLAXOSMITHKLINE-BR2017GSK200334			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Therapeutic Product Effect Decreased	Aerolin			S		Unk		Glaxosmithkline	
	Clenil			S		Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Amoxicilina + Clavulanic Acid	S		850 Mg, Unk		Glaxosmithkline			
	Codeine	S		Unk		Glaxosmithkline			
	Azitromicina	S		Unk		Glaxosmithkline			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14345771	NON-EXPEDITED			US-PFIZER INC-2018002156		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14345788	NON-EXPEDITED			US-PFIZER INC-2018002090		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14345793	NON-EXPEDITED			US-PFIZER INC-2018002006		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cardizem			S		Unk		Not Reported	
	Rocephin			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14346353	EXPEDITED (15-DAY)		HO, LT, OT	NL-SA-200520584GDDC		14 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Supraventricular Tachycardia	Telfast	S	Oral		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Fluticasone W/Salmeterol	C	Nasal	Dose As Used: 1 Respiratory (Inhalation) 100/50 Microg Twice Daily	Not Reported
	Flixonase	C	Nasal	Dose As Used: 1 Inhalation Both Nostrils	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14346892	NON-EXPEDITED			US-PFIZER INC- 2017556071		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cleocin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14347578	NON-EXPEDITED			US-AKORN PHARMACEUTICALS- 2017AKN00263		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Arthralgia; Asthenia; Back Pain; Cough; Eye Pain; Eye Pruritus; Eye Swelling; Gait Disturbance; Headache; Hypersensitivity; Hypoacusis; Impaired Driving Ability; Myalgia; Visual Impairment	Ethambutol Hydrochloride			S		Unk, Once		Akorn	
	Mycobutin			S		300 Mg, 1x/Day		Not Reported	
	Azithromycin			S		250 Unk, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14347619	NON-EXPEDITED			US-TEVA-2017-US-830408			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Nausea	Azithromycin			S		250mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2018	14348290	NON-EXPEDITED			US-PFIZER INC-2017553854		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Penicillin V Potassium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351192	NON-EXPEDITED			US-PFIZER INC-2018000714			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Sulfasalazine			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351218	NON-EXPEDITED			US-PFIZER INC-2018000260			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14351450	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20180101856		58 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchial Carcinoma; Off Label Use; Product Use Issue	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Naproxen			C	Unknown			Not Reported	
	Tramadol			C	Unknown			Not Reported	
	Uvedose			C	Unknown			Not Reported	
	Cortancyl			C	Unknown			Not Reported	
	Imovane			C	Unknown			Not Reported	
	Atenolol			C	Unknown			Not Reported	
	Cotareg			C	Unknown	160 Mg/25 Mg		Not Reported	
	Kardegic			C	Unknown			Not Reported	
	Speciafoldine			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14352008	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2018-US-843495		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	Single Dose Of 500 Mg		Not Reported	
	Methadone			S	Unknown	60mg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14352162	NON-EXPEDITED			US-PFIZER INC-2017551508		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352696	NON-EXPEDITED			US-PFIZER INC-2017548750		72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Paxil			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352719	NON-EXPEDITED			US-PFIZER INC-2017548708			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352752	NON-EXPEDITED			US-PFIZER INC-2017551154		75 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Penicillin G			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352799	NON-EXPEDITED			US-PFIZER INC-2017550140			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jan-2018	14352851	NON-EXPEDITED			US-PFIZER INC-2017547488			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Phenytoin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14353007	EXPEDITED (15-DAY)		LT	AU-GLAXOSMITHKLINE-AU2017201705		10 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S	Unknown	Unk		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim			S				Glaxosmithkline
	Prostacyclin			S	Respiratory (inhalation)	Unk		Glaxosmithkline
	Vancomycin			S	Unknown	Unk		Glaxosmithkline
	Lincomycin			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14355608	DIRECT		OT			37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Hypertension; Palpitations; Panic Reaction; Paranoia	Azithromycin/Z Pack			S	Oral	Quantity:5 Tablet(S);		Not Reported
	Paxil			C				Not Reported
	Xanax			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2018	14355616	DIRECT		OT			56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Back Pain; Chronic Obstructive Pulmonary Disease; Dysphonia; Dyspnoea; Gingival Swelling; Hypersensitivity; Impaired Work Ability; Mouth Swelling; Pharyngeal Swelling; Weight Decreased	Azithromycin Pantapropazole Cholestyramine Powder Probiotics	S C C C	Oral	Quantity:5 Tablet(S);	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	12838875	NON-EXPEDITED			US-PFIZER INC-2016465814			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea	Zithromax			S		Unk		Pfizer
	Hydrocodone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14202516	NON-EXPEDITED		OT	PHEH2017US036500			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Drug Interaction; Hypotension; Sinusitis	Afinitor			S	Unknown	Unk		Novartis
	Lenvatinib			S	Oral	18 Mg, Qd		Not Reported
	Zithromax			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14353327	EXPEDITED (15-DAY)		DE, HO	US-TORRENT-00004488		30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Completed Suicide; Toxicity To Various Agents	Topiramate			S	Oral			Unknown
	Lacosamide			S	Oral			Unknown
	Pregabalin			S	Oral			Unknown
	Phenytoin			S	Oral			Unknown

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	S	Oral	Unknown
Azithromycin	S	Oral	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355181	EXPEDITED (15-DAY)	HO		CN-PFIZER INC-2018002257		90 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain Upper	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer
	Sulperazon			C	Intravenous drip	1.5 G, 3x/Day		Not Reported
	Aminophylline			C	Intravenous drip	0.25 G, 2x/Day		Not Reported
	Ambroxol Hydrochloride			C	Intravenous drip	30 Mg, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355404	NON-EXPEDITED			US-PFIZER INC-2018003931		85 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Fluconazole			S		Unk		Pfizer
	Crestor			S		Unk		Not Reported
	Mobic			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355413	NON-EXPEDITED			US-PFIZER INC-2018003966		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cipro /00697201/			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14355467	NON-EXPEDITED			US-GLAXOSMITHKLINE-		82 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

US2018000646

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chromaturia; Dizziness; Feeling Cold; Feeling Hot; Hyperhidrosis; Vomiting	Breo Ellipta Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), 1d		Glaxosmithkline
	Breo Ellipta Inhalation Powder			S				Glaxosmithkline
	Breo Ellipta Inhalation Powder			S				Glaxosmithkline
	Azithromycin Tablet			S	Oral	500 Mg, 1d (Two 250 Mg Tablets) For 5 Days		Glaxosmithkline
	Eliquis			C				Not Reported
	Glipizide			C				Not Reported
	Toujeo			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14356812	NON-EXPEDITED			US-AKORN-76875		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Scleral Discolouration; Scleritis	Azasite			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2018	14359225	EXPEDITED (15-DAY)		OT	NZ-APOTEX- 2018AP005199		55 YR	Female	NZL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Cholestatic	Azithromycin			S	Oral	Unk		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360279	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR- APL-2018-000523		67 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia; Eosinophilic Pleural Effusion	Amoxicillin+Clavulanic Acid Film- Coated Tablets			S	Oral	1 Df, Every 8 Hours		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azitromicina	S	Oral	500 Mg, Daily	Not Reported
Alopurinol	S	Oral	300 Mg, Daily	Not Reported
Levofloxacino	S	Oral	500 Mg, Daily	Not Reported
Hidroferol	C	Oral	1 Amp	Not Reported
Valsartan/Hct	C	Oral	Unk Unk, Once A Day	Not Reported
Tamsulosina	C	Oral	1 Cp	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360309	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-159181		67 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilia; Eosinophilic Pleural Effusion	Amoxicillin/Clavulanic Acid			S	Oral	1 Df		Ranbaxy
	Azithromycin			S	Oral	500 Mg, Daily, 1 Cp		Sun
	Allopurinol			S	Oral	300 Mg, Daily, 1 Cp		Sun
	Levofloxacin			S	Oral	500 Mg, Daily		Ranbaxy
	Hidroferol 266			C	Oral	1 Amp ()		Not Reported
	Astudir 10			C	Oral	1-0-0 ()		Not Reported
	Valsartan/Hct 32/12.5			C	Oral	1-0-0 ()		Not Reported
	Tamsulosina			C	Oral	1 Cp ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2018	14360656	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS- 2018M1001150		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Venocclusive Disease	Azithromycin			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2018	14360816	NON-EXPEDITED			US-TEVA-2018-US- 843051			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphonia; Swelling Face	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2018	14360818	NON-EXPEDITED			US-TEVA-2017-US-839755			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Product Packaging Difficult To Open	Azithromycin			S	Oral			Teva	
	Azithromycin			S				Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14362383	NON-EXPEDITED			US-TEVA-2017-US-839919		87 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14362408	NON-EXPEDITED			US-DEXPHARM-20171578			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper	Omeprazole Delayed Release Tablets 20 Mg			S	Oral	20 Mg, Qd		Dexcel	
	Azithromycin			S	Oral	Unknown, Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2018	14363799	EXPEDITED (15-DAY)		HO, OT	US-AMGEN-USASP2018000682		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Bite; Feeling Abnormal; Hospitalisation; Infection; Malaise; Nasopharyngitis;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oral Infection; Pain; Papule; Psoriasis; Rash; Rash Papular; Skin Infection; Skin Lesion; Tooth Disorder	Orthovisc	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Azithromycin	S			Not Reported
	Abx (Ambroxol Hydrochloride)	S	Unknown	Unk	Not Reported
	Mtx	C		Unk	Not Reported
	Folic Acid	C		Unk	Not Reported
	Cortisone Tylenol	C C		Unk	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14365755	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-158549		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Amiodarone			S	Unknown	Unk		Taro
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Doxorubicin			S	Intravenous (not otherwise specified)	106mg, Q2weeks		Sun
	Enoxaparin Sodium			S	Subcutaneous	40 Mg, Qd		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Sun
	Hydralazine			S	Intravenous (not otherwise specified)	10 Mg, Q4h		Mutual
	Methylprednisolone			S	Intravenous (not otherwise specified)	125mg, Q6hr		Not Reported
	Paclitaxel			S	Intravenous (not otherwise specified)	297mg, Q2weeks		Not Reported
	Pantoprazole			S	Intravenous (not otherwise specified)	8 Mg, Q1h		Sun
	Pms-Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported
	Digoxin			S	Intravenous (not	10 Mg, Q1h		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Digoxin	S	otherwise specified)	Intravenous (not otherwise specified)	0.25 Mg, Q4h	Not Reported
Diltiazem Cd	S	Oral	Unk	Not Reported	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50mg, Q6hr	Not Reported	Not Reported
Hydromorphone	S	Intravenous (not otherwise specified)	Unk	Not Reported	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5mg, Q6hr	Not Reported	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5mg, Q6hr	Not Reported	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Unk	Not Reported	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060mg, Q2weeks	Not Reported	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060mg, Q2weeks	Not Reported	Not Reported
Trastuzumab	S	Unknown		Not Reported	Not Reported
Filgrastim	C			Not Reported	Not Reported
Gabapentin	C			Not Reported	Not Reported
Metoclopramide	C			Not Reported	Not Reported
Ondansetron	C			Not Reported	Not Reported
Dexamethasone	C			Not Reported	Not Reported
Aprepitant	C			Not Reported	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2018	14368759	NON-EXPEDITED			US-PFIZER INC-2017546544			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	13241788	NON-EXPEDITED			US-PFIZER INC-2017068169			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Duricef			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Quinine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14246679	NON-EXPEDITED			US-PFIZER INC- 2017518113		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14290025	EXPEDITED (15-DAY)		OT	US-JAZZ-2017-US- 016515			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Lower Respiratory Tract Infection; Nasopharyngitis	Xyrem			S	Oral	1.5 G, Bid		Jazz	
	Xyrem			S	Oral	2.25 G, Bid		Jazz	
	Xyrem			S	Oral	Dose Adjustment		Jazz	
	Xyrem			S	Oral	4.5 G, Qd (First Dose)		Jazz	
	Xyrem			S	Oral	3.5 G, Qd (Second Dose)		Jazz	
	Z-Pak			S				Not Reported	
	Cetirizine Hcl			C		Unk		Not Reported	
	Chlorhexidine			C		Unk		Not Reported	
	Fluticasone Propionate			C		Unk		Not Reported	
	Ibuprofen			C		Unk		Not Reported	
	Modafinil			C		Unk		Not Reported	
	Viagra			C		Unk		Not Reported	
	Vitamin D3			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Vicodin	C		Unk		Not Reported
	Neurontin	C		Unk		Not Reported
	Amitriptyline Hcl	C		Unk		Not Reported
	Lipitor	C		Unk		Not Reported
	Pseudoephedrine	C		Unk		Not Reported
	Desoxyn	C		Unk		Not Reported
	Percocet /00446701/	C		Unk		Not Reported
	Tizanidine Hcl	C		Unk		Not Reported
	Tramadol Hcl	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14334149	NON-EXPEDITED			US-TEVA-2017-US-830179			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14340110	NON-EXPEDITED			US-TEVA-2017-US-833518			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Product Taste Abnormal	Azithromycin			S	Oral	200 Mg / 5 MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14351378	NON-EXPEDITED			US-PFIZER INC-2017553559		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
No Adverse Event	Tikosyn			S		125 Mg, 2x/Day, (A.M., P.M.)		Pfizer
	Calan			S		Unk		Pfizer
	Calan Sr			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Covera-Hs	S	Unk	Pfizer
Isoptin Sr	S	Unk	Pfizer
Septra	S	Unk	Pfizer
Zithromax	S	Unk	Pfizer
Tagamet	S	Unk	Not Reported
Tagamet Hb	S	Unk	Not Reported
Isoptin	S	Unk	Not Reported
Verelan	S	Unk	Not Reported
Verelan Pm	S	Unk	Not Reported
Tarka	S	Unk	Not Reported
Nizoral	S	Unk	Not Reported
Xolegel	S	Unk	Not Reported
Estina	S	Unk	Not Reported
Proloprim	S	Unk	Not Reported
Trimpex	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported
Sulfatrim	S	Unk	Not Reported
Compazine	S	Unk	Not Reported
Compro	S	Unk	Not Reported
Megace	S	Unk	Not Reported
Esidrix	S	Unk	Not Reported
Ezide	S	Unk	Not Reported
Hydrodiuril	S	Unk	Not Reported
Microzide	S	Unk	Not Reported
Oretic	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14369856	NON-EXPEDITED			US-DRREDDYS- USA/USA/17/0090879		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dizziness; Nausea; Overdose; Treatment Noncompliance	Habitrol	S	Transdermal	Not Reported
	Prednisone	S	Oral	Not Reported
	Z-Pack	S	Oral	Not Reported
	Spiriva	C	Unknown	Not Reported
	Lipitor	C	Unknown	Not Reported
	Vitamin B12	C	Unknown	Not Reported
	Vitamin D2	C	Unknown	Not Reported
	Enalapril	C	Unknown	Not Reported
	Hydrochlorothiazide	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370470	NON-EXPEDITED			US-PFIZER INC- 2018008876		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Bite; Feeling Abnormal; Infection; Malaise; Nasopharyngitis; Oral Infection; Pain; Papule; Psoriasis; Rash; Rash Papular; Skin Infection; Skin Lesion; Tooth Disorder	Enbrel			S	Unknown	50 Mg, Qwk		Unknown	
	Enbrel			S	Unknown	50 Mg, Qwk		Unknown	
	Enbrel			S	Unknown	50 Mg, Qwk		Unknown	
	Azithromycin			S	Unknown	Unk		Pfizer	
	Orthovisc			S	Unknown	Unk		Not Reported	
	Abx (Ambroxol Hydrochloride)			S	Unknown	Unk		Not Reported	
	Mtx			C		Unk		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Cortisone			C		Unk		Not Reported	
	Tylenol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370519	NON-EXPEDITED			US-PFIZER INC- 2018006825		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zoloft			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S		Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370556	NON-EXPEDITED			US-PFIZER INC-2018005681		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Clindamycin Phosphate				S		Unk		Pfizer
	Azithromycin				S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370651	NON-EXPEDITED			US-PFIZER INC-2018005640		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Zithromax				S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370695	NON-EXPEDITED			US-PFIZER INC-2018005203			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin				S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14370752	NON-EXPEDITED			US-PFIZER INC-2018009966			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371216	NON-EXPEDITED			US-PFIZER INC-2018011562		35 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371230	NON-EXPEDITED			US-PFIZER INC-2018011430		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371457	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP005024		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Exposure During Pregnancy; Pathogen Resistance	Ondansetron			S	Unknown	Unk		Apotex	
	Ondansetron			S				Apotex	
	Azithromycin			S	Oral	500 Mg, First Day		Apotex	
	Azithromycin			S	Oral	250 Mg, Day 2-5		Apotex	
	Cefuroxime			S	Oral	500 Mg, Bid		Apotex	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Bid		Not Reported	
	Enoxaparin			S	Subcutaneous	80 Mg, Bid		Not Reported	
	Ampicillin			S	Intravenous (not otherwise specified)	1 G, Every 4 Hour		Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)	1500 Mg, Bid, Total 9 Doses		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371468	NON-EXPEDITED		DS	US-TEVA-2018-US-844057			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deafness	Z Pack Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14371827	EXPEDITED (15-DAY)		LT	AU-GLENMARK PHARMACEUTICALS- 2017GMK030462		10 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Glenmark
	Lincomycin			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Prostacyclin			S	Respiratory (inhalation)	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14372184	EXPEDITED (15-DAY)		OT	ES-009507513- 1801ESP000620		26 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Betamethasone Acetate (+) Betamethasone Sodium Phosphate			S	Unknown	500 Mg, Q8h		Merck
	Azithromycin			S	Oral	1 G, Unk		Not Reported
	Oxytocin			S	Unknown			Not Reported
	Ampicillin			S	Unknown	2 G Ampicillin Then 1 G/6 H For 48 H		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2018	14372812	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2018008599		79 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acanthoma; Basal Cell Carcinoma	Novatrex	S	Oral	3 Df, Weekly (7 Day Interval)	Pfizer
	Roactemra	S	Intravenous (not otherwise specified)	280 Mg, (15 Day Interval)	Not Reported
	Avodart	C		Unk	Not Reported
	Orocal /00944201/	C		Unk	Not Reported
	Fosavance	C		Unk	Not Reported
	Speciafoldine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14316672	NON-EXPEDITED			US-PFIZER INC-2017541784		28 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14374631	EXPEDITED (15-DAY)		HO, LT, OT	CN-009507513-1801CHN002643		24 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Imipenem (+) Cilastatin Sodium			S		Unk		Merck	
	Moxifloxacin			S		Unk		Not Reported	
	Cefotaxime Sodium			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Cefuroxime Sodium			S		Unk		Not Reported	
	Cefminox Sodium			S		Unk		Not Reported	
	Oseltamivir			S		Unk		Not Reported	
	Oseltamivir			S		Unk		Not Reported	
	Vancomycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14374911	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-001270		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus; Rash Macular	Prednisone			S				Aurobindo	
	Azithromycine			S	Oral	()		Not Reported	
	Gentalline			S	Intravenous (not otherwise specified)	120 Mg, Once A Day		Not Reported	
	Celestamine /00252801/			S	Oral	()		Not Reported	
	Furosemide			C				Not Reported	
	Diffu K			C				Not Reported	
	Inexium /01479302/			C	Oral	()		Not Reported	
	Atovaquone			C				Not Reported	
	Tracleer /01587701/			C	Oral	()		Not Reported	
	Formoterol Fumarate Dihydrate			C	Respiratory (inhalation)	()		Not Reported	
	Tamoxifene Citrate			C	Oral	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14375023	EXPEDITED (15-DAY)		LT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-159652		10 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Meropenem			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Sun	
	Oseltamivir			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole, Trimethoprim			S	Unknown	Unk		Not Reported	
	Lincomycin			S	Unknown	Unk		Not Reported	
	Prostacyclin			S	Respiratory (inhalation)	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14375062	NON-EXPEDITED			US-PFIZER INC-2018012486		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14375428	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-001423			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Azithromycin			S	Transplacental	1 G, Unk		Aurobindo	
	Ampicillin			S	Transplacental	2 G (Then 1 G/6 H For 48 H)		Not Reported	
	Oxytocin Sandoz			S	Transplacental	Unk		Not Reported	
	Betamethasone			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2018	14377950	NON-EXPEDITED			US-TEVA-2018-US-844368			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Dysphagia; Fungal Infection; Lip Swelling; Muscle Spasms; Nausea; Pharyngeal Swelling; Pyrexia; Rash; Swollen Tongue; Tinnitus; Urticaria; Vaginal Discharge; Vulvovaginal Burning Sensation; Vulvovaginal Pain	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	13844867	NON-EXPEDITED			US-PFIZER INC-2017340653			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14318145	EXPEDITED (15-DAY)		OT	ES-009507513-1712ESP007158		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Betamethasone			S	Unknown	500 G, Q8h		Merck	
	Ampicillin			S	Intravenous (not otherwise specified)	2g Followed By 1 G Every 6 Hours		Not Reported	
	Ampicillin			S	Intravenous (not otherwise specified)	1 G, Q6h		Not Reported	
	Azithromycin			S	Oral	1g In Monodosis		Not Reported	
	Oxytocin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379834	NON-EXPEDITED			US-PFIZER INC-2018011232			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Visual Impairment	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379853	NON-EXPEDITED			US-PFIZER INC-2018011059		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379892	NON-EXPEDITED			US-PFIZER INC-2018014045			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379893	NON-EXPEDITED			US-PFIZER INC-2018013938			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Skin Exfoliation	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14379911	EXPEDITED (15-DAY)		DE, HO, LT, OT	CN-STRIDES ARCOLAB LIMITED-2018SP000184			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Vancomycin			S	Intravenous (not otherwise specified)	Unknown		Strides	
	Vancomycin			S	Intravenous (not otherwise specified)	Unknown		Strides	
	Cefotaxime			S	Unknown	Unknown		Not Reported	
	Azithromycin			S	Unknown	Unknown		Not Reported	
	Cefuroxime Sodium			S	Unknown	Unknown		Not Reported	
	Cilastatin Sodium, Imipenem			S	Unknown	Unknown		Not Reported	
	Cefminox Sodium			S	Unknown	Unknown		Not Reported	
	Oseltamivir			S	Unknown	Unknown		Not Reported	
	Oseltamivir			S	Unknown	Unknown		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Osetamivir		S	Unknown	Unknown			Not Reported	
	Moxifloxacin		S	Unknown	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14381600	NON-EXPEDITED			US-PFIZER INC-2018014169			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14381842	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2018015706		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Ceftriaxone Sodium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Fluconazole			S		Unk		Pfizer	
	Caspofungin			S		Unk		Not Reported	
	Oxygen			C		3 L/Minute Of Supplemental		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14382047	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1002850		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Azithromycin			S	Oral	1 G, Unk		Not Reported	
	Betamethasone			S	Unknown	500 Mg, Q8h		Not Reported	
	Ampicillin			S	Unknown	Unk		Not Reported	
	Oxytocin			S	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14392416	DIRECT		HO, OT			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Cough; Heart Rate Increased; Ill-Defined Disorder; Influenza; Nasopharyngitis; Palpitations; Pericardial Effusion; Pneumonia; Pyrexia	Azithromycin			S	Oral	Quantity:2 Tablet(S);		Teva	
	Benicar			C				Not Reported	
	Advair			C				Not Reported	
	Combivent			C				Not Reported	
	Albuterol			C				Not Reported	
	Flonase			C				Not Reported	
	A-Z Minerals			C				Not Reported	
	Probiotics			C				Not Reported	
	Bone Broth Protein Powder			C				Not Reported	
	Hawthorne Berry Powder			C				Not Reported	
	Olive Leaf Powder			C				Not Reported	
	Vitamin E			C				Not Reported	
	Fish Oil			C				Not Reported	
	Quercetin Complex			C				Not Reported	
	Nac			C				Not Reported	
	Vital Reds			C				Not Reported	
	Peptace Fish Peptides			C				Not Reported	
	Lipotropic Enzymes			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14392553	DIRECT					61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Taste Disorder	Azithromicine			S	Oral	Quantity:1 Tablet(S);		Not Reported	
	Crestor			C				Not Reported	
	Sinthroid			C				Not Reported	
	Water Pill			C				Not Reported	
	Coq10			C				Not Reported	
	Vitamin C			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2018	14393128	DIRECT	Y	HO, RI			83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Wall Haematoma; Constipation; Haemoglobin Decreased; International Normalised Ratio Increased; Therapy Cessation; Upper Respiratory Tract Infection	Warfarin Azithromycin			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14383276	EXPEDITED (15-DAY)		HO	ES-CIPLA LTD.- 2018ES00314			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Eosinophilic Pleural Effusion	Levofloxacin			S	Oral	500 Mg, Per Day		Cipla	
	Amoxicillin/Clavulanic Acid			S	Oral	1.1.1		Not Reported	
	Azithromycin			S	Oral	1 Cp, Per Day		Not Reported	
	Allopurinol			S	Oral	1 Cp, Per Day		Cipla	
	Hidroferol 266			C	Oral	1 Amp		Not Reported	
	Astudir 10			C	Oral	1-0-0		Not Reported	
	Valsartan/Hct 32/12.5			C	Oral	1-0-0		Not Reported	
	Tamsulosina			C	Oral	1 Cp		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14383995	NON-EXPEDITED			US-PFIZER INC- 2018011276		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vertigo; Visual Impairment	Azithromycin			S	Oral	500 Mg, Daily (Two Tablets The First Day)		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	250 Mg, 1x/Day (One Tablet The Next Four Days)	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14384422	NON-EXPEDITED			US-PFIZER INC-2018016460			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lipitor			S		Unk		Pfizer
	Heparin Sodium			S		Unk		Unknown
	Neurontin			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14384427	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-154338		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Babesiosis; Drug Resistance; Gene Mutation; Treatment Failure	Azithromycin			S	Unknown	500 Mg, Daily		Sun
	Azithromycin			S	Unknown	1000 Mg, Daily		Sun
	Atovaquone			S	Unknown	750 Mg, Bid		Not Reported
	Atovaquone			S	Unknown	1750 Mg, Daily		Not Reported
	Rituximab			S	Unknown	Unk Unk, 1/Week		Not Reported
	Doxycycline			C	Unknown	100 Mg, Bid		Not Reported
	Proguanil			C	Unknown	400 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2018	14384969	EXPEDITED (15-DAY)		HO, OT	PL-MYLANLABS-2018M1001596		35 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bacterial Infection; Condition Aggravated; Drug Resistance; Immunodeficiency Common Variable; Intentional Product Misuse; Meningism; Neisseria Infection; Neuropathy Peripheral; Periodontitis; Pharyngitis Streptococcal; Pneumococcal Infection; Pneumonia; Staphylococcal Infection; Stomatococcal Infection; Streptococcal Infection; Veillonella Infection	Amoxicillin/Clavulanic Acid	S	Unknown	1000/200mg Three Times A Day	Not Reported
	Azithromycin	S	Unknown	500 Mg, Unk	Not Reported
	Cefadroxil	S	Unknown	500 Mg, Unk	Mylan
	Ceftriaxone	S	Unknown	1000 Mg, Unk	Mylan
	Prednisolone	C	Unknown	Up To 120 Mg/Day	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	13931329	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS- 2017M1054404		1 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bk Virus Infection;	Pranlukast			S	Unknown	Unk		Not Reported
Cytomegalovirus Infection	Pranlukast			S	Unknown	Unk		Not Reported
Reactivation; Drug	Azithromycin			S	Oral	??		Not Reported
Reaction With Eosinophilia	Azithromycin			S	Unknown			Not Reported
And Systemic Symptoms;	Azithromycin			S				Not Reported
Hypoxia; Infection	Bifidobacterium Lactis			C	Oral	??		Not Reported
Reactivation; Multiple	Ambroxol Hydrochloride			C	Oral	??		Not Reported
Organ Dysfunction	Pranlukast			C	Oral	??		Not Reported
Syndrome; Pyrexia; Rash	Tipepidine Hibenazate			C	Oral	??		Not Reported
	Budesonide			C	Oral	??		Not Reported
	Mucodyne			C	Unknown	Unk		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14182957	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK172402			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal; Blood Pressure Increased; Body Temperature Increased; Cataract; Cough; Drug Dependence; Heart Rate Increased; Lung Diffusion Test Decreased; Nasal Disorder; Nasopharyngitis; Obstructive Airways Disorder; Pyrexia; Restrictive Pulmonary Disease; Therapeutic Response Decreased; Type 2 Diabetes Mellitus	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline	
	Advair			S		1 Puff(S), Bid		Glaxosmithkline	
	Azithromycin			S	Oral	250 Mg, 3 Times A Week		Glaxosmithkline	
	Spiriva			S		18 Ug, Qd		Not Reported	
	Zenhale			S		2 Puff(S), Bid		Not Reported	
	Prednisone			S	Oral	8 Mg, Qd		Not Reported	
	Rosuvastatin			C		Unk		Glaxosmithkline	
	Cetirizine			C		20 Mg, Qd		Glaxosmithkline	
	Pariet			C		Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14380842	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1002664			Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Betamethasone Mylan			S	Transplacental	Unk		Mylan	
	Ampicillin			S	Transplacental	2 G (Then 1 G/6 H For 48 H)		Not Reported	
	Ampicillin			S	Transplacental	1 G, Qid		Not Reported	
	Azithromycin			S	Transplacental	1 G, Unk		Not Reported	
	Oxytocin Sandoz			S	Transplacental	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391017	NON-EXPEDITED			US-PFIZER INC-2018016598		44 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391085	NON-EXPEDITED			US-PFIZER INC-2018017981		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Protonix			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391438	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1001033			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Azithromycin			S	Transplacental	1 G, Unk		Not Reported	
	Betamethasone			S	Transplacental			Not Reported	
	Ampicillin			S	Transplacental	2 G, Unk ((Then 1 G/6 H For 48 H))		Not Reported	
	Oxytocin Sandoz			S	Transplacental			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14391616	NON-EXPEDITED			US-PFIZER INC-2018016785			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14394626	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018013441		71 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Amnesia; Balance Disorder; Delirium; Diarrhoea; Hallucination	Zithromax	S	Oral	2 Df, 1x/Day	Pfizer
	Dimetan	S	Oral	Unk	Not Reported
	Pivalone /00803802/	C			Not Reported
	Cortancyl	C			Not Reported
	Paracetamol	C			Not Reported
	Temesta (Lorazepam)	C			Not Reported
	Levothyrox	C			Not Reported
	Calcidose /00944201/	C			Not Reported
	Pantoprazole	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2018	14394638	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018012953		58 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchial Carcinoma	Novatrex			S	Oral	3 Df, Weekly		Pfizer
	Remicade			S	Intravenous drip	400 Mg, Unk, 85th Perfusion		Not Reported
	Pantoprazole			C				Not Reported
	Naproxene			C				Not Reported
	Tramadol			C				Not Reported
	Uvedose			C				Not Reported
	Cortancyl			C				Not Reported
	Imovane			C				Not Reported
	Atenolol			C				Not Reported
	Cotareg			C		160 Mg/25 Mg (Frequency Not Specified)		Not Reported
	Kardegic			C				Not Reported
	Speciafoldine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	11120386	NON-EXPEDITED			US-PFIZER INC-2015162104			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14343107	EXPEDITED (15-DAY)		HO, LT	PHHY2017DE193511		77 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphasia; Asphyxia; Dyspnoea; Stress Cardiomyopathy; Troponin Increased	Azithromycin - 1 A Pharma			S	Unknown	1 Df, Qd,		Novartis	
	Azithromycin - 1 A Pharma			S				Novartis	
	Azithromycin - 1 A Pharma			S				Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14399481	NON-EXPEDITED			US-JNJFOC- 20171227699		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Diflucan		Y	S	Unknown			Not Reported	
	Codeine Phosphate			S	Unknown			Not Reported	
	Effexor			S	Unknown			Not Reported	
	Morphine Sulfate			S	Unknown			Not Reported	
	Nitroglycerin			S	Unknown			Not Reported	
	Solu-Medrol			S	Unknown			Not Reported	
	Metaxalone			S	Unknown			Not Reported	
	Talwin			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Ambien			S	Unknown			Not Reported	
	Advair			S	Unknown			Not Reported	
	Albuterol			S	Unknown			Not Reported	
	Allegra			S	Unknown			Not Reported	
	Allegra D			S	Unknown			Not Reported	
	Amerge			S	Unknown			Not Reported	
	Bentyl			S	Unknown			Not Reported	
	Biaxin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Betadine		S	Unknown	Not Reported
Benadryl	Y	S	Unknown	Not Reported
Buspar		S	Unknown	Not Reported
Chloraseptic		S	Unknown	Not Reported
Decadron		S	Unknown	Not Reported
Elavil		S	Unknown	Not Reported
Flexeril		S	Unknown	Not Reported
Imitrex		S	Unknown	Not Reported
Luvox		S	Unknown	Not Reported
Methazone		S	Unknown	Not Reported
Macrodantin		S	Unknown	Not Reported
Prozac		S	Unknown	Not Reported
Parafon Forte		S	Unknown	Not Reported
Soma		S	Unknown	Not Reported
Serzone		S	Unknown	Not Reported
Uni-Dur		S	Unknown	Not Reported
Unna Boot Bandage		S	Unknown	Not Reported
Ultram		S	Unknown	Not Reported
Versed		S	Unknown	Not Reported
Wygesic		S	Unknown	Not Reported
Zyflo		S	Unknown	Not Reported
Zomig		S	Unknown	Not Reported
Zoto Hc		S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2018	14401132	NON-EXPEDITED			US-PFIZER INC-2018016115			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14401142	NON-EXPEDITED			US-PFIZER INC-2018017116		38 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14402315	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018019862		11 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Resistance; Rheumatic Fever	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Diphenhydramine			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14402316	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018019901		13 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Resistance; Rheumatic Fever	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2018	14404223	NON-EXPEDITED			US-PFIZER INC-2018021850			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Enbrel			C		50 Mg, Weekly		Not Reported	
	Enbrel			C		50 Mg, Qmo		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	13138801	NON-EXPEDITED			US-PFIZER INC-2017025084		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14351380	NON-EXPEDITED			US-PFIZER INC-2017553112			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Secretion Discharge	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14355247	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2018000945		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Eosinophilic Pleural Effusion	Azithromycin			S	Oral	1 Tablet Of 500 Mg Once A Day		Pfizer	
	Levofloxacin			S	Oral	500 Mg, 1x/Day		Not Reported	
	Amoxicillin W/Clavulanic Acid			S	Oral	875 Mg/125 Mg (1.1.1)		Not Reported	
	Allopurinol			S	Oral	1 Tablet Of 300 Mg Once A Day		Not Reported	
	Hidroferol			C	Oral	1 Ampoule Of 266 Ug		Not Reported	
	Valsartan/Hydrochloorthiazide			C	Oral	32/12.5 (1-0-0)		Not Reported	
	Tamsulosina			C	Oral	1 Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14365999	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2017-DE-842383		1 YR	Male	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Prednisone			S	Unknown			Actavis
	Dexamethasone			S	Unknown	10 Mg/M2 For 21 Days Then Tapering		Actavis
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Teva
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported
	Sodium Chloride			S	Nasal	0.9% Nose Spray		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Not Reported
	Voriconazole			S	Other			Not Reported
	Pegylated Asparaginase			S	Unknown			Not Reported
	Liposomal Amphotericin B			S	Unknown	4 Mg/Kg/Day		Not Reported
	Vincristine			C	Unknown			Not Reported
	Daunorubicin			C	Unknown			Not Reported
	Methotrexate			C	Intrathecal			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14405364	EXPEDITED (15-DAY)		DE, HO, OT	AU-APOTEX- 2018AP005524		10 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Meropenem			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Apotex
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Lincomycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Oseltamivir	S	Unknown	Unk	Not Reported
	Sulfamethoxazole	S	Unknown	Unk	Not Reported
	W/Trimethoprim				
	Norepinephrine	C	Unknown	Unk	Not Reported
	Epinephrine	C	Unknown	Unk	Not Reported
	Vasopressin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14406389	EXPEDITED (15-DAY)		DE, HO, LT, OT	CN- GLAXOSMITHKLINE- CN2018GSK007337		24 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Moxifloxacin			S	Unknown	Unk		Glaxosmithkline
	Azithromycin			S	Unknown	Unk		Glaxosmithkline
	Cefuroxime Sodium			S	Unknown	Unk		Glaxosmithkline
	Vancomycin			S		Unk		Glaxosmithkline
	Cefotaxime			S		Unk		Not Reported
	Imipenem + Cilastatin Sodium			S		Unk		Not Reported
	Cefminox Sodium			S		Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported
	Oseltamivir			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2018	14407281	EXPEDITED (15-DAY)		HO	PL-TEVA-2018-PL- 846482		35 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Infection; Condition Aggravated; Drug Resistance; Immunodeficiency Common Variable; Intentional Product Misuse; Meningism;	Azithromycin			S	Unknown			Not Reported
	Amoxicillin			S	Unknown	1000mg Three Times A Day		Not Reported
	Clavulanate			S	Unknown	200mg Three Times A Day		Not Reported
	Cefadroxil			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neisseria Infection; Neuropathy Peripheral; Periodontitis; Pharyngitis Streptococcal; Pneumococcal Infection; Pneumonia; Staphylococcal Infection; Stomatococcal Infection; Streptococcal Infection; Veillonella Infection	Ceftriaxone Prednisolone	S C	Unknown Unknown					Not Reported Not Reported
				Up To 120 Mg/Day				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	10654831	NON-EXPEDITED			US-PFIZER INC- 2014342878			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14409985	NON-EXPEDITED			US-PFIZER INC- 2018022367			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14410050	NON-EXPEDITED			US-PFIZER INC- 2018022764			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14411661	EXPEDITED (15-DAY)		HO, LT, OT	EG-PFIZER INC- 2018023924		60 YR	Male	EGY

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Respiratory Distress	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, 1 Per 1 Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2018	14413850	EXPEDITED (15-DAY)		HO	DE-IMPAX LABORATORIES, INC- 2018-IPXL-00098		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Flushing; Hypotension; Vomiting	Omeprazole Delayed Release			S	Oral	Unk		Impax	
	Omeprazole Delayed Release			S	Oral	1 Tablet, Unk		Impax	
	Azithromycin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2018	14414307	EXPEDITED (15-DAY)		DE, DS, HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-160570		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Azithromycin			S	Oral	1 Cp Dia		Sun	
	Rivaroxaban (8281a)			S	Oral	1 Cp Dia		Not Reported	
	Amiodarona 200 Mg			S	Oral	1 Cp Cada 8h		Not Reported	
	Cefditoreno (7358a)			S	Oral	400 Mg Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14417773	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018025809		47 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Melaena; Nausea	Azithromycin			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14418163	EXPEDITED (15-DAY)		DE, DS, HO	ES-JNJFOC-20180123562		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Xarelto			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Amiodarone Hydrochloride			S	Oral			Not Reported	
	Cefditoren			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14418209	NON-EXPEDITED			US-PFIZER INC-2018022557		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Mood Swings; Rhinorrhoea	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14419988	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018025638			Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Deafness; Product Use In Unapproved Indication; Tonsillitis	Zitromax			S		1.5 MI, Unk		Pfizer	
	Flixotide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14420017	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018025078		73 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Zithromac 250mg			S	Oral	2 Df, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novorapid	C	Unk	Not Reported
Tresiba	C	Unk	Not Reported
Camostat Mesilate	C	Unk	Not Reported
Excelase	C	Unk	Not Reported
Bio-Three	C	Unk	Not Reported
Nexium	C	Unk	Not Reported
Rebamipide	C	Unk	Not Reported
Posterisan	C	Unk	Not Reported
Xeloda	C	Unk	Not Reported
Avolve	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2018	14425757	DIRECT		OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Emotional Disorder; Major Depression; Paranoia; Suicidal Ideation	Azithromycin			S	Oral	Quantity:6 Tablet(S);Other Frequency:2 1st Day Then 1/D;		Teva	
	Lithium			C				Not Reported	
	Wellbutrin			C				Not Reported	
	Protonix			C				Not Reported	
	Fish Oil			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Magnesium			C				Not Reported	
	Ibuprofen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	12649445	EXPEDITED (15-DAY)		OT	CA-009507513-1608CAN005855		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction;	Cancidas			S	Intravenous (not otherwise specified)			Merck	
	Montelukast Sodium			S	Oral			Merck	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Solar Lentigo; Squamous Cell Carcinoma Of Skin	Prednisone	S	Oral		Merck
	Nifedipine	S	Oral		Not Reported
	Azithromycin	S	Oral		Not Reported
	Ciprofloxacin Hydrochloride	S	Oral	Unk	Not Reported
	Mycophenolate Mofetil	S	Oral		Not Reported
	Pantoprazole Sodium	S	Oral		Not Reported
	Tacrolimus	S	Oral		Not Reported
	Sulfamethoxazole (+) Trimethoprim	S	Oral	Unk	Not Reported
	Voriconazole	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	13027302	NON-EXPEDITED			US-PFIZER INC-2016568595		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Ceclor			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14419243	EXPEDITED (15-DAY)		DE, DS, HO	ES-PFIZER INC-2018026406		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Amiodarone Hcl			S	Oral	200 Mg, 3x/Day		Pfizer
	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer
	Cefditoren			S	Oral	400 Mg, 1x/Day		Not Reported
	Rivaroxaban			S	Oral	1 Df, 1x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14422394	EXPEDITED (15-DAY)		OT	PL-WEST-WARD PHARMACEUTICALS CORP.-PL-H14001-18- 00		35 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance; Superinfection Bacterial	Amoxicillin Clavulanic Acid			S	Unknown	1000 Mg, Tid		Hikma	
	Cefadroxil Monohydrate			S	Unknown	500 Mg, Bid		Not Reported	
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
	Ceftriaxone			S	Unknown	1000 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14422924	NON-EXPEDITED			US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-133091			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrooesophageal Reflux Disease	Salbutamol			S	Unknown	Unk		Mutual	
	Z-Pack			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2018	14430739	DIRECT		OT			37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Panic Attack	Azithromycin, Zithromax			S	Oral	Quantity:2 Tablet(S);		Teva	
	Mylantaa			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2018	6432065	EXPEDITED (15-DAY)		HO	GB-BAUSCH- 2007BL003458		19 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Gentamicin Sulfate			S	Intravenous (not			Bausch And Lomb	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Balance Disorder; Blood Creatinine Increased; Deafness Neurosensory; Dizziness; Tinnitus; Toxicity To Various Agents	Gentamicin Sulfate	S	otherwise specified)						Bausch And Lomb
	Tobramycin	S	Intravenous (not otherwise specified)						Bausch And Lomb
	Tobramycin	S	Intravenous (not otherwise specified)		7.6 Mg/Kg/Day				Bausch And Lomb
	Tobramycin	S	Intravenous (not otherwise specified)						Bausch And Lomb
	Azithromycin	S	Unknown						Not Reported
	Meropenem	S	Unknown						Not Reported
	Meropenem	S	Unknown						Not Reported
	Meropenem	S	Unknown						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2018	14430787	EXPEDITED (15-DAY)		DE, HO, OT	JP-ASPEN-JPG2018JP000370			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchopulmonary Aspergillosis	Dexamethasone			S		6.6 Mg, Qd		Aspen
	Ceftriaxone Sodium			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Insulin Human			C	Unknown	10 U In The Morning And 6 U In The Early Evening		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2018	14434423	EXPEDITED (15-DAY)		DE, DS, HO	ES-MYLANLABS-2018M1005090		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Azithromycin			S	Oral	1 Cp Dia		Not Reported
	Rivaroxaban			S	Oral	20 Mg, Qd, 1 Cp Dia		Mylan
	Amiodarona /00133101/			S	Oral	200 Mg, Q8h, 1 Cp Cada		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefditoreno (7358a)

S

Oral

400 Mg, Qd, Dia

Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	13636489	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1945655		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Pressure Increased; Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Pyrexia; Sputum Discoloured	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Amlodipine			S	Oral			Not Reported
	Azithromycin Sandoz			S	Oral	1 Df, Qd		Not Reported
	Azithromycin Sandoz			S	Oral			Not Reported
	Azithromycin Sandoz			S	Oral			Not Reported
	Advair			C	Respiratory (inhalation)	Unk		Not Reported
	Ventolin			C	Respiratory (inhalation)	Unk		Not Reported
	Spiriva			C	Respiratory (inhalation)	Unk		Not Reported
	Brilinta			C	Oral	Unk		Not Reported
	Hydrochlorothiazide			C	Oral	Unk		Not Reported
	Pantoprazole			C	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asa	C	Oral	Not Reported
Singulair	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	13637950	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA163614		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Pressure	Xolair			S	Subcutaneous	225 Mg, Biw		Not Reported
Systolic Increased; Cough;	Xolair			S	Subcutaneous	Unk		Not Reported
Dizziness; Drug	Xolair			S	Subcutaneous	Unk		Not Reported
Ineffective; Dyspnoea;	Xolair			S	Subcutaneous	Unk		Not Reported
Epistaxis; Epistaxis;	Xolair			S	Subcutaneous	Unk		Not Reported
Forced Expiratory Volume	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Forced Vital	Xolair			S	Subcutaneous	Unk		Not Reported
Capacity Decreased;	Xolair			S	Subcutaneous	Unk		Not Reported
Headache; Lung Disorder;	Xolair			S	Subcutaneous	Unk		Not Reported
Malaise; Nasopharyngitis;	Xolair			S	Subcutaneous	Unk		Not Reported
Oxygen Saturation	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Pyrexia;	Xolair			S	Subcutaneous	Unk		Not Reported
Sputum Discoloured	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Amlodipine Sandoz			S	Oral	1 Df, Qd		Not Reported
	Azithromycin Sandoz			S	Oral	3 Df, Unk		Not Reported
	Advair			C	Respiratory (inhalation)	1 Df, Bid		Not Reported
	Ventolin			C	Respiratory (inhalation)	2 Df, Unk		Not Reported
	Spiriva			C	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Brilinta			C	Oral	1 Df, Qd		Not Reported
	Hydrochlorothiazid			C	Oral	1 Df, Qd		Not Reported
	Mylan Pantoprazole			C	Oral	1 Df, Qd		Not Reported
	Asa			C	Oral	1 Df, Qd		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Singulair			C	Oral	1 Df, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14362386	EXPEDITED (15-DAY)		OT	ES-009507513-1801ESP000172			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Betamethasone			S	Transplacental	500 Mg, Q8h		Merck	
	Azithromycin			S	Transplacental	1 G, Unk		Not Reported	
	Ampicillin			S	Transplacental	2 G Ampicillin Then 1 G/6 H For 48 H		Not Reported	
	Oxytocin			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14434933	NON-EXPEDITED			US-TEVA-2018-US-843057			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14435656	EXPEDITED (15-DAY)		OT	ES-009507513-1801ESP009260		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Betamethasone			S	Unknown	500 Mg, Q8h		Merck	
	Azithromycin			S	Oral	1 G, Unk		Not Reported	
	Ampicillin			S	Unknown	2 G Ampicillin Then 1 G/6 H For 48 H		Not Reported	
	Oxytocin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14436606	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-002504		47 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Diarrhoea; Melaena; Nausea	Azithromycin			S	Oral	()		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14436794	EXPEDITED (15-DAY)		DE, DS, HO	ES-AUROBINDO-AUR- APL-2018-002559		61 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Azithromycin			S	Oral	1 Cp Dia ()		Aurobindo	
	Rivaroxaban			S	Oral	1 Cp Dia		Not Reported	
	Amiodarona /00133101/			S	Oral	1 Cp Cada 8h		Not Reported	
	Cefditoreno			S	Oral	400 Mg Dia		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14438313	NON-EXPEDITED			US-PFIZER INC- 2018033250		64 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14438349	NON-EXPEDITED			US-PFIZER INC- 2018032661		75 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jan-2018	14438631	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2018-003032		26 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Azithromycin	S	Oral	1 G, Unk	Aurobindo
	Ampicillin	S	Unknown	2 G Ampicillin Then 1 G/6 H For 48 H	Not Reported
	Betamethasone	S	Unknown	500 Mg, Q8h	Not Reported
	Oxytocin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2018	14438988	NON-EXPEDITED			US-PFIZER INC- 2018029188			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Xeljanz Xr			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14382246	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2017550520			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Low Birth Weight Baby; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	1 G, Unk		Pfizer	
	Betamethasone			S	Transplacental	500 Mg, 3x/Day(Every 8 Hours)		Not Reported	
	Ampicillin Trihydrate			S	Transplacental	2 G Ampicillin Then 1 G/6 H For 48 H		Not Reported	
	Oxytocin			S	Transplacental			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14444644	EXPEDITED (15-DAY)		OT	US-BAXTER- 2018BAX002708		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tubulointerstitial Nephritis	Ceftriaxone Injection, Usp (In Dextrose)			S	Unknown			Baxter	
	Ceftriaxone Injection, Usp (In			S				Baxter	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dextrose)									
Azithromycin		S		Unknown					Not Reported
Azithromycin		S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14445079	NON-EXPEDITED			US-PFIZER INC-2018034282		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14446764	NON-EXPEDITED			US-PFIZER INC-2018034063			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer
	Enbrel			C		Unk Unk, Weekly		Not Reported
	Enbrel			C		Unk, Weekly		Not Reported
	Methotrexate			C	Unknown	Unk		Not Reported
	Folate			C	Unknown	Unk, 1x/Day		Not Reported
	Naproxen			C		Unk, Once Or Twice Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14447102	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-V-DE-2007-1515		19 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Azithromycin			S		Unk		Not Reported
Balance Disorder; Blood	Tobramycin			S		140 Mg, Unk		Not Reported
Creatinine Increased;	Tobramycin			S		80 Mg, Unk		Not Reported
Deafness Neurosensory;	Tobramycin			S	Intravenous (not otherwise specified)	420 Mg, Qd		Not Reported
Dizziness; Off Label Use;	Tobramycin			S				Not Reported
Tinnitus; Toxicity To	Gentamicin			S		120 Mg, Unk		Mylan
Various Agents								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gentamicin	S	120 Mg, Unk	Mylan
Gentamicin	S	240 Mg, Qd	Mylan
Gentamicin	S	360 Mg, Qd	Mylan
Meropenem	S	1 G, Unk	Mylan
Meropenem	S	3 G, Qd	Mylan
Meropenem	S	3 G, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2018	14448114	EXPEDITED (15-DAY)		HO	US- ELI_LILLY_AND_COMP ANY-US201801006286		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Feeling Abnormal; Heart Rate Increased; Myalgia; Vascular Stent Occlusion; Vascular Stent Occlusion	Cialis			S	Unknown	Unk Unk, Unknown		Not Reported	
	Azithromycin			S	Unknown	Unk, Unknown		Not Reported	
	Zocor			C		20 Mg, Unk		Not Reported	
	Metformin			C		500 Mg, Daily		Not Reported	
	Viagra			C		50 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	13981348	NON-EXPEDITED			US-PFIZER INC- 2017396935		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Vistaril			S		Unk		Pfizer	
	Betadine			S		Unk		Not Reported	
	Nubain			S		Unk		Not Reported	
	Stadol			S		Unk		Not Reported	
	Imitrex			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14133795	NON-EXPEDITED			US-PFIZER INC-2017460906			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Influenza Vaccine			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14328166	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2017546280		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Cavity Infection; Pathogen Resistance	Azithromycin			S	Oral	1 G, Unk (1g In Monodosis)		Pfizer	
	Betamethasone			S		500 Mg, 3x/Day (Every 8 Hours)		Not Reported	
	Ampicillin Trihydrate			S	Intravenous (not otherwise specified)	2 G Ampicillin Then 1 G/6 H For 48 H		Not Reported	
	Oxytocin			S	Intravenous (not otherwise specified)	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14452486	NON-EXPEDITED			US-PFIZER INC-2018036760			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14452489	NON-EXPEDITED			US-PFIZER INC-2018035360			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cleocin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14452541	NON-EXPEDITED			US-PFIZER INC-2018037414		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14453326	EXPEDITED (15-DAY)		HO	PHHY2017FR199841		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Venoocclusive Disease	Azithromycin			S	Oral	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14453512	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017533329		73 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
	Novorapid			C	Subcutaneous	6 Df, 3x/Day		Not Reported	
	Tresiba			C	Subcutaneous	4-6 Units Thrice Daily		Not Reported	
	Camostat Mesilate			C	Oral	100 Mg, 1x/Day		Not Reported	
	Excelase			C	Oral	Unk Unk, 3x/Day		Not Reported	
	Bio-Three			C	Oral	Unk Unk, 3x/Day		Not Reported	
	Nexium			C	Oral	20 Mg, 1x/Day		Not Reported	
	Rebamipide			C	Oral	100 Mg, 3x/Day		Not Reported	
	Posterisan Forte /01567801/			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xeloda		C	Oral	1500 Mg, 2x/Day			Not Reported	
	Avolve		C	Oral	0.5 Mg, 1x/Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14453903	NON-EXPEDITED			US-PFIZER INC-2018035289			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14454164	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018033988		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Cholestasis	Novatrex			S		7.5 Mg, Unk		Pfizer	
	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported	
	Prednisolone			S	Oral	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14455052	NON-EXPEDITED			US-PFIZER INC-2018039525			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2018	14459676	DIRECT	Y	HO			62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral			Not Reported	
	Rosuvastatin			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ezetimibe			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14456812	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-160754		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Ampicillin			S	Unknown	2 G Ampicillin Then 1 G/6 H For 48 H		Not Reported	
	Azithromycin			S	Oral	1 G, Unk		Sun	
	Betamethasone			S	Unknown	500mg, Tid (Q8h)		Taro	
	Betamethasone			S		Unk		Taro	
	Oxytocin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14456879	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-00358		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Kidney Fibrosis; Renal Tubular Injury; Tubulointerstitial Nephritis	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14457531	NON-EXPEDITED			US-PFIZER INC- 2018037492		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14457638	NON-EXPEDITED			US-PFIZER INC- 2018040988		44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14458349	NON-EXPEDITED		HO, OT	US-ACORDA- ACO_134900_2017		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nasopharyngitis; Sinusitis; Wrist Fracture	Ampyra			S	Oral	10 Mg, Bid		Acorda	
	Z-Pak			S	Unknown	Unk		Not Reported	
	Z-Pak			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14459547	EXPEDITED (15-DAY)		OT	PHHY2017IT165756		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Oral	1 Df, Total (1 Ug/Litre)		Novartis	
	Omeprazole			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14460708	NON-EXPEDITED			US-PFIZER INC- 2018036758			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2018	14461453	NON-EXPEDITED			US-PFIZER INC- 2018038852			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	13279043	NON-EXPEDITED			US-ALLERGAN-1700923US		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Hypersensitivity	Savella			S				Allergan	
	Lyrica			S		225 Mg, Bid		Not Reported	
	Zithromax			S				Not Reported	
	Zyrtec			S	Oral	1 Tablet, Qd		Not Reported	
	Lipitor			S	Oral	Take 1 Tablet, Qd		Not Reported	
	Tessalon Perle			S	Oral	1-2 Capsules 3 Times, Daily, Prn		Not Reported	
	Albuterol			C	Respiratory (inhalation)	Inhale 2 Puffs Into The Lungs Every 4 Hours, Prn		Not Reported	
	Ascorbic Acid			C	Oral	500 Mg, Qd		Not Reported	
	Aspirin			C	Oral	81 Mg, Qd		Not Reported	
	Lipitor			C		Unk		Not Reported	
	Canagliflozin			C	Oral	1 Tablet Before Breakfast, Qd		Not Reported	
	Temovate			C		Apply Ato Affected Area Twice Daily, Prn		Not Reported	
	Krill Oil			C	Oral	1 Capsule, Qd		Not Reported	
	Flonase			C	Nasal	1 Spray, Bid		Not Reported	
	Folvite			C	Oral	800 Mg, Qd		Not Reported	
	Novolog			C		30 Units With Breakfast, 20 Units With Lunch, And 30 Units With Evening Meal, Tid		Not Reported	
	Lantus			C	Subcutaneous	45 Units, Bid		Not Reported	
	Nizoral			C		Apply To Groin Twice Daily, Prn		Not Reported	
	Nizoral			C		Use To Wash Hair, Qd, X 4 Weeks		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	L-Lysine	C	Oral	500 Mg, Qd	Not Reported
	Acidophilus	C		As Directed	Not Reported
	Lisinopril	C	Oral	20 Mg, Qd	Not Reported
	Mobic	C	Oral	7.5 Mg, Qd	Not Reported
	Glucophage	C		1000 Mg, Bid, With Meals	Not Reported
	Prilosec	C	Oral	20 Mg, Qd	Not Reported
	Ultram	C	Oral	2 Tabs, Tid	Not Reported
	Kenalog	C		Apply To Affected Area Twice Daily, Prn	Not Reported
	Cyanocobalamin	C	Intramuscular	1000 Mg/MI, Q Month	Not Reported
	Calcium	C		400 Mg, X2	Not Reported
	D3	C		500 Iu, X2	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14326296	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-157544		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S	Unknown	500 Mg, Single		Sun
	Methadone			S	Unknown	60 Mg, Daily, For The Last 5 Years		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2018	14470474	EXPEDITED (15-DAY)		HO	PHHY2018FR011928		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Confusional State	Azithromycin Sandoz			S	Oral			Novartis
	Innovair			C	Respiratory (inhalation)			Not Reported
	Prednisone			C	Oral	60 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levothyrox			C		Oral		1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
31-Jan-2018	14471248	NON-EXPEDITED			US-PRAGMA PHARMACEUTICALS, LLC-2017PRG00078			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Keflex			S		Unk		Pragma Pharmaceuticals		
	Z-Pack			S		Unk		Not Reported		
	Dilaudid			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
31-Jan-2018	14472185	EXPEDITED (15-DAY)		HO, OT	CN-MYLANLABS- 2018M1005786		30 YR	Female	CHN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Cholestasis; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown	500 Mg Loading Dose		Not Reported		
	Azithromycin			S	Unknown	250 Mg Daily		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
31-Jan-2018	14474270	DIRECT	Y	HO, LT			69 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Ventricular Fibrillation; Ventricular Tachycardia	Azithromycin			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
01-Feb-2018	11880488	NON-EXPEDITED			US-PFIZER INC- 2015466019			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Nausea; Rash	Zithromax			S		Unk		Pfizer		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14111080	NON-EXPEDITED			US-PFIZER INC-2017448065			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use	Zithromax			S		250 Mg, Unk		Pfizer	
	Zithromax			S		200 Mg, Daily		Pfizer	
	Clofazimine			C		50 Mg, Daily		Not Reported	
	Amikacin			C		Unk Unk, (3 Times Weekl)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14184568	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2017485212		63 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Malaise; Muscular Weakness; Pollakiuria; Rhabdomyolysis	Zithromac 250mg			S	Oral	2 Df, 1x/Day		Pfizer	
	Bisoprolol			C	Oral	1 Df, 2x/Day		Not Reported	
	Equmet Hd			C	Oral	1 Df, 2x/Day		Not Reported	
	Glimicron			C	Oral	1 Df, 2x/Day		Not Reported	
	Rebamipide			C	Oral	1 Df, 3x/Day		Not Reported	
	Losartan			C	Oral	Unk Unk, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14473261	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2017-45341		1 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Vomiting	Cefdinir Oral Suspension			S	Oral	5 Ml, Once		Aurobindo	
	Azithromycin			S		Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14473779	NON-EXPEDITED			US-PFIZER INC-2018041424		53 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Cymbalta			S		Unk		Not Reported	
	Triple Antibiotic (Bacitracin Zinc\Neomycin Sulfate\Polymyxin B Sulfate)			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14473840	NON-EXPEDITED		OT	US-PFIZER INC-2018043705			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14474031	NON-EXPEDITED		HO	US-TEVA-2018-US-853809		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	
	Vancomycin			S	Oral			Not Reported	
	Piperacillin-Tazobactam			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2018	14474660	EXPEDITED (15-DAY)		OT	PT-TEVA-2018-PT-850362		37 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eye Irritation; Pruritus; Rash; Skin Exfoliation; Swelling Of Eyelid	Azitromicina Ratiopharm	S	Oral	500 Milligram Daily; 1 Per Day 24/24 Hours	Not Reported
	Sodolac	C	Unknown		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14475186	EXPEDITED (15-DAY)		LT	CN-PFIZER INC- 2018042107		60 YR	Female	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chills; Dizziness; Fatigue; Pallor	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14475369	NON-EXPEDITED			US-PFIZER INC- 2018044082			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash; Urticaria	Azithromycin			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Feb-2018	14475582	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2018- 001923		69 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bronchitis; Cholestasis	Prednisolone			S	Oral			Bausch And Lomb	
	Rituximab ((Mammifere/Hamster/Cellules Cho))			S	Intravenous (not otherwise specified)			Not Reported	
	Novatrex			S	Unknown			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Feb-2018	13748751	EXPEDITED (15-DAY)		HO, OT	FR-ROCHE-1962088		79 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acanthoma; Basal Cell Carcinoma; Leukopenia; Sebaceous Carcinoma	Roactemra	S	Intravenous drip	Not Reported
	Novatrex	S	Oral	Not Reported
	Avodart	C		Not Reported
	Orocal (France)	C		Not Reported
	Fosavance	C		Not Reported
	Speciafoldine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14341764	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2017-47211		35 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Bacterial Infection; Cold Agglutinins Positive; Condition Aggravated; Drug Resistance; Haemorrhage; Headache; Immunodeficiency Common Variable; Immunodeficiency Common Variable; Intentional Product Misuse; Meningism; Neisseria Infection; Neuropathy Peripheral; Paraesthesia; Periodontitis; Pharyngitis Streptococcal; Pneumococcal Infection; Pneumonia; Pyogenic Granuloma; Raynaud'S Phenomenon; Staphylococcal Infection; Stomatococcal Infection; Streptococcal Infection; Veillonella Infection	Amoxicillin+Clavulanic Acid			S	Unknown	1000mg Three Times A Day		Aurobindo	
	Azithromycin			S	Unknown	500 Mg, Daily		Aurobindo	
	Cefadroxil			S	Unknown	500 Mg, Two Times A Day		Not Reported	
	Ceftriaxone			S	Unknown	1000 Mg, Daily		Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Amoxicillin			S	Unknown	1000 Mg, 3 Times A Day		Not Reported	
	Clavulanic Acid			S	Unknown	200 Mg, 3 Times A Day		Not Reported	
	Prednisolone			C	Unknown	120 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14378082	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018008871		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus; Rash Macular	Azithromycin			S	Oral	Unk		Pfizer	
	Celestamine			S	Oral	Unk		Not Reported	
	Gentalline Unilabo			S	Intravenous (not otherwise specified)	120 Mg, 1x/Day		Not Reported	
	Prednisone			C		Unk		Not Reported	
	Furosemide			C		Unk		Not Reported	
	Diffu K			C		Unk		Not Reported	
	Inexium			C	Oral	Unk		Not Reported	
	Atovaquone			C		Unk		Not Reported	
	Tracleer			C	Oral	Unk		Not Reported	
	Formoterol			C	Respiratory (inhalation)	Unk		Not Reported	
	Tamoxifene			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14474212	NON-EXPEDITED			US-PFIZER INC-2018041423		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Infection	Enbrel			S		Unk		Pfizer	
	Celebrex			S				Pfizer	
	Erythromycin			S				Pfizer	
	Cymbalta			S				Not Reported	
	Zithromax Z-Pak			S				Not Reported	
	Triple Antibiotic /00038301/			S				Not Reported	
	Humira			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14478903	NON-EXPEDITED			US-PFIZER INC-2018046123		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14480780	EXPEDITED (15-DAY)		LT	CN-PFIZER INC-2018041580		9 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Dyspnoea; Hypersensitivity	Zithromax			S	Intravenous drip	250 Mg, 1x/Day		Pfizer	
	Sulperazon			C	Intravenous drip	1 G, 3x/Day (Q8h)		Not Reported	
	Sulperazon			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2018	14482549	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2018-004528		10 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cryptosporidiosis Infection; Diarrhoea; Off Label Use; Varicella; Weight Decreased	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Sirolimus			S	Unknown	Unk		Not Reported	
	Sirolimus			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2018	14482828	NON-EXPEDITED			US-TEVA-2018-US-845185		72 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vision Blurred	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14003199	EXPEDITED (15-DAY)		OT	US-JNJFOC-20170916369			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aneurysm; Body Height Decreased; Deafness Unilateral; Drug Ineffective For Unapproved Indication; Fall; Lip Injury; Lip Pain; Memory Impairment; Meningeal Disorder; Migraine; Muscular Weakness; Off Label Use; Tinnitus; Wrong Technique In Product Usage Process	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Topamax			S	Oral			Not Reported
	Tylenol Extra Strength		Y	S	Oral			Not Reported
	Z-Pak			S	Unknown			Not Reported
	L Arginine			C	Oral			Not Reported
	L Arginine			C	Oral			Not Reported
	Vitamin D3			C	Oral			Not Reported
	Vitamin D3			C	Oral	Once Or Twice Weekly		Not Reported
	Xanax			C	Oral			Not Reported
	Atenolol			C	Oral			Not Reported
	Triamterene/Hctz			C	Oral			Not Reported
	Triamterene/Hctz			C	Oral			Not Reported
	Ketorolac			C	Oral			Not Reported
	Butalbital, Acetaminophen And Caffeine			C	Oral			Not Reported
	Dilantin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14485117	NON-EXPEDITED			US-PFIZER INC-2018045990			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14485176	NON-EXPEDITED			US-PFIZER INC-2018045963		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14485305	NON-EXPEDITED			US-PFIZER INC-2018049891		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2018	14493093	DIRECT					42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dehydration; Diarrhoea; Insomnia; Pain	Azithromycin			S	Oral	Quantity:6 Tablet(S);		Lupin	
	Propecia			C				Not Reported	
	Vitamin D Nos			C				Not Reported	
	Vitamin B-12			C				Not Reported	
	Biotin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14491003	NON-EXPEDITED			US-PFIZER INC-2018048306		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Amoxil			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491058	NON-EXPEDITED			US-PFIZER INC-2018050399		65 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491082	NON-EXPEDITED			US-PFIZER INC-2018050925			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491083	NON-EXPEDITED			US-PFIZER INC-2018052534		40 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491098	NON-EXPEDITED			US-PFIZER INC-2018050020			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Feb-2018	14491099	NON-EXPEDITED			US-PFIZER INC-2018050689		15 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2018	14491221	NON-EXPEDITED			US-PFIZER INC-2018050582		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Macrobid			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14184359	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20170804764			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Fatigue; Haemoglobin Decreased; Headache; Nausea	Otezla			S	Oral	30 Milligram		Celgene	
	Valacyclovir			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Purinethol			C	Oral	50 Milligram		Not Reported	
	Gleevec			C	Oral	400 Milligram		Not Reported	
	Pantoloc			C	Oral	40 Milligram		Not Reported	
	Zofran			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14190709	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2017GSK048119		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Pneumonia; Rash Pruritic	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk (Monthly)		Glaxosmithkline	
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk		Glaxosmithkline	
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin

S

500 Mg, Unk

Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14499898	EXPEDITED (15-DAY)		HO, OT	PL-MYLANLABS-2018M1007678		10 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptosporidiosis Infection; Diarrhoea; Immunosuppressant Drug Level Increased; Off Label Use; Varicella; Weight Decreased	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S			Not Reported	
	Tacrolimus			S			Not Reported	
	Tacrolimus			S			Not Reported	
	Mycophenolate Mofetil			S		Unk	Not Reported	
	Mycophenolate Mofetil			S		Unk	Not Reported	
	Sirolimus			S		Unk	Mylan	
	Sirolimus			S		Unk	Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2018	14509719	DIRECT	Y	HO			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nephritis; Tubulointerstitial Nephritis	Pantoprazole			S	Oral			Not Reported
	Azithromycin			S			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14328232	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2017495830		17 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antinuclear Antibody; Autoimmune Hepatitis; Cholestasis; Drug-Induced Liver Injury	Zithromac 250mg			S	Oral	Unk		Pfizer
	Tranexamic Acid			S	Oral	Unk		Not Reported
	Calonal			S	Oral	Unk		Not Reported
	Benza Block L			S		Unk		Not Reported
	Tramcet			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14503035	NON-EXPEDITED			US-PFIZER INC-2018048130		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Benazepril Hcl			S		Unk		Not Reported	
	Bactrim Ds			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Incruse Ellipta			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14503208	NON-EXPEDITED			US-PFIZER INC-2018054702			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2018	14506415	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-855759		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Tubulointerstitial Nephritis	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	10004896	NON-EXPEDITED			US-PFIZER INC-2014071763		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Dilantin	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Epinephrine	S	Unk	Unknown
	Morphine Sulfate	S	Unk	Unknown
	Apresoline	S	Unk	Not Reported
	Aspirin	S	Unk	Not Reported
	Codeine	S	Unk	Not Reported
	Proglycem	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14281091	EXPEDITED (15-DAY)		HO	JP-JNJFOC-20171211314		74 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Skin Eruption	Canaglu			S	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Cefcapene Pivoxil Hydrochloride			S	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Azithromycin			S	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Herbesser			S	Oral			Not Reported
	Teprenone			C	Oral			Not Reported
	Almylar			C	Oral			Not Reported
	Zetia			C	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Irtra			C	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Trazenta			C	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Pletaal			C	Oral	Administration Started In Third Week On Nov-2017		Not Reported
	Bayaspirin			C	Oral	Administration Started In Third Week On Nov-2017		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vesicare	C	Oral	Administration Started In Third Week On Nov-2017	Not Reported
Tenormin	C	Oral	Administration Started In Third Week On Nov-2017	Not Reported
Pontal	C	Oral		Not Reported
Dimemorfan Phosphate	C	Oral		Not Reported
Chlorpheniramine Maleate	C	Oral		Not Reported
Cetraxate Hydrochloride	C	Oral		Not Reported
Mucobulin	C	Oral		Not Reported
Medicon	C	Oral		Not Reported
Carbocisteine	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14417098	NON-EXPEDITED			US-PFIZER INC-2018026967			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cimzia			S		Unk		Not Reported	
	Remicade			S		Unk		Not Reported	
	Macrobid			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14461259	NON-EXPEDITED			US-TEVA-2018-US-846579		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14509240	NON-EXPEDITED			US-TEVA-2018-US-848545			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Malaise		Azithromycin		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14509813	NON-EXPEDITED			US-PFIZER INC-2018057553		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2018	14512092	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-857781			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epistaxis; Haemoptysis	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2018	14515601	NON-EXPEDITED			US-TEVA-2018-US-848797		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breath Sounds Abnormal; Diarrhoea; Insomnia; Throat Irritation	Azithromycin			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14248832	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2017516369		49 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Renal Tubular Necrosis	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer	
	Zithromac Sr 2g			S				Pfizer	
	Loxonin			S	Oral	60 Mg, 1x/Day		Not Reported	
	Pioglitazone			C	Oral	1 Df, 1x/Day		Not Reported	
	Amlodipine			C	Oral	1 Df, 1x/Day		Not Reported	
	Bayaspirin			C	Oral	1 Df, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Feburic	C	Oral	2 Df, 1x/Day	Not Reported
Diovan	C	Oral	1 Df, 1x/Day	Not Reported
Crestor	C	Oral	1 Df, 1x/Day	Not Reported
Xyzal	C	Oral	1 Df, Daily	Not Reported
Metgluco	C	Oral	2 Df, 3x/Day	Not Reported
Tresiba	C	Subcutaneous	20 lu, 1x/Day	Not Reported
Novorapid	C	Subcutaneous	150-200 lu, Daily	Not Reported
Victoza	C	Subcutaneous	0.3 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14362999	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018002786		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Venoocclusive Disease	Azithromycin			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14517709	NON-EXPEDITED			US-TEVA-2018-US-849092			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspepsia; Expired Product Administered	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14517904	NON-EXPEDITED			US-PFIZER INC-2018058058			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14518205	NON-EXPEDITED			US-PFIZER INC-2018059253			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14518220	NON-EXPEDITED			US-PFIZER INC-2018059472			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14518235	NON-EXPEDITED			US-PFIZER INC-2018059386		52 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Pruritus; Urticaria	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14518239	NON-EXPEDITED			US-PFIZER INC-2018059459		69 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14518265	NON-EXPEDITED			US-PFIZER INC-2018059648			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2018	14518382	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018054641		88 YR	Male	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Body Temperature Increased; Chills; Heart Rate Increased; Infusion Related Reaction; Wheezing	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Sodium Chloride			C	Intravenous drip	250 MI, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2018	14521906	NON-EXPEDITED			PHEH2018US005608			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Headache	Azithromycin			S	Unknown			Novartis	
	Tigecycline			S	Unknown			Not Reported	
	Amikacin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14525143	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018023183		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Disorder	Breo Ellipta Inhalation Powder			S	Respiratory (inhalation)			Glaxosmithkline	
	Z-Pak			S				Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14525435	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR-APL-2018-006152		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coombs Negative Haemolytic Anaemia	Azithromycin Film-Coated Tablets			S	Oral	500 Mg, Daily		Aurobindo	
	Actithiol			S	Oral	30 MI, Daily		Not Reported	
	Codeisan			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14526260	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-854865		72 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Superinfection	Azitromicina Teva 500mg			S	Oral	Azitromicina 500mg (1-0-0, Monday, Wednesday, Friday)		Not Reported	
	Imbruvica 140 Mg Capsula			S	Oral	320 Mg C/24h		Not Reported	
	Prednisona Alonga 5 5mg			C	Oral	5 Mg C/24h		Not Reported	
	Incruse 55mcg Polvo Para Inhalacion			C	Respiratory (inhalation)	1 Inh C/24h		Not Reported	
	Relvar Ellipta 184/22mcg Inhalacion			C	Respiratory (inhalation)	1 Inh C/24h		Not Reported	
	Zarzio 30 Mu/0,5 MI Jeringa Precargada			C	Subcutaneous	30 Mu/0,5 MI		Not Reported	
	Singulair 10mg 28 Comprimidos Recubiertos Con Pelicula			C	Oral	10 Milligram Daily; 10 Mg C/24h		Not Reported	
	Acido Acetilsalicilico 100 Mg			C	Oral	100 Milligram Daily; 100 Mg C/247h		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14526305	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2018-005263		28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Gastrointestinal Motility Disorder; Rectal Tenesmus	Azithromycin			S		Unk		Aurobindo	
	Azithromycin			S		Unk		Aurobindo	
	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
	Piperacillin+Tazobactam			S	Oral	Unk		Aurobindo	
	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
	Ceftriaxone			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14527405	NON-EXPEDITED		OT	PHEH2018US004543		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Mycobacterium Avium Complex Infection	Azithromycin			S	Unknown	50 Mg, Qd		Novartis	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Amikacin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14527602	NON-EXPEDITED			US-PFIZER INC- 2018063035			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14530909	DIRECT	Y	OT			49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2018	14531338	DIRECT					49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14508257	EXPEDITED (15-DAY)			ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-162895		69 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Bronchospasm; Palatal Oedema	Azithromycin			S	Oral	500 Mg, Qd		Sun	
	Acetilcisteina 200 Mg Solucion/Suspension Oral 30 Sobres			S	Oral	200 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14530505	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2018-006752		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Venoocclusive Disease	Azithromycin			S	Oral	Unk ()		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14530799	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2018060537		69 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Bronchospasm; Palatal Oedema	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Acetylcysteina			S	Oral	200 Mg, 3x/Day (Every 8 Hours)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2018	14531357	EXPEDITED (15-DAY)		HO	RU-ASTRAZENECA- 2018SE17933		81 YR	Male	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Poisoning; Rhinitis; Vomiting; Weight Decreased	Symbicort Turbuhaler			S	Respiratory (inhalation)	2 To 10 Inhalations Per Day		Astrazeneca	
	Azithromycin			S	Oral	Took One Tablet On An Empty Stomach Instead Of Taking After Meal		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	13477108	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-PFIZER INC-2017173965		60 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Cardiovascular Disorder; Diarrhoea; Multiple Organ Dysfunction Syndrome; Pseudomembranous Colitis; Sepsis; Septic Shock; Vomiting	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Azithromycin			S				Pfizer	
	Ramipril			C	Oral	10 Mg, Unk		Not Reported	
	Amlodipin			C	Oral	5 Mg, Daily, Long-Term Therapy		Not Reported	
	Novalgine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313229	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45334		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Cardiac Failure; Pneumonia; Venooclusive Disease	Azithromycin			S	Oral	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313254	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2017-45335		62 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Hypokalaemia	Azithromycin Arrow			S	Oral	250 Mg, Daily, 3 Times A Week For 21 Days		Aurobindo	
	Neoral			C	Oral	300 Mg, Unk		Not Reported	
	Cellcept /01275102/			C	Oral	1500 Mg, Unk		Not Reported	
	Heparin			C	Intravenous (not otherwise specified)	6000 Ui, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313255	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45336		62 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Oxygen Saturation Decreased; Pyrexia	Azithromycin			S		250 Mg, 3 Times A Week		Aurobindo	
	Neoral			C		300 Mg Per Os, Daily		Not Reported	
	Neoral			C		150 Mg,Daily		Not Reported	
	Cellcept /01275102/			C		1500 Mg, Daily		Not Reported	
	Heparin			C	Intravenous (not otherwise specified)	6000 Ui, Daily		Not Reported	
	Clamoxyl /00249601/			C	Oral	500 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313259	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45339		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression	Azithromycin			S	Unknown	250 Mg, Weekly		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313260	EXPEDITED (15-DAY)		LT	FR-AUROBINDO-AUR-APL-2017-45338			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhagic Stroke	Azithromycin			S	Unknown	250 Mg, Three Time A Week		Aurobindo	
	Azithromycin			S	Unknown	250 Mg, Daily 3 Times A Week		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313263	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45567		52 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Febrile Bone Marrow	Azithromycin	S	Unknown	Unk	Aurobindo
Aplasia; Pneumonia;	Vfend	C	Unknown		Not Reported
Pyrexia; Respiratory	Bricanyl	C	Unknown		Not Reported
Failure					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313264	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2017-45392		32 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sepsis; Toxic Epidermal Necrolysis	Azithromycin Arrow			S		Unk		Aurobindo
	Azithromycin Arrow			S	Oral	250 Mg, Unk		Aurobindo
	Tazocilline			C				Not Reported
	Fungizone			C				Not Reported
	Dacryoserum /00951201/			C				Not Reported
	Paracetamol			C				Not Reported
	Smecta /00837601/			C				Not Reported
	Ursolvan			C				Not Reported
	Zelitrex			C				Not Reported
	Pantoprazole			C				Not Reported
	Neoral			C				Not Reported
	Vfend			C				Not Reported
	Imipenem/Cilastatin			C				Not Reported
	Primperan			C				Not Reported
	Cymevan			C				Not Reported
	Acetylcysteine			C				Not Reported
	Oxynorm			C				Not Reported
	Largactil /00011901/			C				Not Reported
	Largactil /00011901/			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313287	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR- APL-2017-45647		38 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukaemia Recurrent	Azithromycin			S	Oral	250 Mg, 3 Times A Week		Aurobindo
	Levothyroxine /00068002/			C	Unknown			Not Reported
	Hyperium			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313306	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2017-45754		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin			S	Oral	250 Mg, Daily,3 Times A Week For 1 Year And 4 Months(		Aurobindo	
	Azithromycin			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313307	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45761			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin			S	Oral	250 Mg, Per Day, Three Times A Week For 11 Weeks		Aurobindo	
	Azithromycin			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313325	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45764		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin			S		250 Mg, 3 Times Weekly		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313674	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-45342		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Electrolyte Imbalance; Hepatocellular Injury; Oliguria; Renal Failure	Azithromycin Arrow			S	Oral	Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313675	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2017-45340		46 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent; Respiratory Tract Infection; Septic Shock	Azithromycin			S	Oral	Unk		Aurobindo	
	Clofarabine			C		Unk		Not Reported	
	Mitoxantrone			C				Not Reported	
	Etoposide			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313818	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2017-45766		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin			S	Oral	250 Mg Per Day 3 Times A Week		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313848	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45771		28 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin			S		250 Mg, Daily		Aurobindo	
	Hydrea			C	Unknown	Unk		Not Reported	
	Cortancyl			C	Unknown	Unk		Not Reported	
	Zelitrex			C	Unknown	Unk		Not Reported	
	Xanax			C	Unknown	Unk		Not Reported	
	Imovane			C	Unknown	Unk		Not Reported	
	Toplexil /00167901/			C	Unknown	Unk		Not Reported	
	Nexium /01479302/			C	Unknown	Unk		Not Reported	
	Profenid			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313849	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-45772		29 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Condition Abnormal; Malnutrition	Azithromycin			S	Oral	250 Mg,Per Day ,3 Times A Week		Aurobindo	
	Tienam			C				Not Reported	
	Ciflox /00697201/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313862	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-45950			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Azithromycin Arrow			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313863	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2017-45954		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin Arrow			S	Oral	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313866	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45964		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
T-Cell Lymphoma Recurrent	Azithromycin			S	Oral	250 Mg, Three Times A Week		Aurobindo	
	Valaciclovir			C	Unknown	Unk		Not Reported	
	Oracilline /00001801/			C	Unknown	Unk		Not Reported	
	Atovaquone			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313867	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2017-45955		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant; Multiple Organ Dysfunction Syndrome	Azithromycin Arrow			S		250 Mg, Per Day 3 Times A Week 13 Months		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313868	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2017-45956		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Pulmonary Embolism	Azithromycin 250 Mg			S	Oral	250 Mg, 3 Times A Week		Aurobindo	
	Valaciclovir			C	Unknown			Not Reported	
	Neoral			C	Unknown			Not Reported	
	Oracillin /00001802/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313892	EXPEDITED (15-DAY)		HO, LT	FR-AUROBINDO-AUR-APL-2017-46119		30 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disturbance In Attention; Encephalopathy; Hallucination	Azithromycin			S		250 Mg, 3 Times A Week		Aurobindo	
	Zovirax /00587301/			C		1 G, Per Day		Not Reported	
	Cefazoline			C		30 G, Per Day		Not Reported	
	Cyclosporine			C				Not Reported	
	Tazocilline			C		16 G,Per Day		Not Reported	
	Tienam			C		3 G,Per Day		Not Reported	
	Vancocine			C		2 G,Per Day		Not Reported	
	Vfend			C		400 Mg, Per Day		Not Reported	
	Cellcept /01275102/ Defibrotide			C		1500 Mg, Per Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Candidas			C		70 Mg, Per Day			Not Reported
	Oxynorm			C		1 Mg, Per Hour			Not Reported
	Thiophene Carboxylate Sodium			C		600 Mg,Total Dose			Not Reported
	Busulfan			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313893	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-46046		25 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukaemia Recurrent	Azithromycin				S	Oral	250 Mg, Daily, 3 Times A Week		Aurobindo
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313898	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-46123			Male	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Loss Of Consciousness; Malaise	Azithromycin				S	Oral	250 Mg, Daily		Aurobindo
	Solumedrol				C	Unknown	Unk		Not Reported
	Vancocine				C	Unknown			Not Reported
	Dalacine /00166002/				C	Unknown	Unk		Not Reported
	Tazocilline				C		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313913	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-45640		51 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukaemia Recurrent	Azithromycin Arrow				S	Oral	Unk		Aurobindo
	Vfend				C				Not Reported
	Bricanyl				C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313914	EXPEDITED (15-DAY)		DE, LT	FR-AUROBINDO-AUR-APL-2017-45551		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Leukaemia Recurrent; Lymphadenopathy; Myelocytosis; Splenomegaly	Azithromycin			S	Oral	107 Mg, Daily		Aurobindo	
	Prednisone			C	Subcutaneous			Not Reported	
	Valaciclovir			C	Subcutaneous			Not Reported	
	Azacididine			C	Subcutaneous			Not Reported	
	Cyclosporin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313917	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-45719		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchopulmonary Aspergillosis; Diarrhoea; Graft Versus Host Disease In Gastrointestinal Tract	Azithromycin Arrow			S	Oral	250 Mg, Daily, 3 Times A Week		Aurobindo	
	Rapamune			C	Unknown	Unk		Not Reported	
	Solumedrol			C		Unk		Not Reported	
	Entocort			C		Unk		Not Reported	
	Cortancyl			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313918	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45718		60 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Febrile Bone Marrow Aplasia; Leukaemia Recurrent	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, 3 Times A Week		Aurobindo	
	Zelitrex			C	Unknown	Unk		Not Reported	
	Vidaza			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313919	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2017-45649			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Leukaemia Recurrent; Septic Shock	Azithromycin 250 Mg			S		250 Mg, Daily		Aurobindo	
	Hydrocortisone			C	Unknown	Unk		Not Reported	
	Laroxyl			C	Unknown	Unk		Not Reported	
	Lyrica			C	Unknown	Unk		Not Reported	
	Lasilix /00032601/			C	Unknown			Not Reported	
	Lexomil			C	Unknown			Not Reported	
	Zelitrex			C	Unknown	Unk		Not Reported	
	Ibrutinib			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313929	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2017-45721		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinomycotic Pulmonary Infection; Diarrhoea; Marrow Hyperplasia; Pyrexia; Septic Shock	Azithromycin			S	Oral	250 Mg, Per Day, Three Times A Week For Eight Months		Aurobindo	
	Azithromycin			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313932	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45720		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Hyperthermia; Odynophagia; Pyrexia	Azithromycin Arrow			S	Oral	250 Mg, Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313938	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-46145		53 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Failure; Sepsis	Azithromycin 250 Mg			S	Oral	250 Mg, 3 Times A Week		Aurobindo	
	Simvastatin			C	Unknown	20 Mg, Daily		Not Reported	
	Metformine			C	Unknown	1 G, 3 Times A Day		Not Reported	
	Amarel			C	Unknown	1 Mg, Daily		Not Reported	
	Uvedose			C	Unknown	At 1 Vial Every 3 Months		Not Reported	
	Ciclosporine			C	Intravenous (not otherwise specified)	Iv 3 Mg/Kg/Day		Not Reported	
	Prograf			C	Oral	1 Mg, Two Times A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14313949	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-46125		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchial Disorder; Graft Versus Host Disease In Skin; Mucormycosis; Septic Shock; Toxic Epidermal Necrolysis	Azithromycin Arrow			S	Oral	Unk		Aurobindo	
	Cortancyl			C				Not Reported	
	Mikicort			C				Not Reported	
	Atarax /00058401/			C				Not Reported	
	Oxynorm			C				Not Reported	
	Oxycontin			C				Not Reported	
	Doliprane			C				Not Reported	
	Bactrim			C				Not Reported	
	Lederfoline			C				Not Reported	
	Zelitrex			C				Not Reported	
	Citalopram			C				Not Reported	
	Ditropan			C				Not Reported	
	Xatral			C				Not Reported	
	Inexium /01479302/			C				Not Reported	
	Lyrica			C				Not Reported	
	Tiorfan			C				Not Reported	
	Ulcar /00434701/			C				Not Reported	
	Zolpidem			C				Not Reported	
	Zopiclone			C				Not Reported	
	Fungizone			C				Not Reported	
	Candidas			C				Not Reported	
	Cefepime			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exacyl			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314123	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2017-45767		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myeloid Leukaemia	Azithromycin 250 Mg			S	Oral	250 Mg, 3 Times A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314125	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45774		46 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Septic Shock	Azithromycin			S		250 Mg, Daily 3 Times A Week		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314187	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45951		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Febrile Neutropenia; Leukaemia Recurrent; Septic Shock	Azithromycin Arrow			S	Oral	250 Mg, 3 Times A Week		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314188	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45945		32 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukaemia Recurrent	Azithromycin			S		Unk		Aurobindo	
	Blinatumomab			C		Unk		Not Reported	
	Iclusig			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314193	EXPEDITED (15-DAY)		DE, HO	FR-AUROBINDO-AUR-APL-2017-45965		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paraparesis	Azithromycin			S	Oral	250 Mg, Once A Day, 3 Times A Week		Aurobindo	
	Valaciclovir			C	Unknown			Not Reported	
	Neoral			C	Unknown			Not Reported	
	Oracilline /00001801/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314203	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2017-45966			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
T-Cell Lymphoma Recurrent	Azithromycin			S	Oral	Unk		Aurobindo	
	Neoral			C	Unknown			Not Reported	
	Valaciclovir			C	Unknown			Not Reported	
	Oracillin /00001802/			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14314206	EXPEDITED (15-DAY)		HO, LT	FR-AUROBINDO-AUR-APL-2017-46124		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Atrial Fibrillation; Chest Pain; Erythema; Pericardial Effusion; Pericarditis; Weight Increased	Azithromycin			S	Oral	Unk		Aurobindo	
	Ciclosporine			C		Unk		Not Reported	
	Cellcept /01275102/			C		Unk		Not Reported	
	Oxynorm			C		Unk		Not Reported	
	Clamoxyl /00249601/			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14444499	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR-APL-2018-003045		35 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Ceftriaxone			S	Unknown	1000 Mg, Once A Day		Not Reported	
	Ceftriaxone			S	Unknown	()		Not Reported	
	Azithromycin			S	Unknown	500 Mg, Qd		Aurobindo	
	Azithromycin			S	Unknown	500 Mg, Qd		Aurobindo	
	Azithromycin			S	Unknown	()		Aurobindo	
	Amoxicillin+Clavulanic Acid			S	Unknown	1000 Mg, Tid		Aurobindo	
	Cefadroxil Monohydrate			S	Unknown	500 Mg, Bid		Not Reported	
	Cefadroxil Monohydrate			S	Unknown	()		Not Reported	
	Prednisolone			C	Unknown	1 Df, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14534238	EXPEDITED (15-DAY)		HO	PHHY2018ES021910		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Eosinophilic Pleural Effusion	Allopurinol			S	Oral	1 Cp		Novartis	
	Azitromicina			S	Oral	1 Cp		Not Reported	
	Levofloxacin			S	Oral	500 Mg, Qd		Not Reported	
	Amoxicillin Trihydrate+Potassium Clavulanate			S	Oral	1.1.1		Not Reported	
	Hydroferol			C	Oral	1 Amp		Not Reported	
	Valsartan/Hct			C	Oral	1-0-0		Not Reported	
	Tamsulosina			C	Oral	1 Cp		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14534447	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2017-37725			Unknown	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clinical Trial Participant; Recurrent Cancer	Azithromycin Arrow Film-Coated Tablets 250mg			S		Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536350	NON-EXPEDITED			US-TEVA-2018-US- 849104		304 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Dysgeusia; Product Storage Error; Wrong Technique In Product Usage Process	Azithromycin			S	Oral	200 Mg/5 MI		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2018	14536351	NON-EXPEDITED			US-TEVA-2018-US- 849099		4 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Dysgeusia; Product Storage Error; Wrong Technique In Product Usage Process	Azithromycin			S	Oral	200 Mg/5 MI		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	12085504	EXPEDITED (15-DAY)		HO, LT, OT	JP-PFIZER INC- 2016081960		1 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hypoxia; Rash	Zithromac			S	Oral	Unk		Pfizer	
	Onon			S	Oral	Unk		Not Reported	
	Lac-B			C	Oral	Unk		Not Reported	
	Pulsmarin A			C	Oral	Unk		Not Reported	
	Asverin /00465502/			C	Oral	Unk		Not Reported	
	Pulmicort			C	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mucodyne			C			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14517923	NON-EXPEDITED			US-PFIZER INC-2018057324		35 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14521562	EXPEDITED (15-DAY)		DE, HO, OT	BR-PFIZER INC-2018049030		40 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dizziness; Headache; Hyperhidrosis; Hypotension; Malaise	Zitromax			S	Intravenous (not otherwise specified)	Unk Unk, 2x/Day (12/12h)		Pfizer	
	Zitromax			S				Pfizer	
	Ranitidine			C		Unk		Not Reported	
	Carvedilol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14538338	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-163365		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Venooclusive Disease	Azithromycin			S	Oral	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2018	14544141	EXPEDITED (15-DAY)		HO	AU-009507513- 1802AUS006745		48 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Montelukast Sodium			S				Merck	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin		S		Unk		Not Reported			
Corticosteroids (Unspecified)		C				Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2018	14194535	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2017-43552		78 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Catheter Site	Amiodarone			S	Unknown	100 Mg, Three Times A Week		Aurobindo	
Haemorrhage; Drug	Amiodarone			S	Unknown	Unk		Aurobindo	
Ineffective; Dyspnoea;	Amiodarone			S	Oral	100 Mg, 3 Times/Wk		Aurobindo	
Haemoglobin Decreased;	Amiodarone			S	Oral	100 Mg, 3 Times/Wk		Aurobindo	
Haemoptysis; Pneumonia	Amiodarone			S	Oral	100 Mg, 3 Times/Wk		Aurobindo	
Pneumococcal; Productive	Azithromycin			S	Unknown			Aurobindo	
Cough; Pulmonary	Apixaban			S		5 Mg, Two Times A Day		Not Reported	
Alveolar Haemorrhage;	Apixaban			S	Unknown	5 Mg, Bid		Not Reported	
Purulent Discharge;	Apixaban			S	Unknown	2.5 Mg, Bid		Not Reported	
Pyrexia; Respiratory									
Failure; Streptococcus									
Test Positive									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14545857	EXPEDITED (15-DAY)		OT	FR-ROCHE-2070010		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Cholestasis	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Novatrex			S	Unknown			Not Reported	
	Prednisolone			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14546551	NON-EXPEDITED			US-TEVA-2018-US-859601			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Physical Issue									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14546873	NON-EXPEDITED			US-PFIZER INC-2018065969		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14546965	NON-EXPEDITED			US-PFIZER INC-2018066303		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Diclofenac Potassium			S		Unk		Not Reported	
	Zyrtec			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14546967	NON-EXPEDITED			US-PFIZER INC-2018067238		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547035	NON-EXPEDITED			US-PFIZER INC-2018067631		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547063	NON-EXPEDITED			US-PFIZER INC-2018066995		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547068	NON-EXPEDITED			US-PFIZER INC-2018068076			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Sinusitis	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547093	NON-EXPEDITED			US-PFIZER INC-2018069264		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
	Doxycycline Monohydrate			S		Unk		Pfizer	
	Avelox			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Macrobid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2018	14547572	EXPEDITED (15-DAY)		HO	JP-BAUSCH-BL-2018-004234		74 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Skin Eruption	Herbesser R			S	Oral			Not Reported	
	Canaglu			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	Not Reported
Cefcapene Pivoxil Hydrochloride	S	Oral	Not Reported
Zetia	C		Not Reported
Irtra	C		Not Reported
Trazenta	C		Not Reported
Pletaal	C		Not Reported
Bayaspirin	C		Not Reported
Vesicare	C		Not Reported
Almylar	C		Not Reported
Pontal	C		Not Reported
Dimemorfan Phosphate	C		Not Reported
Chlorpheniramine Maleate	C		Not Reported
Cetraxate Hydrochloride	C		Not Reported
Mucobulin	C		Not Reported
Medicon	C		Not Reported
Teprenone	C		Not Reported
Carbocisteine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14194440	NON-EXPEDITED			US-PFIZER INC-2017491357			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14491482	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-00507		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea Haemorrhagic; Vomiting	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin
	Losartan			C	Unknown	Not Provided		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14518213	NON-EXPEDITED		OT	US-PFIZER INC-2018059778			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14551211	NON-EXPEDITED			US-TEVA-2018-US-861468			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin "Z Pack" 65-150			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2018	14551928	NON-EXPEDITED			US-PFIZER INC-2018068775		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Allergic Reaction To Excipient	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	12834666	NON-EXPEDITED			US-PFIZER INC-2016471393		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Codeine Phosphate			S		Unk		Not Reported	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Ceclor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14243803	EXPEDITED (15-DAY)		OT	PHHY2017CA136924		34 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chapped Lips; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder; Stomatitis; Urticaria	Azithromycin Sandoz			S	Unknown	250 Mg, Die		Novartis	
	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Zyrtec			C	Oral	1 Df, Qd		Not Reported	
	Benadryl			C	Oral	1 Df, Prn		Not Reported	
	Singular			C	Oral	10 Mg, Qd		Not Reported	
	Prednisone			C	Oral	1 Df, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558235	EXPEDITED (15-DAY)		HO	GXKR2007GB08142		19 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Kidney Injury; Balance Disorder; Blood Creatinine Increased; Deafness Neurosensory; Dizziness; Off Label Use; Tinnitus; Toxicity To Various Agents	Gentamicin			S	Unknown	120 Mg, Tid (360 Mg)		Novartis	
	Gentamicin			S	Unknown	120 Mg, Bid		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown	1 G, Tid		Not Reported	
	Meropenem			S	Unknown	1 Mg, Tid		Not Reported	
	Tobramycin			S	Unknown	140 G, Tid		Not Reported	
	Tobramycin			S	Unknown	80 Mg, Bid		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2018	14558972	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-857474		67 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eosinophilia; Eosinophilic Pleural Effusion	Amoxicilina/Acido Clavulanico 875 Mg/125 Mg Comprimido			S	Oral	1.1.1		Teva	
	Azitromicina			S	Oral	1 Cp		Not Reported	
	Alopurinol 300			S	Oral	1 Cp		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levofloxacin (2791a)	S	Oral		Not Reported
Hydroferol 266	C	Oral	1 Amp	Not Reported
Astudir 10	C	Oral	1-0-0	Not Reported
Valsartan/Hct 32/12.5	C	Oral	1-0-0	Not Reported
Tamsulosina	C	Oral	1 Cp	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2018	14562377	DIRECT	Y	OT			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Haemodynamic Instability; Hypotension; Mental Status Changes; Somnolence	Azithromycin	Y		S	Intravenous (not otherwise specified)			Fresenius Kabi
	Tacrolimus			C				Not Reported
	Posaconazole			C				Not Reported
	Mycophenolate Mofetil			C				Not Reported
	Amphotericin Conventional			C				Not Reported
	Small Volume Nebulization							
	Basiliximab			C				Not Reported
	Amikacin Small Volume			C				Not Reported
	Nebulization							
	Imipenem-Cilastatin			C				Not Reported
	Ganciclovir			C				Not Reported
	Tigecycline			C				Not Reported
	Methylprednisolone			C				Not Reported
	Vancomycin			C				Not Reported
	Pantoprazole			C				Not Reported
	Furosemide			C				Not Reported
	Nystatin			C				Not Reported
	Chlorehexidine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	12218049	NON-EXPEDITED			US-PFIZER INC- 2016174942			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Augmentin			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14229273	NON-EXPEDITED			US-PFIZER INC-2017508837		74 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer		
	Glipizide			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14423737	NON-EXPEDITED			US-PFIZER INC-2018030198		8 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14444823	EXPEDITED (15-DAY)		HO	PHHY2018HU008753		13 YR	Male	HUN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Condition Aggravated; Pityriasis Lichenoides Et Varioliformis Acuta; Staphylococcal Skin Infection	Azithromycin			S	Unknown			Not Reported		
	Amoxicillin			S	Unknown			Novartis		
	Dapsone			S	Unknown	50 Mg, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Feb-2018	14560895	EXPEDITED (15-DAY)		DE, HO	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18-01		62 YR	Female	PRT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Dyspnoea; Fatigue; Hypoxia	Ceftriaxone			S	Unknown	()		Hikma		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	()	Not Reported
Amlodipine	S	Unknown	()	Not Reported
Tenofovir/Emtricitabine/Efavirenz	C	Unknown	()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14561428	NON-EXPEDITED			US-PFIZER INC-2018076901		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2018	14563835	NON-EXPEDITED			US-TEVA-2018-US-853352			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration	Azithromycin			S		500 Milligram Daily; One Tablet On His First Day And Taking Two Tablets On His Second Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14564864	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-164110		71 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
	Cordarone 200 Mg Comprese			C	Oral	200 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14565929	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-009139		71 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bradycardia; Electrocardiogram Qt Prolonged	Azithromycin Cordarone	S C	Oral Oral	Aurobindo Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566066	NON-EXPEDITED			US-PFIZER INC- 2018077601		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Robitussin		Y	S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Azithromycin			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Doxycycline Calcium			S		Unk		Pfizer
	Hydromorphone Hydrochloride			S		Unk		Unknown
	Clarithromycin			S		Unk		Not Reported
	Lactase			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Gluten			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Lactose			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566072	NON-EXPEDITED			US-PFIZER INC- 2018077073		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Ciprofloxacin			S		Unk		Unknown
	Zithromax			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566241	NON-EXPEDITED			US-PFIZER INC-2018074618			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Feldene			S		Unk		Pfizer	
	Celexa			S		Unk		Not Reported	
	Cymbalta			S		Unk		Not Reported	
	Flexeril			S		Unk		Not Reported	
	Viibryd			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14566393	EXPEDITED (15-DAY)		DE	IT-AUROBINDO-AUR-APL-2018-009643		76 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis; Hepatic Enzyme Increased; Jaundice	Azithromycin			S	Oral	500 Mg, Two Times A Day		Aurobindo	
	Deltacortene			C	Oral			Not Reported	
	Oxygen			C	Respiratory (inhalation)	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14567225	EXPEDITED (15-DAY)		DE, HO	PT-AUROBINDO-AUR-APL-2018-009704		62 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Dyspnoea; Fatigue; Hypoxia; Product Use In Unapproved Indication	Azithromycin			S	Unknown	()		Aurobindo	
	Amlodipine			S	Unknown	()		Aurobindo	
	Ceftriaxone			S	Unknown	()		Not Reported	
	Tenofovir & Emtricitabine & Efaviranz			C		()		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14567352	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-008551		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hypoxia; Mycoplasma Test Positive; Pleural Effusion; Pneumonia; Respiratory Distress	Prednisone			S	Unknown			Aurobindo	
	Azithromycin			S	Unknown	3 Times Per Week		Aurobindo	
	Trimethoprim+Sulfamethoxazole			S	Unknown			Aurobindo	
	Methylprednisolone			S	Unknown			Aurobindo	
	Tacrolimus			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Vancomycin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14567376	EXPEDITED (15-DAY)		DE, DS, HO	ES-TEVA-2018-ES-859472		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Azithromycin			S	Oral	1 Tablet Per Day		Not Reported	
	Rivaroxaban (8281a)			S	Oral	1 Tablet Per Day		Not Reported	
	Amiodarona 200 Mg			S	Oral	1 Tablet Every 8 Hours		Not Reported	
	Cefditoreno (7358a)			S	Oral	400 Mg/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2018	14569171	DIRECT		OT			52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Dreams; Tinnitus; Tinnitus	Azithromycin			S	Oral	Quantity:6 Tablet(S);Other Frequency:2 First Day;		Teva	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Feb-2018	14569718	NON-EXPEDITED			US-TEVA-2018-US-862387			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2018	14576950	DIRECT		HO, LT			40 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Fear; Hyperhidrosis; Product Complaint; Seizure	Azithromycin Tablets Usp			S	Oral	Quantity:1 Tablet(S);		Lupin	
	250mgs			C				Not Reported	
	Epipen			C				Not Reported	
	Atorvastatin			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	12652404	NON-EXPEDITED			US-PFIZER INC-2016372881			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Dextromethorphan Hbr		Y	S		Unk		Unknown	
	Codeine			S		Unk		Not Reported	
	Scopolamine			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	
	Aleve			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14301840	EXPEDITED (15-DAY)		OT	PHHY2017ES185863		26 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Oxytocin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Betamethasone	S	Unknown	500 G, Q8h	Novartis
	Betamethasone	S	Unknown	500 Mg, Q8h	Novartis
	Azithromycin	S	Oral	1 G, Unk	Not Reported
	Ampicillin	S	Intravenous (not otherwise specified)	2 G, Unk	Not Reported
	Ampicillin	S	Intravenous (not otherwise specified)	1 G, Q6h For 48 H	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14570891	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-164414		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Diarrhoea; Muscle Spasms	Azithromycin			S	Oral	500 Mg, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14571714	NON-EXPEDITED			US-PFIZER INC- 2018079499			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2018	14571759	NON-EXPEDITED			US-PFIZER INC- 2018080883		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14573093	NON-EXPEDITED			US-PFIZER INC-2018079543			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14573296	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018078438		5 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Generalised Exanthematous Pustulosis; Drug Reaction With Eosinophilia And Systemic Symptoms; Erythema Multiforme; Fixed Eruption; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Zithromax			S	Oral	Unk		Pfizer	
	Azithromycin			S	Oral	Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14573714	EXPEDITED (15-DAY)		DE, DS, HO	PHHY2018ES031400		61 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cardio-Respiratory Arrest; Hypoxic-Ischaemic Encephalopathy	Azitromicina			S	Oral	1 Cp Dia		Novartis	
	Rivaroxaban			S	Oral	20 Mg, 1 Cp Dia		Not Reported	
	Amiodarona			S	Oral	200 Mg, 1 Cp Cada 8h		Not Reported	
	Cefditoreno			S	Oral	400 Mg Dia		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Feb-2018	14577697	DIRECT		OT			63 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Tongue Coated; Tongue Discolouration	Azithromycin			S	Oral	Quantity:6 Tablet(S);		Not Reported	
	Vitamin D3			C			Not Reported		
	Calcium			C			Not Reported		
	Antihistimin			C			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	13756592	EXPEDITED (15-DAY)			IT-PFIZER INC- 2017301635		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Palatal Oedema; Product Use In Unapproved Indication; Pruritus	Zitromax			S	Oral	1 Df, 1x/Day		Pfizer	
	Zitromax			S			Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14515363	NON-EXPEDITED			PHEH2018US003826			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin 250 Mg			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14575781	NON-EXPEDITED			US-TEVA-2018-US- 861801			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14576212	EXPEDITED (15-DAY)		LT	FR-ROCHE-2081263		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Lucentis			S	Intraocular	Dose Of 10mg/ML In Right		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Azyter		S		Intraocular		Eye 3 Gtt, Qd(Right Eye)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14577577	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018081945			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Azithromycin			S		Unk		Pfizer	
	Cefoxitin Sodium			S		Unk		Unknown	
	Amikacin Sulfate			S	Intravenous (not otherwise specified)	Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14577580	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018081939			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Azithromycin			S		Unk		Pfizer	
	Amikacin Sulfate			S	Intravenous (not otherwise specified)	Unk		Unknown	
	Linezolid			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14577581	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018081940			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Azithromycin			S		Unk		Pfizer	
	Amikacin Sulfate			S	Intravenous (not otherwise specified)	Unk		Unknown	
	Linezolid			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2018	14578771	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018079691			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatotoxicity	Azithromycin			S		Unk		Pfizer	
	Linezolid			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Ethambutol			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	10161179	NON-EXPEDITED			US-PFIZER INC-2014126849			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	
	Zocor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14580682	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-863073		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Diarrhoea; Dizziness; Dyspnoea; Fatigue; Headache; Loss Of Consciousness; Palpitations; Pharyngeal Swelling; Pharyngitis; Vomiting	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14580733	NON-EXPEDITED			US-TEVA-2018-US-853712			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication	Azithromycin			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14581097	NON-EXPEDITED			US-PFIZER INC-2018083421		8 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Renal Disorder	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14581723	NON-EXPEDITED			US-TEVA-2018-US-854663			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14582060	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-860400		34 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Chills; Cold Sweat; Diarrhoea; Diarrhoea; Diarrhoea Haemorrhagic; Dizziness; Malaise; Nausea	Azimed			S	Oral	500 Mg; 1 Tadleta Na Dan		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14582155	NON-EXPEDITED			US-TEVA-2018-US-855187			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Unknown			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14582350	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018081938			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Azithromycin			S		Unk		Pfizer	
	Linezolid			S		Unk		Pfizer	
	Moxifloxacin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14583075	EXPEDITED (15-DAY)		OT	FI-TEVA-2018-FI-860809		31 YR	Male	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Candidiasis; Pharyngeal Oedema; Pyrexia	Azithromycin			S	Oral			Not Reported	
	Agrippal			S	Intramuscular	1,Df,X1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2018	14583077	NON-EXPEDITED		OT	US-TEVA-2018-US-863086			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Platelet Count Decreased	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	13277325	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2017080167		20 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Pancreatitis Acute	Triflucan			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Fortum /00559701/			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Nebcine	S		Unk	Not Reported
	Nureflex	S	Oral	Unk	Not Reported
	Mucomyst /00082801/	C		Unk	Not Reported
	Creon	C		Unk	Not Reported
	Inipomp	C		Unk	Not Reported
	Beclometasone Dipropionate	C		Unk	Not Reported
	Pulmozyme	C		Unk	Not Reported
	Innovair	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	13741841	NON-EXPEDITED			US-PFIZER INC-2017299026		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Cipro /00697201/			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14585586	NON-EXPEDITED			US-PFIZER INC-2018083889			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ceftriaxone Sodium			S		Unk		Pfizer	
	Vantin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2018	14585627	NON-EXPEDITED			US-PFIZER INC-2018084986		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14061024	EXPEDITED (15-DAY)		HO, OT	US-AMGEN- USASP2017148133		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
Adverse Reaction;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
Arthralgia; Asthenia;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
Bradyphrenia; Chronic	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
Kidney Disease; Chronic	Enbrel			S	Unknown	50 Mg, Qwk		Amgen
Obstructive Pulmonary	Amoxicillin			S	Unknown	Unk		Not Reported
Disease; Contusion;	Baclofen			S	Unknown	Unk		Not Reported
Decreased Appetite;	Fosamax			S	Unknown	Unk		Not Reported
Dizziness; Fall; Fatigue;	Percocet			S	Unknown	Unk		Not Reported
Full Blood Count	Welchol			S	Unknown	Unk		Not Reported
Decreased; Hepatic	Zithromax			S	Unknown	Unk		Not Reported
Cancer; Hip Arthroplasty;	Azulfidine			S	Oral	500 Mg, Qd		Not Reported
Hypoaesthesia; Influenza;	Azulfidine			S	Oral	500 Mg, Bid		Not Reported
Knee Arthroplasty;	Albuterol			S	Unknown	Unk		Not Reported
Liposarcoma; Lumbar	Celebrex			C	Oral	200 Mg, Bid		Not Reported
Spinal Stenosis; Mineral	Hcq			C		100 Mg, Unk		Not Reported
Supplementation; Mobility	Hcq			C		200 Mg, Unk		Not Reported
Decreased; Muscle	Orencia			C	Subcutaneous	125 Mg/ML, Qwk		Not Reported
Spasms; Nausea;	Albuterol Sulfate And			C	Nasal	Unk (0.5-2.5 Mg/ML)		Not Reported
Nephrolithiasis; Nerve	Ipratropium Bromide			C	Oral	2 Mg, Unk (4 Times Daily)		Not Reported
Injury; Neuropathy	Xanax			C	Oral	2.5 Mg, Qd		Not Reported
Peripheral; Off Label Use;	Norvasc			C	Oral	Unk Unk, Bid (160-4.5		Not Reported
Oral Contusion;	Symbicort			C	Nasal	Mcg/Act Inhaler)		Not Reported
Osteochondrosis;	Wellbutrin			C	Oral	150 Mg, Bid		Not Reported
Paraesthesia; Peroneal	Cholecalciferol			C	Oral	1000 Unit, Qd		Not Reported
Nerve Injury; Pneumonia;								
Product Storage Error;								
Pruritus; Renal Cancer;								
Rheumatoid Arthritis;								
Sciatica; Skin Papilloma;								
Soft Tissue Sarcoma;								
Spinal Fracture; Spinal								
Osteoarthritis; Swelling;								
Thoracic Vertebral								
Fracture; Vertebroplasty;								
Wheezing; Wrong								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Technique In Product Usage Process	Colace	C	Oral	100 Mg, Bid	Not Reported
	Allegra D 24 Hour	C	Oral	Unk Unk, Qd (180-240 Mg)	Not Reported
	Flonase	C	Nasal	50 Mug, Qd	Not Reported
	Lasix	C	Oral	20 Mg, Qd	Not Reported
	Norco	C	Oral	Unk Unk, Q4h (10-325 Mg) As Needed	Not Reported
	Nexium	C	Oral	40 Mg, Qd	Not Reported
	Mycostatin	C	Oral	Unk Unk, Q4h (100000 MI/Unit Take 5 MI)	Not Reported
	Singulair	C	Oral	10 Mg, Unk (Nightly)	Not Reported
	Vitamin D3	C		Unk	Not Reported
	Caltrate	C		Unk Unk, Qd	Not Reported
	Caltrate	C		Unk (Per Three Day)	Not Reported
	Reclast	C	Unknown	Unk	Not Reported
	Ambien	C	Oral	10 Mg, Unk (Nightly As Needed)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14260377	NON-EXPEDITED			US-PFIZER INC-2017522738		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Azithromycin			S	Oral	1500 Mg, Daily		Pfizer	
	Zithromax			S		1 To 2 Gm		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14480821	NON-EXPEDITED			US-TEVA-2018-US-845193			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Malaise	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14589517	NON-EXPEDITED			US-TEVA-2018-US-856725		15 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Reaction To Excipient	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2018	14592313	EXPEDITED (15-DAY)		HO	FR-BIOVITRUM-2018FR0200		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Arterial Hypertension	Kineret			S	Subcutaneous			Not Reported	
	Imurel			S	Oral			Not Reported	
	Cortancyl			S	Oral			Not Reported	
	Novatrex			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2018	14595701	NON-EXPEDITED			US-TEVA-2018-US-857786			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2018	14595901	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-164993		334 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia;	Azithromycin			S	Oral	()		Sun	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pharyngeal Erythema;
Rash

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2018	14596596	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-011060		334 DAY	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Conjunctival Hyperaemia; Pharyngeal Erythema; Rash	Azithromycin			S	Oral	()		Aurobindo	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	13351597	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017117417		28 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Clostridium Difficile Colitis; Gastrointestinal Disorder; Irritable Bowel Syndrome	Azithromycin			S	Oral	250 Mg, Daily		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14585647	NON-EXPEDITED			US-PFIZER INC-2018083058			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Mar-2018	14597901	NON-EXPEDITED			US-PFIZER INC-2018086997		81 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14597976	NON-EXPEDITED			US-PFIZER INC-2018090413		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14598005	NON-EXPEDITED			US-PFIZER INC-2018091291		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		100 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14598666	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018090710		10 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Presyncope	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14600024	EXPEDITED (15-DAY)		OT	US-BAXTER-2018BAX007249		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pulmonary Embolism	Vancomycin Injection, Usp			S	Unknown			Baxter	
	Vancomycin Injection, Usp			S				Baxter	
	Vancomycin Injection, Usp			S				Baxter	
	Ceftriaxone Injection, Usp (In Dextrose)			S	Unknown			Baxter	
	Ceftriaxone Injection, Usp (In Dextrose)			S				Baxter	
	Ceftriaxone Injection, Usp (In Dextrose)			S				Baxter	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Cefepime Injection	S	Unknown					Baxter
	Cefepime Injection	S						Baxter
	Cefepime Injection	S						Baxter
	Azithromycin	S	Unknown					Not Reported
	Azithromycin	S						Not Reported
	Azithromycin	S						Not Reported
	Meropenem	S	Unknown					Not Reported
	Meropenem	S						Not Reported
	Meropenem	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2018	14600062	NON-EXPEDITED			US-PFIZER INC-2018090336		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	13680004	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017267518		2 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Zitromax			S	Oral	1 Df, Daily		Pfizer	
	Nurofen (Gsl)			C	Oral	5 MI, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14518591	NON-EXPEDITED			US-PFIZER INC-2018061829		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14602511	NON-EXPEDITED			US-PFIZER INC-2018091068		56 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14602811	EXPEDITED (15-DAY)		DE, OT	FR-GLENMARK PHARMACEUTICALS- 2017GMK032855			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Hepatic Failure; Hepatitis; Off Label Use	Hydrocortisone Butyrate			S	Intravenous (not otherwise specified)	100 Mg, Qd		Glenmark	
	Trimebutine Arrow			S	Oral	100 Mg, Bid		Not Reported	
	Vfend			S	Intravenous (not otherwise specified)	200 Mg, Bid		Not Reported	
	Vfend			S	Intravenous (not otherwise specified)	400 Mg, Bid		Not Reported	
	Bisoce			S	Oral	5 Mg, Qd		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported	
	Iclusig			S	Oral	45 Mg, Qd		Not Reported	
	Zyloric			S	Oral	100 Mg, Bid		Not Reported	
	Zyloric			S	Oral	100 Mg, Qd		Not Reported	
	Zyloric			S	Oral	100 Mg, Qd		Not Reported	
	Lasilix /00032601/			S	Oral	40 Mg, Qd		Not Reported	
	Lasilix /00032601/			S	Oral	20 Mg, Qd		Not Reported	
	Polaramine			S	Intravenous (not otherwise specified)	5 Mg, Qd		Not Reported	
	Zithromax			S	Unknown	500 Mg		Not Reported	
	Zithromax			S	Unknown	250 Mg, Qd		Not Reported	
	Hydrea			S	Oral	500 Mg, Bid		Not Reported	
	Fasturtec			C	Intravenous (not otherwise specified)	7.5 Mg, Single ; In Total		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Stilnox	C	Unknown	10 Mg, Unk	Not Reported
Topalgic /00599202/	C	Unknown	50 Mg, Unk	Not Reported
Renagel /01459901/	C	Unknown	800 Mg, Bid	Not Reported
Cortancyl	C	Unknown	40 Mg, Qd	Not Reported
Movicol /08437601/	C	Unknown	Unk	Not Reported
Atarax /00058401/	C	Unknown	12.5 Mg, Qd	Not Reported
Spasfon /00934601/	C	Unknown	80 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2018	14604827	EXPEDITED (15-DAY)	LT, OT		CN-PFIZER INC-2018089655		49 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Blood Pressure Decreased; Cyanosis; Dyspnoea; Flushing; Heart Rate Increased; Hypoaesthesia; Oxygen Saturation Decreased; Skin Discolouration; Unresponsive To Stimuli	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	10192028	EXPEDITED (15-DAY)	OT		CA-PFIZER INC-2014140347		21 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Blood Lactic Acid Increased; Maternal Exposure During Pregnancy	Amlodipine Besilate			S	Transplacental	Unk		Pfizer	
	Azithromycin			S	Transplacental	Unk		Pfizer	
	Cefotaxime			S	Transplacental	Unk		Unknown	
	Abacavir			S	Transplacental	Unk, 2x/Day		Not Reported	
	Intelence			S	Transplacental	200 Mg, 2x/Day		Not Reported	
	Monopril			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Prezista	S	Transplacental	600 Mg, 2x/Day		Not Reported			
	Ritonavir	S	Transplacental	100 Mg, 2x/Day		Not Reported			
	Tenofovir	S	Transplacental	300 Mg, 1x/Day		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607378	NON-EXPEDITED			US-PFIZER INC-2018093799		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14607858	EXPEDITED (15-DAY)		CA	PT-TEVA-2018-PT-864189		83 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dowling-Degos Disease	Azithromycin			S	Oral			Not Reported	
	Diclofenac			C	Oral			Not Reported	
	Allopurinol			C	Oral			Not Reported	
	Concor			C	Oral			Not Reported	
	Candesartan			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2018	14608284	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018092227		90 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Granulocyte Count Decreased; Platelet Count Decreased	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Ceftazidime			S	Intravenous drip	1 G, 2x/Day		Not Reported	
	Montelukast Sodium			C	Oral	10 Mg, 1x/Day		Not Reported	
	Proscar			C	Oral	5 Mg, 1x/Day		Not Reported	
	Harnal			C	Oral	0.2 Mg, 1x/Day		Not Reported	
	Tamiflu			C	Oral	75 Mg, 2x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14608663	NON-EXPEDITED			US-TEVA-2018-US-864832			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chills; Cold Sweat; Malaise; Muscular Weakness	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Mar-2018	14608835	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2018091450		3 YR	Female	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pharyngeal Disorder; Rash; Tonsillar Hypertrophy	Zithromax			S	Intravenous drip	0.16 G, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14287294	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017532235		35 YR	Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Hot Flush; Suffocation Feeling	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2018	14510935	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018049258		53 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Papilloedema; Vision Blurred; Visual Acuity Reduced	Zithromax			S	Oral	Unk		Pfizer	
	Zithromax			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14610803	EXPEDITED (15-DAY)		HO	US-AXELLIA-001445		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Off Label Use; Pulmonary Embolism	Azithromycin			S				Not Reported	
	Vancomycin			S				Xellia Pharmaceuticals	
	Ceftriaxone			S				Not Reported	
	Cefepime			S				Not Reported	
	Meropenem			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14613179	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180309477		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenic Purpura	Tramadol Hydrochloride			S	Oral			Not Reported	
	Helicidine			S	Oral			Not Reported	
	Ordipha			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14614230	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2018M1014709		2 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Auscultation; Cough; Drug Ineffective; Electrolyte Imbalance; Mucosal Dryness; Pneumonitis; Pyrexia; Renal Failure	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14614881	NON-EXPEDITED			US-TEVA-2018-US-861467			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Chest Pain; Dysphagia; Oesophageal Disorder		Azithromycin		S		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14614967	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018092873		334 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia; Pharyngeal Erythema; Rash	Azithromycin			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14615069	EXPEDITED (15-DAY)		HO, LT, OT	GH-PFIZER INC- 2018092372			Male	GHA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Incorrect Drug Administration Rate; Loss Of Consciousness	Zithromax			S	Intravenous bolus	500 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14615106	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC- 2018091925		4 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain	Zithromax			S	Oral	160 Mg, 1x/Day		Pfizer	
	Qi Xian			S	Intravenous drip	160 Mg, 1x/Day		Not Reported	
	Erythromycin Lactobionate			S	Intravenous drip	160 Mg, 2x/Day		Not Reported	
	Sodium Bicarbonate			C	Intravenous drip	1.6 MI, 2x/Day		Not Reported	
	Glucose Injection			C	Intravenous drip	160 MI, 2x/Day		Not Reported	
	Glucose Injection			C	Intravenous drip	160 MI, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14615500	NON-EXPEDITED		OT	CN-LUPIN PHARMACEUTICALS INC.-2018-01707		6 YR	Male	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Azithromycin			S	Intravenous (not otherwise specified)	0.25 G, Unk		Lupin	
	Cefmetazole Sodium			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2018	14615537	NON-EXPEDITED		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-07228		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Urticaria	Levofloxacin			S		Unk		Not Reported	
	Levofloxacin			S	Oral	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Lupin	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ampicillin And Sulbactam			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615596	NON-EXPEDITED			TR-LUPIN PHARMACEUTICALS INC.-2017-07415		50 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fixed Eruption	Azithromycin			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615632	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-07424		8 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Ear Infection	Azithromycin Tablets			S	Unknown	Unk		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615708	NON-EXPEDITED			GB-LUPIN PHARMACEUTICALS INC.-2017-07946		10 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia	Azithromycin			S	Unknown	Unk		Lupin	
	Lansoprazole Dispersible Tablets			S	Oral	15 Mg, Qd		Not Reported	
	Creon			S	Unknown	10,000 Capsules At An Unknown Dose		Not Reported	
	Orkambi			C	Unknown	Unk		Not Reported	
	Cotrimoxazole			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Tobramycin			C	Unknown	Unk		Not Reported	
	Pulmozyme			C	Unknown	Unk		Not Reported	
	Promixin [Colistimethate Sodium]			C	Unknown	Unk		Not Reported	
	Moxifloxacin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615718	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00120			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Cefuroxime Axetil Tablets Usp, 250 Mg			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615725	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00123		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chromaturia	Azithromycin Tablets Usp, 250 Mg	S	Oral	250 Mg, Qd	Lupin				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615735	NON-EXPEDITED		HO, OT	CN-LUPIN PHARMACEUTICALS INC.-2018-00139		30 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Exposure During Pregnancy	Azithromycin			S	Unknown	500 Mg, Qd (Loading Dose)		Lupin	
	Azithromycin			S	Unknown	250 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615752	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00333			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Dizziness	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615769	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00517			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14615801	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00531			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Headache; Nausea	Azithromycin Tablets Usp, 250 Mg			S	Oral	Unk		Lupin	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616012	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-01054		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Nocturia	Azithromycin Tablets Usp, 250 Mg			S	Oral	500 Mg, Qd 2 Tablets		Lupin	
	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
	Benzonatate			C	Unknown	100 Mg, Prn 1gel Capsule Every 8 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616013	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00782		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gait Inability; Muscular Weakness	Azithromycin Tablets Usp, 250 Mg			S	Oral	2 Df, Qd		Lupin	
	Azithromycin Tablets Usp, 250 Mg			S	Oral	1 Df, Qd		Lupin	
	Losartan			C	Unknown	Unk		Not Reported	
	Potassium Citrate			C		10 Meq, Bid		Not Reported	
	Aspirin /00002701/			C	Unknown	1 Df, Single, Approximately 680mg		Not Reported	
	Aspirin /00002701/			C	Unknown	2 Df, 12 Hours Apart		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616014	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00546			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Residue Present	Azithromycin Tablets Usp, 500 Mg			S	Oral	500 Mg, Qd		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616015	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00900		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Head Discomfort; Product Use In Unapproved Indication	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Bid		Lupin	
	Tramadol			C	Oral	Unk		Not Reported	
	Amlodipine			C	Oral	5 Mg, Qd		Not Reported	
	Diazepam			C	Oral	300 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616016	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00702			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14616017	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-00535		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Peripheral Swelling; Urticaria	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14619611	EXPEDITED (15-DAY)		OT	UA-TEVA-2018-UA- 865549		62 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Sumamed			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2018	14619613	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-864969		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Immunoglobulin E Increased; Dizziness; Intestinal Obstruction; Pruritus	Azitromicina Teva			S	Oral				Not Reported
	Azitromicina Teva			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2018	14624460	DIRECT		OT			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Memory Impairment	Azithromycin 250 Mg Dose Pack			S	Oral	Quantity:5 Tablet(S);			Teva
	Epzicom			C					Not Reported
	Viramune			C					Not Reported
	Bystolic			C					Not Reported
	Diovan			C					Not Reported
	Praluent			C					Not Reported
	Vit C			C					Not Reported
	Vit D3			C					Not Reported
	Multi Vit			C					Not Reported
	Folate			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2018	14623118	EXPEDITED (15-DAY)		DS	PHHY2018FR039441		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Unilateral	Cosentyx			S	Subcutaneous	300 Mg, Qmo			Novartis
	Cosentyx			S	Subcutaneous	300 Mg, Qmo			Novartis
	Azithromycin Anhydrous			S	Oral	Unk			Not Reported
	Effexor			C	Oral				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	13952610	NON-EXPEDITED		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-03294		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	13952612	NON-EXPEDITED		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-03315		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	13952614	NON-EXPEDITED		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2017-03316		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14624182	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US- 866635		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Decreased Appetite; Dysphagia; Dyspnoea; Facial Pain; Gait Inability	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14624675	NON-EXPEDITED			US-PFIZER INC-2018099596			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Xeljanx Xr			C		Unk		Not Reported	
	Tamiflu			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14624764	NON-EXPEDITED			US-PFIZER INC-2018098224			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14624856	NON-EXPEDITED			US-PFIZER INC-2018100633			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tachycardia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14625243	EXPEDITED (15-DAY)		HO, OT	DE-GLENMARK PHARMACEUTICALS-2017GMK033010			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Glenmark	
	Voriconazole			S	Other	8 Mg/Kg, Qd		Glenmark	
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Glenmark	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Amphotericin B, Liposome	S	Unknown	4 Mg/Kg, Qd	Not Reported
	Pegaspargase	S	Unknown	Unk	Not Reported
	Sodium Chloride	S	Nasal	0.9% Nose Spray	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Dexamethasone	S	Unknown	10 Mg/M2 For 21 Days Then Tapering ()	Not Reported
	Methotrexate	C	Intrathecal	Unk	Not Reported
	Vincristine	C	Unknown	Unk	Not Reported
	Daunorubicin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14627356	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2018100668		47 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pericarditis	Azithromycin			S		Unk		Pfizer
	Hydroxychloroquine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2018	14629359	DIRECT		OT			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Congestion; Tinnitus	Azithromycin 250 Mg Tablet			S	Oral	Quantity:6 Tablet(S);		Pliva
	Synthroid			C				Not Reported
	Baby Aspirin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14346711	NON-EXPEDITED			US-TEVA-2017-US-837997			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glossodynia; Hypoaesthesia Oral; Intentional Product Use Issue	Azithromycin			S		200 Mg/5 MI; 22 MI Suspension		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14485313	NON-EXPEDITED			US-PFIZER INC- 2018046612		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Mesalamine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14630006	NON-EXPEDITED			US-PFIZER INC- 2018102369			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14631022	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2018100447		86 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Pruritus; Rash	Zithromax			S	Oral	1 Df, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14631416	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018097335		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bone Marrow Failure; Drug Interaction; Renal Failure	Novatrex	S	Oral	15 Mg, Weekly	Pfizer
	Ciprofloxacin Kabi	S	Intravenous (not otherwise specified)	800 Mg, 1x/Day	Not Reported
	Calciparine	C	Subcutaneous	Unk	Not Reported
	Fenofibrate Arrow	C	Oral	160 Mg, 1x/Day	Not Reported
	Omeprazole Mylan /00661201/	C	Intravenous (not otherwise specified)	80 Mg, 1x/Day	Not Reported
	Gabapentine Arrow	C	Oral	1200 Mg, 1x/Day	Not Reported
	Furosemide Renaudin	C	Intravenous (not otherwise specified)	40 Mg, 1x/Day	Not Reported
	Cortancyl	C	Oral	5 Mg, 1x/Day	Not Reported
	Skenan Lp	C	Oral	20 Mg, 1x/Day	Not Reported
	Loxen L P	C		50 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14632147	NON-EXPEDITED			US-PFIZER INC- 2018102294			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2018	14632166	NON-EXPEDITED			US-TEVA-2018-US- 857681			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Amoxicillin			S		400/5ml, 75 MI		Teva
	Azithromycin			S		30 MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	13949503	EXPEDITED (15-DAY)		LT	IT-PFIZER INC- 2017389868		2 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Chest Pain; Hypotonia; Loss Of Consciousness; Pain In Extremity; Rash	Zitromax	S	Oral	Unk				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14634375	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-866874		72 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Dry Mouth; Fatigue; Loss Of Consciousness; Taste Disorder	Sumamed			S	Unknown	500 Milligram Daily;		Not Reported	
	Sumamed			S		.5 Dosage Forms Daily; Half Tablet (500 Mg) Once Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14636654	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-867321		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus; Rash Macular	Azithromycin			S	Oral			Not Reported	
	Gentalline Unilabo			S				Not Reported	
	Celestamine			S	Oral			Not Reported	
	Prednisone			C				Not Reported	
	Furosemide			C				Not Reported	
	Diffu K			C				Not Reported	
	Inexium 40 Mg Gastro-Resistant Tablet			C	Oral			Not Reported	
	Atovaquone			C				Not Reported	
	Tracleer			C	Oral			Not Reported	
	Formoterol			C	Respiratory (inhalation)			Not Reported	
	Tamoxifen			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2018	14637461	NON-EXPEDITED			US-TEVA-2018-US-858924			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14639334	NON-EXPEDITED			PHEH2018US009844			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort	Azithromycin 250 Mg			S	Oral	250 Mg, Unk		Novartis	
	Azithromycin 250 Mg			S				Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14640176	EXPEDITED (15-DAY)		HO, OT	PHHY2016NL186191		65 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Appetite Disorder; Back Pain; Bone Pain; Chronic Obstructive Pulmonary Disease; Dehydration; Dizziness; Fatigue; Headache; Hypersensitivity; Malaise; Myalgia; Nausea; Pneumonia; Sense Of Oppression; Vomiting; Weight Decreased	Azithromycin			S	Unknown			Novartis	
	Adenuric			S	Unknown			Not Reported	
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported	
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported	
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported	
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported	
	Nebusal			S	Respiratory (inhalation)	2 Df, Qd		Not Reported	
	Spironolacton			C	Oral	1 Df, Qd		Not Reported	
	Beclometasone Dipropionate W/Formoterol Fumar			C	Oral	6 Df, (2 Df, Tid)		Not Reported	
	Budesonide			C	Oral			Not Reported	
	Pantoprazol			C	Oral	2 Df, Qd (1 Df, Bid)		Not Reported	
	Itraconazol			C	Oral	2 Df, Qd (1 Df, Bid)		Not Reported	
	Macrogol			C	Oral			Not Reported	
	Benzbromaron			C	Oral	1 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Benzbromaron	C	Oral	0.5 Df, Qd	Not Reported
Levothyroxine	C	Oral	3 Df, Qd	Not Reported
Levothyroxine	C		1 Df, Qd	Not Reported
Paracetamol	C	Oral	4 Df, Qd (1 Df, Qid)	Not Reported
Paracetamol	C	Oral	3 Df, Qd (1 Df, Tid)	Not Reported
Hidroxocobalamina	C	Subcutaneous		Not Reported
Kaliumchloride	C	Oral	3d1t	Not Reported
Oxicodona	C	Oral	8 Df, Qd (2 Df, Qid)	Not Reported
Colchicine	C	Oral	2 Df, Qd (1 Df, Bid)	Not Reported
Codeine	C	Oral	3 Df, Qd (1 Df, Tid)	Not Reported
Azitromycine	C	Oral	3 Df, Qw (1 Df, 3/W)	Not Reported
Sodium Chloride	C	Subcutaneous	1 Df, Qmo (1 Df, Monthly (1/M))	Not Reported
Paracetamol Codeine	C	Rectal		Not Reported
Acetylcysteine	C	Oral	1 Df, Qd	Not Reported
Calciumcarbonaat	C	Oral	2 Df, Qd	Not Reported
Ipratropium W/Salbutamol	C	Oral		Not Reported
Algeldrate W/Magnesium Hydroxide	C	Oral	30 MI, Qd (15 MI, Bid)	Not Reported
Fentanyl	C	Topical		Not Reported
Oxycodon	C	Oral		Not Reported
Labetalol	C	Oral	1 Df, Qd	Not Reported
Sumatriptan	C	Oral		Not Reported
Desloratadine	C	Oral	2 Df, Qd (1 Df, Bid)	Not Reported
Metoclopramide	C	Oral	1 Df, Prn	Not Reported
Colistine	C	Oral	2 Df, Qd (1 Df, Bid)	Not Reported
Ezetimibe W/Simvastatin	C	Oral	1 Df, Qd	Not Reported
Pregabalin	C	Oral	6 Df, Qd (3 Df, Bid)	Not Reported
Salbutamol	C	Respiratory (inhalation)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nystatine	C	Oral	20 MI, Qd (5 MI, Qid)	Not Reported
Colecalciferol	C	Oral	2 Df, Unk	Not Reported
Moxifloxacin	C	Oral	1 Df, Qd	Not Reported
Carbasalaatcalcium	C	Oral	1 Df, Qd	Not Reported
Metoclopramide	C	Rectal	1 Df, Prn	Not Reported
Metformine	C	Oral	2 Df, Qd (1 Df, Bid)	Not Reported
Prednisolon	C		1 Df, Qd	Not Reported
Tiotropium	C	Oral	2 Df, Qd	Not Reported
Nortriptyline	C	Oral		Not Reported
Bumetanide	C	Oral	2 Df, Qd (1 Df, Bid)	Not Reported
Fluticasone Furoate	C	Nasal	2 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2018	14640513	NON-EXPEDITED			US-PFIZER INC-2018107705			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	12334739	NON-EXPEDITED			US-PFIZER INC-2016235280		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Zithromax			S	Oral	1500 Mg, 2x/Day		Pfizer	
Intentional Product Use	Zithromax			S	Oral	1500 Mg, 2x/Day		Pfizer	
Issue; Joint Dislocation;	Zithromax			S		Unk		Pfizer	
Lymphoedema; Nausea;	Zithromax			S				Pfizer	
Product Complaint;	Zithromax			S				Pfizer	
Product Use In	Zithromax			S				Pfizer	
Unapproved Indication;	Azasite			C		1 Gtt, Unk, [One Drop In Each Eye]		Not Reported	
Product Use Issue; Rash									
Macular; Skin Disorder;	Levaquin			C		Unk		Not Reported	
Suspected Counterfeit Product									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14586797	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2018085902		51 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Shock	Precedex			S	Intravenous (not otherwise specified)	0.3 - 0.6 Mcg/Kg/Hr		Pfizer
	Ceftriaxone Sodium			S	Intravenous drip	2 G, Daily (2 G/24hr)		Pfizer
	Vancomycin Hcl			S	Intravenous drip	0.5 G, 2x/Day (0.5 G/12hr)		Pfizer
	Zithromac			S	Intravenous drip	500 Mg, Daily (500 Mg/24hr)		Pfizer
	Blinded Therapy			S	Intravenous (not otherwise specified)	11.2 Mcg + Distilled Water 1 MI (1 In 1 Day, Scheduled To Be Administered For 6 Days)		Not Reported
	Heparin Sodium			S	Intravenous (not otherwise specified)	2000 Units/Hr		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14605216	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL027161		35 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Infection;	Ceftriaxone			S	Unknown	1000 Mg, Qd		Novartis
Condition Aggravated;	Ceftriaxone			S				Novartis
Drug Ineffective; Drug Resistance;	Amoxicillin			S	Unknown	1000 Mg, Tid		Not Reported
Immunodeficiency	Amoxicillin			S				Not Reported
Common Variable;	Amoxicillin			S	Unknown	Amoxicillin 1000 Mg Thrice Daily Plus Clavulanate 200 Mg Thrice		Not Reported
Intentional Product Misuse; Meningism;	Trihydrate+Potassium Clavulanate							
Neisseria Infection;	Amoxicillin			S				Not Reported
Neuropathy Peripheral;	Trihydrate+Potassium Clavulanate							
Periodontitis; Pharyngitis	Cefadroxil Monohydrate			S	Unknown	500 Mg, Bid		Not Reported
Streptococcal;	Cefadroxil Monohydrate			S				Not Reported
Pneumococcal Infection; Pneumonia;	Cefadroxil Monohydrate							Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Staphylococcal Infection;	Azithromycin	S	Unknown	500 Mg, Qd	Not Reported
Stomatococcal Infection;	Azithromycin	S			Not Reported
Streptococcal Infection;	Azithromycin	S			Not Reported
Veillonella Infection	Azithromycin	S			Not Reported
	Clavulanic Acid	S	Unknown	200 Mg, Tid	Not Reported
	Clavulanic Acid	S			Not Reported
	Prednisolone	C	Unknown	1 Df (Upto 120 Mg Per Day), Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14647232	NON-EXPEDITED			US-PFIZER INC-2018106381			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Wheezing	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14647401	NON-EXPEDITED			US-PFIZER INC-2018110483		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14648587	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1015866		54 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Visual Acuity Reduced	Azithromycin			S	Oral	3 Días		Not Reported
	Prednisona Cinfa			S	Oral	30 Mg, Qd		Mylan
	Algiasdin			S	Oral	600 Mg, Q3d		Mylan
	Acido Acetilsalicilico Stada			C	Oral	100 Mg, Qd		Mylan
	Dolocatil Codeina			C		Unk		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14649111	EXPEDITED (15-DAY)		HO	US-FRESENIUS KABI-FK201803208		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vanishing Bile Duct Syndrome	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Cotrimoxazole			S	Unknown			Not Reported	
	Nevirapine			S	Unknown			Not Reported	
	Unspecified Antiretroviral Therapy			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14650019	EXPEDITED (15-DAY)		OT	NO-PFIZER INC-2018104170		61 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Haemorrhagic	Azitromax			S		500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2018	14651387	DIRECT		OT			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin Tablets Usp 250mg			S	Oral	Quantity:6 Tablet(S);		Teva	
	Claritin			C				Not Reported	
	Multi-Vitamin			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Calcium			C				Not Reported	
	Flaxseed Oil			C				Not Reported	
	Glucosamine			C				Not Reported	
	Mucinex			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14269425	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2017491626		23 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cold Sweat; Diarrhoea; Hepatitis Acute; Nausea; Pain; Vasoconstriction	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14505287	EXPEDITED (15-DAY)		HO	HU-PFIZER INC-2018051722		13 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pityriasis Lichenoides Et Varioliformis Acuta; Staphylococcal Skin Infection	Azithromycin			S	Oral	Unk		Pfizer	
	Amoxicillin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14527559	EXPEDITED (15-DAY)		HO, OT	DE-SHIRE-DE201804665			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Oncaspar			S	Unknown			Shire	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Not Reported	
	Voriconazole			S	Other	8 Mg/Kg, Unk		Not Reported	
	Sodium Chloride			S	Nasal	0.9% Nose Spray		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Liposomal Amphotericin B	S	Unknown	4 Mg/Kg/Day	Not Reported				
	Dexamethasone	S	Unknown	10 Mg/M2 For 21 Days Then Tapering	Not Reported				
	Vincristine	C	Unknown		Not Reported				
	Methotrexate	C	Intrathecal		Not Reported				
	Daunorubicin	C	Unknown		Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14543880	NON-EXPEDITED			US-PFIZER INC- 2018065843			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Insomnia	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14652640	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-153928		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Drug Reaction With Eosinophilia And Systemic Symptoms; Liver Function Test Increased; Vasculitis	Amoxicillin Clavulanic Acid			S	Unknown	Unk		Ranbaxy	
	Amoxicillin Clavulanic Acid			S	Unknown	Unk		Ranbaxy	
	Azithromycin			S	Unknown			Sun	
	Oseltamivir			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14653820	NON-EXPEDITED			US-PFIZER INC- 2018109860		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swollen Tongue	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14653849	NON-EXPEDITED			US-PFIZER INC-2018110816			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Heart Rate Irregular; Tremor; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14653902	NON-EXPEDITED			US-PFIZER INC-2018110421		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14654682	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-02215		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vanishing Bile Duct Syndrome	Nevirapine			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Lupin	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14655413	EXPEDITED (15-DAY)		OT	PHHY2018PT039746		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Thoracic Cavity Drainage	Azithromycin	S	Unknown	Unk	Novartis
Test Abnormal	Amoxicillin Sodium+Potassium Clavulanate	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14655635	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-869458		14 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Sumamed			S	Unknown	500 Milligram Daily;		Not Reported	
Arthralgia; Fatigue;	Sumamed			S				Not Reported	
Headache; Loss Of	Lactoangin			C		1 Dosage Form =		Not Reported	
Consciousness; Myalgia;						Metabolites Of Lactic Acid			
Nausea						Bacteria From The Genus			
						Lactobacillus + Menthol			
						+Mint Oil			
	Probiotic			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2018	14655779	EXPEDITED (15-DAY)		OT	PHHY2018PT040166		60 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Dyspnoea;	Salmeterol/Fluticasone			S	Unknown			Not Reported	
Productive Cough;	Azithromycin			S	Unknown			Novartis	
Rhinorrhoea; Sputum	Fluticasone			S	Nasal			Not Reported	
Retention; Wheezing	Erdosteine			S	Unknown			Not Reported	
	Lansoprazole			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14607417	NON-EXPEDITED			US-PFIZER INC-2018092868		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Azithromycin			S		Unk		Pfizer	
Urticaria									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14658227	NON-EXPEDITED		HO	US-TEVA-2018-US-871251			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14658474	NON-EXPEDITED			US-PFIZER INC-2018114094		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
	Losartan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14659271	NON-EXPEDITED			US-TEVA-2018-US-863294			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Dizziness; Dyspepsia; Nausea; Nervousness	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14659366	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018107119		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Arterial Hypertension	Novatrex			S	Oral	12.5 Mg, Weekly		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imurel /00001501/	S	Oral	50 Mg, 1x/Day	Not Reported
Kineret	S	Subcutaneous	100 Mg, 1x/Day	Not Reported
Cortancyl	S	Oral	2.5 Mg, 4x/Day (Every 6 Hours)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2018	14660837	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018113010		62 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Drug Interaction; Hyperkalaemia; Metabolic Acidosis; Product Use Issue	Azithromycin			S	Oral	480 Mg, 2x/Day (Once In 12 Hours)		Pfizer
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	Unk		Unknown
	Cotrimoxazol			S	Intravenous (not otherwise specified)	1 Df, 4x/Day (Every 6 Hours)		Not Reported
	Ciclosporin			S	Oral	75 Mg, 2x/Day (Once In 12 Hours)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14572625	NON-EXPEDITED			US-PFIZER INC-2018078908			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14662706	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-014865			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea; Dyspnoea; Nausea; Vomiting	Azithromycin			S		()		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14663452	NON-EXPEDITED			US-PFIZER INC-2018113627			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
White Blood Cell Count Decreased	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14663521	NON-EXPEDITED			US-PFIZER INC-2018118237		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14663680	NON-EXPEDITED			US-PFIZER INC-2018117975		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Medrol			S	Oral	24mg (6 Tablets Once)		Pfizer	
	Z-Pak			S	Oral	500mg (Two Tablets Once)		Not Reported	
	Promethazine			S		25 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14664734	NON-EXPEDITED			US-PFIZER INC-2018113657		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Palpitations; White Blood Cell Count Decreased	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14665947	EXPEDITED (15-DAY)		OT	PHHY2018US040639		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestatic Liver Injury; Hepatomegaly; Jaundice; Muscle Atrophy; Skin Abrasion; Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown			Novartis	
	Nevirapine			S	Unknown			Not Reported	
	Nevirapine			S				Not Reported	
	Sulfamethoxazol/Trimetoprim			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2018	14668751	DIRECT		DS, HO, LT			36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Guillain-Barre Syndrome; Muscle Tightness; Peroneal Nerve Palsy	Azithromycin	Y		S				Pfizer	
	Soma			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14654207	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2018US013464		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Tacrolimus			S	Unknown	Unk Unk, Unknown Freq.		Astellas	
	Ondansetron			S	Intravenous (not otherwise specified)			Not Reported	
	Prochlorperazine			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Azithromycin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	
	Levalbuterol			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14654252	EXPEDITED (15-DAY)		OT	US-ASTELLAS-2018US013460		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Tacrolimus			S	Unknown	Unk, Unknown Freq.		Astellas	
	Ondansetron			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk, Unknown Freq.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14662049	EXPEDITED (15-DAY)		HO	US-ABBVIE-18K-163-2288015-00		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Sodium Decreased; Diarrhoea; Drug Ineffective; Fall; Femur Fracture; Pharyngitis Streptococcal	Creon			S	Oral	5 Capsules Per Day		Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	
	Lisinopril			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14663532	NON-EXPEDITED			US-PFIZER INC-2018116628		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Sulfadiazine Silver			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14667804	NON-EXPEDITED			US-PFIZER INC-2018118616			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14667810	NON-EXPEDITED			US-PFIZER INC-2018119201		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Fatigue	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14668490	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2018113517		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Extradural Haematoma; International Normalised Ratio Increased	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Ceftazidime Arrow			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported	
	Ciprofloxacin Arrow			S	Oral	500 Mg, 1x/Day		Not Reported	
	Previscan (Fluindione)			S	Oral	30 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14668914	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1016979		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown	Unk		Not Reported	
	Sulphamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported	
	Nevirapine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14669528	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2018GMK033479		50 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Granuloma; Hepatitis; Vanishing Bile Duct Syndrome	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Glenmark	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2018	14670838	NON-EXPEDITED			US-PFIZER INC- 2018118490			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Compazine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	13539578	EXPEDITED (15-DAY)		OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-17- 01		88 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Amoxicillin/Clavulanic Acid			S	Unknown			Hikma	
	Azithromycin			S	Unknown			Not Reported	
	Bisoprolol			C	Unknown			Not Reported	
	Bromazepam			C	Unknown			Not Reported	
	Pentoxifylline			C	Unknown			Not Reported	
	Triflusal			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
	Cyamemazine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14661541	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2018112205		38 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Pfizer	
	Tacrolimus			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Prochlorperazine			S		Unk		Not Reported	
	Levalbuterol /01419301/			C		Unk		Not Reported	
	Trimethoprim Sulfamethoxazole			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14672621	NON-EXPEDITED			US-PFIZER INC- 2018122601		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14672657	NON-EXPEDITED			US-PFIZER INC- 2018122385		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14673660	NON-EXPEDITED		HO	US-TEVA-2018-US- 871791			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Hyperhidrosis; Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2018	14674571	EXPEDITED (15-DAY)		HO	PL-AUROBINDO-AUR- APL-2018-015807		2 YR	Female	POL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anaemia; Auscultation; Cough; Drug Ineffective; Electrolyte Imbalance; Mucosal Dryness; Pneumonitis; Pyrexia; Renal Failure	Azithromycin			S	Unknown	Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14674816	EXPEDITED (15-DAY)		OT	PHHY2018ES049761		69 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Angioedema; Bronchospasm; Palatal Oedema	Azitromicina			S	Oral	500 Mg, Qd		Novartis	
	Acetilcisteina			S	Oral	200 Mg, Q8h		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14675239	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018119610		31 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Delirium; Dizziness; Medication Error	Zithromax			S	Oral	1000 Mg, 1x/Day		Pfizer	
	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14675980	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-867797		45 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea; Paraesthesia; Swollen Tongue	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Mar-2018	14677219	DIRECT		HO, OT			55 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Supraventricular Tachycardia	Azithromycin Tablets 250mg Distran Tec Greenstone Llc Peapock, Nj 07977-Made In India	S	Oral	Quantity:1 Capsule(S);	Teva
	Metformin	C			Not Reported
	Verapamil	C			Not Reported
	Bromphen	C			Not Reported
	Mucinex Waldryl	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2018	14677479	EXPEDITED (15-DAY)		DS	PT-MYLANLABS-2018M1017382		85 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
	Mometasona Sandoz			S	Nasal	2 Df, Qd		Mylan	
	Losartan			C	Oral	50 Mg, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14570900	EXPEDITED (15-DAY)		DE, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2017R1-164271		76 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis; Hepatic Enzyme Increased; Jaundice	Azitromicina			S	Oral	500 Mg, Bid		Not Reported	
	Oxygen			C	Respiratory (inhalation)	Unk		Not Reported	
	Deltacortene 25 Mg Compresse			C	Oral	25 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14678815	NON-EXPEDITED			US-TEVA-2018-US-874006			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14678872	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose ; In Total		Westward	
	Azithromycin			S	Unknown	()		Not Reported	
	Tacrolimus			S	Unknown	()		Not Reported	
	Sulfamethoxazole And Trimethoprim			C	Unknown	()		Westward	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14679007	EXPEDITED (15-DAY)		OT	US-WEST-WARD PHARMACEUTICALS CORP.-US-H14001-18-02		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose ; In Total		Westward	
	Prochlorperazine			S	Unknown	()		Westward	
	Tacrolimus			S	Unknown	()		Not Reported	
	Azithromycin			S	Unknown	()		Not Reported	
	Sulfamethoxazole And Trimethoprim			C	Unknown	()		Not Reported	
	Levalbuterol			C	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14679285	NON-EXPEDITED			US-PFIZER INC- 2018120395			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680263	NON-EXPEDITED			US-TEVA-2018-US-873337		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Weight Decreased	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680534	NON-EXPEDITED			US-TEVA-2018-US-874317			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Heart Rate Irregular	Azithromycin			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680629	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2018GMK033569		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	In Total		Glenmark	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole W/Trimethoprim			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14680640	EXPEDITED (15-DAY)		OT	US-GLENMARK PHARMACEUTICALS-2018GMK033568		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg (In Total)		Glenmark	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Prochlorperazine	S	Unknown	Unk				Not Reported	
	Tacrolimus	S	Unknown	Unk				Not Reported	
	Azithromycin	S	Unknown	Unk				Not Reported	
	Levalbuterol /01419301/	C	Unknown	Unk				Not Reported	
	Sulfamethoxazole W/Trimethoprim	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14681229	NON-EXPEDITED			US-TEVA-2018-US-873342			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14681306	NON-EXPEDITED			US-PFIZER INC-2018123861		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk			Pfizer
	Zithromax			S					Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2018	14682069	NON-EXPEDITED			US-PFIZER INC-2018124544		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
	Morphine Sulfate			S		Unk			Unknown
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14618646	EXPEDITED (15-DAY)		HO, LT, OT	BG-PFIZER INC-2018086088		63 YR	Male	BGR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis		Azithromycin		S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14682919	NON-EXPEDITED			PHEH2018US011383			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Azithromycin			S	Ophthalmic	Unk			Novartis
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683029	NON-EXPEDITED			US-TEVA-2018-US-875142		11 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nasopharyngitis; Product Storage Error	Azithromycin			S		200 Mg/5 MI			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683057	NON-EXPEDITED			US-TEVA-2018-US-875423			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Storage Error	Azithromycin			S		200 Mg/5 MI			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683411	NON-EXPEDITED			US-PFIZER INC-2018126406		52 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
	Morphine Sulfate			S		Unk			Unknown
	Levaquin			S		Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14683427	NON-EXPEDITED			US-PFIZER INC-2018125923			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14683451	NON-EXPEDITED			US-PFIZER INC-2018126103			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14683576	EXPEDITED (15-DAY)		OT	PHHY2018US044700		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Once/Single		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Prochlorperazine			S	Unknown	Unk		Novartis	
	Levalbuterol			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683786	NON-EXPEDITED			US-TEVA-2018-US-874180			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Diarrhoea	Azithromycin			S	Oral			Teva	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683879	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-016749		50 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chest Discomfort	Azithromycin			S	Unknown	Unk		Aurobindo	
	Atrovent			C	Respiratory (inhalation)	2 Puffs Up To Four Times A Day () ; As Necessary		Not Reported	
	Omeprazole			C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683907	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-017210		14 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Muscle Swelling	Azithromycin			S	Oral	As Necessary		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14683976	NON-EXPEDITED			US-TEVA-2018-US-874320			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Diarrhoea	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2018	14686342	NON-EXPEDITED			US-TEVA-2018-US-875132		90 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Prescribing Error	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2018	14686816	NON-EXPEDITED			US-PFIZER INC-2018126082		4 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cough; Heart Rate Increased; Vomiting	Azithromycin			S	Oral	One And A Half Teaspoons		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14212086	EXPEDITED (15-DAY)		HO, OT	US-DSJP-DSU-2017-154431			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Adverse Reaction;	Welchol			S	Unknown	Unk		Daiichi	
Arthralgia; Asthenia;	Enbrel			S	Unknown	50 Mg, Once Every 1 Wk		Not Reported	
Bradyphrenia; Chronic	Enbrel			S	Unknown	50 Mg, Once Every 1 Wk		Not Reported	
Kidney Disease; Chronic	Enbrel			S	Unknown	50 Mg, Once Every 1 Wk		Not Reported	
Obstructive Pulmonary	Enbrel			S	Unknown	50 Mg, Once Every 1 Wk		Not Reported	
Disease; Contusion;	Enbrel			S	Unknown	50 Mg, Once Every 1 Wk		Not Reported	
Decreased Appetite;	Amoxicillin			S	Unknown	Unk		Not Reported	
Dizziness; Fall; Fatigue;	Baclofen			S	Unknown	Unk		Not Reported	
Full Blood Count	Fosamax			S	Unknown	Unk		Not Reported	
Decreased; Hepatic	Percocet /00446701/			S	Unknown	Unk		Not Reported	
Cancer; Hip Arthroplasty;	Zithromax			S	Unknown	Unk		Not Reported	
Hypoaesthesia; Influenza;	Azulfidine			S	Oral	500 Mg, Qd		Not Reported	
Knee Arthroplasty;	Azulfidine			S	Oral	500 Mg, Bid		Not Reported	
Liposarcoma; Lumbar	Albuterol /00139501/			S	Unknown	Unk		Not Reported	
Spinal Stenosis; Mineral	Hcq			C	Unknown	Unk		Not Reported	
Supplementation; Mobility	Orencia			C	Unknown	Unk		Not Reported	
Decreased; Muscle									
Spasms; Nausea;									
Nephrolithiasis;									
Neuropathy Peripheral;									
Oral Contusion;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Osteochondrosis; Paraesthesia; Peroneal Nerve Injury; Pneumonia; Pruritus; Renal Cancer; Rheumatoid Arthritis; Sciatica; Skin Papilloma; Soft Tissue Sarcoma; Spinal Fracture; Spinal Osteoarthritis; Swelling; Thoracic Vertebral Fracture; Vertebroplasty; Wheezing	Albuterol Sulfate And Ipratropium Bromide Xanax Norvasc Symbicort Wellbutrin Cholecalciferol Colace Allegra D 24 Hour Flonase /00908302/ Lasix /00032601/ Norco Nexium /01479302/ Mycostatin Singulair Vitamin D /00107901/ Caltrate /00944201/ Reclast Ambien Celebrex	C C C C C C C C C C C C C C C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14354697	EXPEDITED (15-DAY)		OT	GB-LUPIN PHARMACEUTICALS INC.-2017-07696		40 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Moxifloxacin			S	Unknown	400 Mg, Qd		Lupin	
Drug Resistance; Dysuria;	Doxycycline			S	Unknown	100 Mg, Bid		Not Reported	
Urethral Discharge	Azithromycin			S	Unknown	1 G, Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Pristinamycin			C	Unknown	1 G, Qid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14576899	EXPEDITED (15-DAY)		HO, OT	IL-LUPIN PHARMACEUTICALS INC.-2018-01429		45 YR	Female	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Hypersensitivity; Nausea; Pneumonia; Q Fever; Treatment Failure	Doxycycline Tablets			S	Oral	100 Mg, Unk		Not Reported	
	Doxycycline			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Moxifloxacin			S	Unknown	Unk		Lupin	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14620184	EXPEDITED (15-DAY)			FR-009507513- 1803FRA003324		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Montelukast Sodium			S		10 Mg, Daily		Merck	
	Azithromycin			S		250 Mg, Every Other Day 3 Months		Not Reported	
	Azithromycin			S		250 Milligram,Every Other Day For 3 Months		Not Reported	
	Levocetirizine			S		5 Mg, Daily		Not Reported	
	Albuterol			S		6 Puffs/Day		Not Reported	
	Fluticasone			C	Nasal	55 Microgram/Day		Not Reported	
	Fluticasone			C	Nasal	55 ?G/Day		Not Reported	
	Salmeterol			C		Unknown Dose		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688132	NON-EXPEDITED			US-PFIZER INC-2018128783		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688215	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-168492		82 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyponatraemia	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688264	EXPEDITED (15-DAY)		OT	US-ACCORD-064822		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Accord	
	Tacrolimus			S				Accord	
	Azithromycin			S				Not Reported	
	Sulfamethoxazole/Trimethoprim			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14688268	EXPEDITED (15-DAY)		OT	US-ACCORD-064823		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Accord	
	Tacrolimus			S				Accord	
	Prochlorperazine			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Azithromycin		S					Not Reported
		Sulfamethoxazole/Trimethoprim		C					Not Reported
		Levosaltbutamol		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14689517	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2018126091		70 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Linezolid			S		Unk		Pfizer	
	Meropenem			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2018	14690423	EXPEDITED (15-DAY)		DE, HO	PT-MYLANLABS-2018M1018156		62 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Azithromycin			S		Unk		Not Reported	
Drug Ineffective;	Amlodipine			S		Unk		Not Reported	
Dyspnoea; Fatigue;	Ceftriaxone			S		Unk		Mylan	
Hypoxia; Product Use In Unapproved Indication	Tenofovir + Efavirenz + Emtricitabine			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	10957117	NON-EXPEDITED		OT	US-PFIZER INC-2015105743			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	13603675	EXPEDITED (15-DAY)		DE, HO, OT	IT-MYLANLABS-2017M1031928		76 YR	Female	ITA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis; Drug Abuse; Hepatic Enzyme Increased; Jaundice	Azithromycin			S	Oral	500 Mg, Qod		Not Reported	
	Deltacortene			C	Oral	25 Mg, Unk		Mylan	
	Oxygen			C	Respiratory (inhalation)	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14691743	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-168480		14 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain; Muscle Swelling	Azithromycin			S	Oral	500 Mg, Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14692568	NON-EXPEDITED			US-PFIZER INC-2018130622			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14694136	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20180328229		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Pneumonia	Stelara			S	Subcutaneous			Not Reported	
	Stelara			S	Subcutaneous			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Amoxicillin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14694671	NON-EXPEDITED			US-PFIZER INC-2018130374			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14694672	NON-EXPEDITED			US-PFIZER INC-2018130516			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Inderal			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Cephalexin Hydrochloride			S		Unk		Not Reported	
	Co-Trimoxazole			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14694768	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, INC-2018-IPXL-00926		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lung Abscess; Product Use In Unapproved Indication	Doxycycline Hyclate Delayed Release			S	Oral	Unk		Impax	
	Doxycycline Hyclate Delayed Release			S				Impax	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azathioprine	C	Unknown	Chronic, Unk	Not Reported
Prednisone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14695311	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018126649		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Injury; Optic Nerve Injury; Peripheral Nerve Injury; Product Use In Unapproved Indication	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Azithromycin			S	Oral	250 Mg, 2x/Day		Pfizer
	Ethambutol Hcl			S	Oral	400 Mg, 2x/Day		Not Reported
	Ethambutol Hcl			S	Oral	400 Mg, 3x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14695443	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2018M1019238		85 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug Level Above Therapeutic; Drug Interaction; Peripheral Swelling	Azithromycin			S	Unknown			Not Reported
	Warfarin			S	Unknown			Not Reported
	Cefuroxime			S	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2018	14695662	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-874851		50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown			Teva
	Cotrimoxazole			S	Unknown			Not Reported
	Nevirapine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14678585	EXPEDITED (15-DAY)		HO	US-STRIDES ARCOLAB LIMITED-			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2018SP002229

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestatic Liver Injury; Faeces Pale; Fatigue; Granulomatous Liver Disease; Hepatomegaly; Jaundice; Malaise; Muscle Atrophy; Pruritus; Vanishing Bile Duct Syndrome	Nevirapine			S	Unknown	Unk		Strides	
	Azithromycin			S	Unknown	Unknown		Not Reported	
	Cotrimoxazole			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14698420	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-168643		70 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Paraspinal Abscess	Azithromycin			S	Unknown	Unk		Sun	
	Rifampin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Amikacin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14698727	NON-EXPEDITED			US-PFIZER INC- 2018130191			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14698781	NON-EXPEDITED			US-PFIZER INC- 2018130173			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Pruritus; Rash	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14698999	EXPEDITED (15-DAY)		HO, OT	US-MICRO LABS LIMITED-ML2018-00444		50 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vanishing Bile Duct Syndrome	Nevirapine			S	Unknown			Micro Labs	
	Azithromycin			S	Unknown			Not Reported	
	Cotrimoxazole			S	Unknown			Not Reported	
	Antiretroviral Therapy			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699052	NON-EXPEDITED			US-TEVA-2018-US- 875133			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Contusion; Swelling	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14699591	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2018M1018814		55 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Colitis; Diarrhoea; Muscle Spasms	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Mar-2018	14700208	EXPEDITED (15-DAY)		HO	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18- 02		57 YR	Female	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated;	Co-Amoxiclav	S	Unknown	Hikma
Haemoptysis; Nocardiosis;	Co-Amoxiclav	S		Hikma
Pleural Effusion;	Azithromycin	S	Unknown	Not Reported
Pneumonia Necrotising;	Azithromycin	S		Not Reported
Product Use In Unapproved Indication				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14700231	EXPEDITED (15-DAY)		OT	PT- GLAXOSMITHKLINE- PT2018048876		60 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Dyspnoea;	Fluticasone			S	Nasal	Unk		Glaxosmithkline	
Productive Cough;	Erdosteine			S	Unknown	Unk		Glaxosmithkline	
Rhinorrhoea; Sputum	Azithromycin			S	Unknown	Unk		Glaxosmithkline	
Retention; Wheezing	Fluticasone + Salmeterol			S	Unknown			Not Reported	
	Lansoprazole			C	Unknown	Unk		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2018	14701384	NON-EXPEDITED			US-PFIZER INC- 2018130239			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Erythromycin Base			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2018	14702429	EXPEDITED (15-DAY)		DE, OT	PHHY2017CA194393		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Death; Decreased Appetite; Drug Ineffective; Fatigue; Malignant Neoplasm	Afinitor	S	Oral	5 Mg, Qd (Take Two Days Then One Day Off)	Novartis
Progression; Pancreatic Neuroendocrine Tumour; Platelet Count Decreased;	Sandostatin Lar	S	Unknown	60 Mg, Unk	Not Reported
Rash; Somnolence; Weight Decreased	Octreotide	S	Subcutaneous	Test Dose	Not Reported
	Ciprofloxacin	S	Unknown		Not Reported
	Trimethoprim	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2018	14722281	DIRECT	Y	OT			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin#			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	13459371	EXPEDITED (15-DAY)		DE, HO, LT	GXKR2017DE002301		60 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Cardiovascular Disorder; Diarrhoea; Multiple Organ Dysfunction Syndrome; Pseudomembranous Colitis; Sepsis; Vomiting	Azithromycin			S	Oral	500 Mg, Unk		Novartis	
	Azithromycin			S				Novartis	
	Ramipril			C	Oral	10 Mg, Unk		Not Reported	
	Amlodipin			C	Oral	5 Mg, Qd		Not Reported	
	Novalgine (Metamizole Sodium)			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14262439	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-155806		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Oral	1 Df In Total		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omeprazole			C	Oral	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14702751	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2018SP002450			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Tacrolimus			S	Unknown	Unk		Strides	
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Not Reported	
	Prochlorperazine			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk		Not Reported	
	Levalbuterol /01419301/			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14702753	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2018SP002448			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Tacrolimus			S	Unknown	Unk		Strides	
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14703062	NON-EXPEDITED			US-TEVA-2018-US-876665			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14703404	EXPEDITED (15-DAY)		OT	PHEH2018US011603			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Fall; Mycobacterium Avium Complex Infection; Pathogen Resistance; Vomiting	Rifampin Capsules Usp			S	Unknown	Unk		Novartis	
	Azithro			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14703454	EXPEDITED (15-DAY)		OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18- 02		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thoracic Cavity Drainage Test Abnormal	Amoxicillin Sodium+Potassium Clavulanate			S	Unknown	Unk ()		Hikma	
	Amoxicillin Sodium+Potassium Clavulanate			S	Unknown	Unk ()		Hikma	
	Azithromycin			S	Unknown	Unk ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14705251	EXPEDITED (15-DAY)		OT	US-MYLANLABS- 2018M1020178		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Sulphamethoxazole/Trimethopri m			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2018	14705311	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180335203		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hodgkin'S Disease Nodular Sclerosis	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Inflectra			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14519180	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018057740		70 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Melaena	Zithromac Sr 2g			S	Oral	Single Dose		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14706846	NON-EXPEDITED			US-TEVA-2018-US-875957			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Supraventricular Tachycardia	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14707922	NON-EXPEDITED			US-PFIZER INC-2018133536			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Speech Disorder	Zithromax			S				Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14707967	NON-EXPEDITED			US-PFIZER INC-2018133634			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S	Unknown	Unk		Pfizer	
	Erythromycin			S	Unknown	Unk		Pfizer	
	Zithromax			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14708032	NON-EXPEDITED			US-PFIZER INC-2018134576		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14708065	NON-EXPEDITED			US-PFIZER INC-2018135437		7 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14709168	EXPEDITED (15-DAY)		HO	FR-GLAXOSMITHKLINE-FR2018051418		30 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Latent Tuberculosis	Benlysta			S	Intravenous drip	Cyclical		Glaxosmithkline	
	Novatrex			S	Oral	20 Mg, We		Glaxosmithkline	
	Cortancyl			S	Oral	10 Mg, Qd		Not Reported	
	Pantoprazole			C	Oral	Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Kardegic		C	Oral		Unk			Not Reported
	Plaquenil		C	Oral		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14709684	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2018-017501		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thoracic Cavity Drainage Test Abnormal	Azithromycin			S	Unknown	Unk ()		Aurobindo	
	Amoxicillin Sodium And Clavulanate Potassium			S	Unknown	Unk ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14711059	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-875002		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia; Liver Disorder	Azitromicina 500			S	Oral	1 Df Per Day		Not Reported	
	Cymbalta 30 Mg Capsulas Duras Gastrorresistentes , 7 Cápsulas			C	Oral	1 Df Per Day		Not Reported	
	Pravastatina Alter 10 Mg Comprimidos Efg, 28 Comprimidos			C	Unknown	0-0-1		Not Reported	
	Amoxicilina Clavulanico			C	Oral	1-1-1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2018	14733151	DIRECT					7 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin For Oral Suspension, Cherry Flavored			S	Oral	Quantity:1 3.75 MI;		Greenstone	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14712481	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR-APL-2018-017452		57 YR	Female	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Haemoptysis;	Amoxicillin+Clavulanic Acid			S		()		Aurobindo
Necrosis; Nocardiosis;	Amoxicillin+Clavulanic Acid			S				Aurobindo
Pleural Effusion;	Azithromycin			S	Unknown	()		Aurobindo
Pneumonia; Product Use In Unapproved Indication	Azithromycin			S				Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14712556	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2018-017584		60 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis; Dyspnoea;	Azithromycin			S	Unknown	()		Aurobindo
Productive Cough;	Fluticasone			S	Nasal	()		Not Reported
Rhinorrhoea; Sputum	Erdosteine			S	Unknown	()		Not Reported
Retention; Wheezing	Salmeterol/Fluticasonepropionate			S	Unknown	()		Not Reported
	Lansoprazole			C	Unknown	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14712700	NON-EXPEDITED			US-TEVA-755089ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vision Blurred	Raloxifene Hydrochloride			S				Teva
	Cipro			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14712791	EXPEDITED (15-DAY)		LT, OT	US-BAUSCH-BL-2018- 009561		21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Metronidazole			S	Unknown			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Azithromycin		S	Unknown				Not Reported
		Hydroxychloroquine		C					Not Reported
		Solmedrol		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14713129	NON-EXPEDITED			US-PFIZER INC-2018135808			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14713171	NON-EXPEDITED			US-PFIZER INC-2018137358		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14713270	NON-EXPEDITED			US-TEVA-2018-US-876764			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Feeling Abnormal; Syncope; Vertigo; Vomiting	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14713343	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2018-018099			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Three Days Per Week		Aurobindo	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Methylprednisolone			S	Intravenous (not	Three Day Courses On A		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methylprednisolone			S		otherwise specified) Monthly Base Unknown Systemic ()		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14713448	NON-EXPEDITED			US-TEVA-2018-US-877040			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Diplopia; Rash; Rash Pruritic	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14714386	EXPEDITED (15-DAY)		HO	US-SCIEGEN PHARMACEUTICALS INC-2018SCILIT00160		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Vanishing Bile Duct Syndrome	Nevirapine Tablets			S	Unknown	Unk			Unknown
	Azithromycin			S	Unknown	Unk			Not Reported
	Sulfamethoxazole\Trimethoprim			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2018	14826532	DIRECT		OT			62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Asthenia; Dizziness; Heart Rate Irregular; Nasal Discomfort; Paranasal Sinus Discomfort; Tinnitus	Azithromycin			S	Oral	Daily; Oral; 06 Tablet(S)			Not Reported
	Ibuprofen			C					Not Reported
	Lisinopril			C					Not Reported
	Saw Palmetto			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14248137	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1075100		78 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; No Adverse Event		Azithromycin		S					Not Reported
		Apixaban		C					Mylan
		Amiodarone		C					Mylan
		Amoxicillin Clavulanic Acid		C					Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14531613	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1009481		69 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema;	Acetylcysteine			S	Oral	200 Mg, Q8h			Not Reported
Bronchospasm; Palatal Oedema	Azithromycin			S	Oral	500 Mg, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14723502	EXPEDITED (15-DAY)		OT	FR-ROCHE-2102826		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Mabthera			S	Intravenous drip				Not Reported
	Zithromax			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2018	14723976	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-877357		85 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Above Therapeutic;	Azithromycin			S	Unknown				Not Reported
Drug Interaction;	Cefuroxime			S	Unknown				Not Reported
Peripheral Swelling	Warfarin			S	Unknown				Barr
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14726542	NON-EXPEDITED			US-PFIZER INC-2018140257			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14727215	EXPEDITED (15-DAY)		OT	US-LPDUSPRD-20180501		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron Injection (4420-01)			S	Intravenous (not otherwise specified)	Single Dose Of 4 Mg		Luitpold	
	Azithromycin			S	Unknown	Unknown		Not Reported	
	Levoalbuterol			S	Unknown	Unknown		Not Reported	
	Trimethoprim-Sulfamethoxazole			S	Unknown	Unknown		Not Reported	
	Tacrolimus			S	Unknown	Unknown		Not Reported	
	Prochlorperazine			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14727216	EXPEDITED (15-DAY)		OT	US-LPDUSPRD-20180500		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron Injection (4420-01)			S	Intravenous (not otherwise specified)	Single Dose Of 4 Mg		Luitpold	
	Azithromycin			S	Unknown	Unknown		Not Reported	
	Trimethoprim-Sulfamethoxazole			S	Unknown	Unknown		Not Reported	
	Tacrolimus			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14727314	NON-EXPEDITED			US-PFIZER INC-2018141195		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Pyrexia	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14727450	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2018-018085		10 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Pallor	Azithromycin 250 Mg Film Coated Tablet			S	Oral	1 Dosage Form, Total		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14728011	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018139033		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Confusional State; Diarrhoea; Dizziness; Malaise; Somnolence	Azithromycin			S	Oral	2000 Mg, Single (Single Dose (8x250mg))		Pfizer	
	Truvada			C		Unk		Not Reported	
	Imodium			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2018	14731123	EXPEDITED (15-DAY)		HO, OT	US-BAUSCH-BL-2017-032396		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Adverse Reaction; Arthralgia; Asthenia; Bradyphrenia; Chronic Kidney Disease; Chronic Obstructive Pulmonary Disease; Contusion; Decreased Appetite; Dizziness; Fall; Fatigue; Full Blood Count	Albuterol			S	Unknown			Bausch And Lomb	
	Welchol			S	Unknown			Not Reported	
	Baclofen			S	Unknown			Not Reported	
	Enbrel			S	Unknown	Once Every Week		Not Reported	
	Enbrel			S	Unknown	Once Every Week		Not Reported	
	Amoxicillin			S	Unknown			Not Reported	
	Fosamax			S	Unknown			Not Reported	
	Percocet			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Azulfidine			S	Oral			Not Reported	
	Liposarcoma; Lumbar								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spinal Stenosis; Mineral Supplementation; Mobility Decreased; Muscle Spasms; Nausea; Nephrolithiasis; Neuropathy Peripheral; Oral Contusion; Osteochondrosis; Paraesthesia; Peroneal Nerve Injury; Pneumonia; Pruritus; Renal Cancer; Rheumatoid Arthritis; Sciatica; Skin Papilloma; Soft Tissue Sarcoma; Spinal Fracture; Spinal Osteoarthritis; Swelling; Vertebroplasty; Vertebroplasty; Wheezing	Azulfidine Salbutamol Sulfate Ipratropium Bromide Wellbutrin Cholecalciferol Vitamin D2 Hydroxychloroquine Sulfate Orencia Colace Allegra-D, 24 Hr Flonase Lasix Norco Nexium Mycostatin Singulair Caltrate Reclast Ambien Celebrex Xanax Norvasc Symbicort	S C C C C C C C C C C C C C C C C C C C C C C	Oral	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	10171202	NON-EXPEDITED			US-PFIZER INC-2014126510			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Benzoin			S		Unk		Not Reported
	Hydralazine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14726526	NON-EXPEDITED			US-PFIZER INC-2018138994			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trichoglossia		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14732800	NON-EXPEDITED			US-PFIZER INC-2018139975		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Actos			S		Unk		Not Reported	
	Crestor			S		Unk		Not Reported	
	Azmacort			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14732810	NON-EXPEDITED			US-PFIZER INC-2018141908		64 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14732837	NON-EXPEDITED			US-PFIZER INC-2018140018			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2018	14732865	NON-EXPEDITED			US-PFIZER INC-2018143137		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14732965	NON-EXPEDITED			US-AUROBINDO-AUR-APU-2018-004315		32 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Storage Error	Azithromycin For Injection Usp 500mg			S		Unk, Once		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733112	NON-EXPEDITED			US-PFIZER INC-2018144263		69 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14733348	EXPEDITED (15-DAY)		OT	FR-GLENMARK PHARMACEUTICALS-2018GMK033891			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Asthma; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Fluticasone Propionate			S	Unknown	Unk Unk, Qd		Glenmark	
	Fluticasone Propionate			S	Nasal	Unk Unk, Qd		Glenmark	
	Levocetirizine			S	Unknown	5 Mg, Daily		Glenmark	
	Montelukast Sodium			S	Unknown	10 Mg, Qd		Glenmark	
	Salmeterol			S	Unknown	(100 ?G), Qd		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Qod For 3 Months		Not Reported	
	Salbutamol			S	Unknown	(6 Puffs), Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2018	14735087	EXPEDITED (15-DAY)		HO	PHHY2018DE062017		243 DAY	Male	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Osteomyelitis; Pyrexia; Sepsis		Azithromycin		S	Unknown		Novartis		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	13613197	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2017IT077097		76 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis; Drug Abuse; Hepatic Enzyme Increased; Jaundice	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Deltacortene			C	Oral	25 Mg, Unk		Not Reported	
	Oxygen			C	Respiratory (inhalation)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14635547	EXPEDITED (15-DAY)		DS, OT	FR-PFIZER INC-2018099461		48 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Sudden Hearing Loss; Vision Blurred	Novatrex			S	Oral	20 Mg, Weekly (4 Tablets In The Morning And 4 In The Evening The Same Day)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14678735	EXPEDITED (15-DAY)		HO	PL-AUROBINDO-AUR-APL-2018-015720		2 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Auscultation; Blood Lactate Dehydrogenase Increased; Cough; Drug Ineffective; Dry Mouth; Electrolyte Imbalance; Hyponatraemia; Pneumonitis; Pyrexia; Renal Failure; Streptococcus Test	Azithromycin			S	Unknown	Unk		Aurobindo	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Positive

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14739321	EXPEDITED (15-DAY)		DE	US-CIPLA LTD.- 2018US14764			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure	Levofloxacin			S	Unknown	Unk		Cipla	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14739743	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-169617		31 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Faeces Soft; Haematochezia; Mucous Stools	Azithromycin			S	Oral	500 Mg, Qd, In Total		Sun	
	Azithromycin			S	Oral	250 Mg, Qd		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14740516	NON-EXPEDITED			US-PFIZER INC- 2018143782			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14741474	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2018143904		9 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Ocular Hyperaemia; Rash;	Azithromycin			S	Oral	0.125 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tachypnoea

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2018	14741875	EXPEDITED (15-DAY)		OT	PHHY2018US055809		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Leukocytosis; Pyrexia; Rash	Vancomycin			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Zosyn			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14683381	NON-EXPEDITED			US-PFIZER INC-2018125068		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14733028	EXPEDITED (15-DAY)			US-TORRENT-00006013			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Sedation	Quetiapine			S		Unknown		Unknown
	Docusate			S		Unknown		Unknown
	Hydroxyzine			S		Unknown		Unknown
	Azithromycin			S		Unknown		Unknown
	Oseltamivir			S		Unknown		Unknown
	Topiramate			S		Unknown		Unknown
	Lithium			S		Unknown		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14744576	NON-EXPEDITED			US-TEVA-2018-US-871258			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745004	NON-EXPEDITED			US-PFIZER INC-2018148492		65 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745017	NON-EXPEDITED			US-PFIZER INC-2018148383		60 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745066	NON-EXPEDITED			US-PFIZER INC-2018146685		53 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745114	NON-EXPEDITED			US-TEVA-2018-US-859611			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Platelet Count Increased	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Apr-2018	14745972	EXPEDITED (15-DAY)		HO, LT	GB-BAYER-2018-066347			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaemia; Angina Pectoris; Arrhythmia; Blood Iron Decreased; Dizziness; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Nausea; Pain; Pulmonary Congestion; Syncope; Torsade De Pointes; Transferrin Saturation Decreased; Vomiting	Moxifloxacin Hcl Azithromycin Cefotaxime	S S C	Bayer Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2018	14748581	NON-EXPEDITED			US-AMGEN- USASP2017167767		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Cystitis; Fungal Infection; Lipids Increased; Urinary Tract Infection; Weight Increased	Prolia			S	Unknown	60 Mg Q6mo		Amgen	
	Bactrim			S	Unknown	Unk		Not Reported	
	Bactrim			S				Not Reported	
	Cipro			S	Unknown	Unk		Not Reported	
	Cipro			S				Not Reported	
	Z-Pak			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14134720	EXPEDITED (15-DAY)		OT	CA-ROCHE-2010473		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction;	Mycophenolate Mofetil			S	Oral			Not Reported	
Photodermatosis;	Lansoprazole			S	Oral			Not Reported	
Photosensitivity Reaction;	Pantoprazole			S	Oral			Not Reported	
Solar Lentigo; Squamous Cell Carcinoma Of Skin	Azithromycin			S	Oral			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Sulfamethoxazole/Trimethoprim			S	Oral			Not Reported	
	Tacrolimus			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Voriconazole	S	Oral	Not Reported
Atorvastatin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14350235	NON-EXPEDITED			US-PFIZER INC-2018003423		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14678973	EXPEDITED (15-DAY)		HO	PHHY2018SI049611		40 YR	Male	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dehydration; Fatigue; Heart Rate Increased; Pneumonia Staphylococcal; Respiratory Rate Increased	Azithromycin			S	Unknown	1 Df, Qd (For 6 Days)		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14735466	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018AU061035		67 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower;	Metoprolol			S	Unknown	25 Mg, Bid		Novartis
Abdominal Pain Upper;	Roxithromycin			S	Unknown			Not Reported
Anaemia; Anisocytosis;	Azithromycin			S	Unknown			Not Reported
Arrhythmia; Atrial Fibrillation; Chronic Kidney Disease; Chronic	Allopurinol			S	Oral	300 Mg, Qd		Not Reported
Myelomonocytic	Ceftriaxone			S	Unknown			Not Reported
Leukaemia; Decubitus	Oxycodone Hydrochloride			S	Oral	5 Mg, Qid (Prn)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ulcer; Deep Vein	Targin	S	Oral	1 Df, Bid	Not Reported
Thrombosis; Diarrhoea;	Duodart	S	Oral	1 Df, Qd	Not Reported
Duodenitis; Dysplasia;	Frusemide	S	Oral	80 Mg, Unk	Not Reported
Dyspnoea Exertional;	Frusemide	S	Oral	40 Mg, Unk	Not Reported
Early Satiety; Fluid	Magmin	S	Oral	2 Df, Tid	Not Reported
Overload; Leukostasis	Spirolactone	S	Oral	25 Mg, Bid	Not Reported
Syndrome; Macrocytosis;	Hydroxyurea	S	Oral	1.5 G, Qd	Not Reported
Mastocytosis;	Enoxaparin	S	Subcutaneous	120 Mg, Qd	Not Reported
Monocytosis; Obstruction	Coloxyl With Senna	S	Oral	2 Df, Bid	Not Reported
Gastric; Pleural Effusion;	Augmentin	S	Unknown		Not Reported
Pleurisy; Pulmonary	Progout	S	Unknown		Not Reported
Oedema; Renal	Tazocin	S	Unknown		Not Reported
Impairment; Respiratory	Movicol	C	Oral	2 Df, Bid	Not Reported
Failure; Splenic Infarction;	Vitamin K	C	Unknown		Not Reported
Splenomegaly;					
Tachypnoea;					
Thrombocytopenia;					
Tumour Lysis Syndrome;					
Ventricular Tachycardia;					
Vomiting; Weight					
Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14739958	NON-EXPEDITED			US-PFIZER INC-2018146215		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Topamax			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2018	14749913	EXPEDITED (15-DAY)		DE, HO, OT	US-CIPLA LTD.-2018US15078			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Antiphospholipid	Levofloxacin			S	Unknown	Unk		Cipla
Antibodies; Cerebral	Ceftriaxone			S	Unknown	Unk		Not Reported
Haemorrhage; Condition	Azithromycin			S	Unknown	Unk		Not Reported
Aggravated; Factor V								
Inhibition								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Apr-2018	14750738	NON-EXPEDITED			US-PFIZER INC-2018149297			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Apr-2018	14753427	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-881663		62 YR	Female	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Kidney Injury; Drug Interaction; Hyperkalaemia; Metabolic Acidosis	Azitromicina (7019a)			S	Oral				Not Reported	
	Ciclosporina (406a)			S	Oral				Not Reported	
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)				Not Reported	
	Cotrimoxazol, 960 Mg/10 MI, Infusion Intravenosa			S	Intravenous (not otherwise specified)				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Apr-2018	14777853	DIRECT						Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Nightmare	Azithromycin			S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Apr-2018	14754964	EXPEDITED (15-DAY)		OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201804-001130			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hypersensitivity; Rash; Urticaria	Plaquenil			S					Not Reported	
	Zithromax			S					Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14755914	NON-EXPEDITED			US-PFIZER INC-2018150855		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Protonix			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14755966	NON-EXPEDITED			US-PFIZER INC-2018152679		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14756277	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2018US15123			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Exposure During Pregnancy; Hepatic Enzyme Increased; Odynophagia; Weight Decreased	Levofloxacin			S	Unknown	Unk		Cipla	
	Linezolid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Propofol			S	Unknown	100 Mg, Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Succinylcholine /00057701/			S	Unknown	50 Mg, Unk		Not Reported	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Isoniazid			S	Unknown	Unk		Not Reported	
	Isoniazid			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Bupivacaine	S	Intrathecal	10.5 Mg, Single-Shot				Not Reported	
	Fentanyl	S	Intrathecal	15 Mg, Single-Shot				Not Reported	
	Morphine	S	Intrathecal	150 Mg, Single-Shot				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14757451	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-881757		34 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia; Decreased Appetite; Diarrhoea; Helplessness; Palpitations; Speech Disorder; Vision Blurred	Sumamed 500 Mg			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14758967	NON-EXPEDITED			US-PFIZER INC-2018151074			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Celecoxib			S		Unk			Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk			Pfizer
	Cefazolin Sodium			S		Unk			Not Reported
	Omeprazole			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14759196	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2018147711			Female	ZMB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Product Use In Unapproved Indication	Zithromax			S		Unk			Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14759292	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-880879		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hepatocellular Injury	Methotrexate			S	Oral	.5 Dosage Forms Daily;		Barr	
	Zithromax			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Hemigoxine Nativelle 0,125 Mg, Comprimé			S	Oral			Not Reported	
	Eliquis			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14790222	DIRECT		DS			81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Arthralgia; Asthenia; Bronchitis; Diarrhoea; Diarrhoea; Dry Skin; Fall; Gait Disturbance; General Physical Health Deterioration; Hallucination, Auditory; Hypersomnia; Hypoacusis; Myalgia; Nausea; Pruritus; Rash Erythematous; Skin Exfoliation; Skin Exfoliation; Somnolence; Tooth Disorder; Tooth Fracture; Tremor; Tremor; Visual Impairment	Azithromycin			S		Other Strength:500 Ivpb X2 500mg ;		Not Reported	
	Atenelol			C				Not Reported	
	Methadone			C				Not Reported	
	Oxycodone			C				Not Reported	
	Sumatriptan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2018	14836259	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaphylactic Reaction		Azithromycin		S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14682519	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-016620		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S		Unk		Aurobindo	
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose ; In Total		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole, Trimethoprim, Bromhexine Hy (Bromhexine\Clorprenaline\Sulfa methoxazole\Trimethoprim)			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14705253	EXPEDITED (15-DAY)		OT	US-MYLANLABS- 2018M1020225		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Prochlorperazine			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Levosaltbutamol			S	Unknown			Not Reported	
	Sulphamethoxazole/Trimethopri m			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14762126	NON-EXPEDITED			US-TEVA-2018-US- 880352			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Eye; Eye Pruritus; Eye	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Swelling; Influenza; Ocular
Hyperaemia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14762441	NON-EXPEDITED			US-TEVA-2018-US-867565			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14763087	EXPEDITED (15-DAY)		DE, HO	PHHY2017PT202161		62 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Ceftriaxone			S	Unknown			Novartis	
Drug Ineffective;	Azithromycin			S	Unknown	Unk		Not Reported	
Dyspnoea; Fatigue;	Amlodipine			S	Unknown	Unk		Not Reported	
Hypoxia; Product Use In Unapproved Indication	Tenofovir & Emtricitabine & Efaviranz			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14765181	NON-EXPEDITED			US-TEVA-2018-US-880341			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Muscle Spasms; Nausea; Product Dose Omission; Vomiting; Wrong Technique In Product Usage Process	Azithromycin			S	Unknown	Took Half Of The Azithromycin And The Another Hour Lated Took The Other Half Of The Azitromycin		Not Reported	
	Azithromycin			S				Not Reported	
	Tamiflu			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14765734	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-880473			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Pruritus	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14765737	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-880467		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Loss Of Consciousness; Myocardial Infarction; Overdose	Azithromycin			S	Unknown	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14765845	EXPEDITED (15-DAY)		HO	FR-009507513-1804FRA005027		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia	Singular			S	Oral	1 Df, Qd		Merck	
	Aerius (Desloratadine)			S	Oral	Unk		Merck	
	Pulmozyme			S	Respiratory (inhalation)			Not Reported	
	Bactrim Forte			S	Oral	2 Df, Qd		Not Reported	
	Pyostacine			S	Oral	1 Df, Qd		Not Reported	
	Zithromax Tripak			S	Oral	3 Df, Qw		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2018	14832850	DIRECT					53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Nausea	Azithromycin 500mg	S	Oral	Quantity:7 Tablet(S);	Teva
	Simvastatin	C			Not Reported
	Daily Multi Vitamin	C			Not Reported
	Preservision With Areds2	C			Not Reported
	Vit B12	C			Not Reported
	Vit C	C			Not Reported
	Baby Aspirin	C			Not Reported
	Vit D3	C			Not Reported
	Omega 3	C			Not Reported
	Probiotic	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14678972	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2017CA009858		74 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Xolair			S	Subcutaneous	150 Mg, Every 4 Weeks		Not Reported
Asthma; Blood Pressure	Xolair			S	Subcutaneous	Unk		Not Reported
Increased; Death;	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased Appetite;	Xolair			S	Subcutaneous	Unk		Not Reported
Dyspnoea; Forced	Xolair			S	Subcutaneous	Unk		Not Reported
Expiratory Volume	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Forced Vital	Xolair			S	Subcutaneous	Unk		Not Reported
Capacity Decreased;	Xolair			S	Subcutaneous	Unk		Not Reported
Heart Rate Increased;	Xolair			S	Subcutaneous	Unk		Not Reported
Inappropriate Schedule Of	Xolair			S	Subcutaneous	Unk		Not Reported
Product Administration;	Xolair			S	Subcutaneous	150 Mg, Every 4 Weeks		Not Reported
Influenza; Malaise;	Azithromycin Sandoz			S	Oral	1 Df, Qd		Novartis
Obstructive Airways	Xarel			C	Oral	1 Df, Qd		Not Reported
Disorder; Oxygen								
Saturation Decreased;								
Product Use In								
Unapproved Indication								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2018	14682517	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-016619		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Azithromycin			S		Unk		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged	Ondansetron	S	Intravenous (not otherwise specified)	Single Dose ; In Total	Aurobindo
	Prochlorperazine	S		()	Not Reported
	Tacrolimus	S		()	Not Reported
	Levalbuterol /01419301/	C		()	Not Reported
	Sulfamethoxazole, Trimethoprim, Bromhexine Hy (Bromhexine\Clorprenaline\Sulfa methoxazole\Trimethoprim)	C		()	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767532	NON-EXPEDITED			US-PFIZER INC-2018155884		67 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767558	NON-EXPEDITED			US-PFIZER INC-2018157098		63 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767559	NON-EXPEDITED			US-PFIZER INC-2018157137			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767561	NON-EXPEDITED			US-PFIZER INC-2018155094			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Nausea	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14767898	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-020533			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; Electrocardiogram Qt Prolonged	Azithromycin			S				Aurobindo	
	Levalbuterol			S				Aurobindo	
	Trimethoprim+Sulfamethoxazole			S				Aurobindo	
	Ondansetron			S				Not Reported	
	Tacrolimus			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14769558	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2018149643		50 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chest Discomfort	Azithromycin			S		Unk		Pfizer	
	Omeprazole			C		2 Dosage Forms Daily		Not Reported	
	Atrovent			C	Respiratory (inhalation)	2 Puffs Up To Four Times A Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Apr-2018	14770494	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018155169		16 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eyelid Oedema; Rash	Zitromax			S	Oral	1 Df, Single (Total)		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Apr-2018	14720732	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US- 877400		38 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron	S	Intravenous (not otherwise specified)	4 Mg Single Dose	Teva
	Azithromycin	S	Unknown		Not Reported
	Prochlorperazine	S	Unknown		Teva
	Levalbuterol	S	Unknown		Teva
	Tacrolimus	S	Unknown		Not Reported
	Trimethoprim-Sulfamethoxazole	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14720734	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US- 877403		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg Single Dose		Teva
	Azithromycin			S	Unknown			Not Reported
	Cotrimoxazole			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772285	NON-EXPEDITED			US-TEVA-2018-US- 876768			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Storage Error	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772705	NON-EXPEDITED			US-TEVA-2018-US- 865318			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Prescribing Error	Azithromycin			S		1500 Milligram Daily;		Pliva

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772885	NON-EXPEDITED			US-PFIZER INC-2018157368		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Gabapentin			S		Unk		Pfizer	
	Sulfasalazine			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
	Tizanidine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14772918	NON-EXPEDITED			US-PFIZER INC-2018157561		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773051	EXPEDITED (15-DAY)		HO	FR-ROCHE-2106707		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia	Bactrim Forte			S	Oral			Not Reported	
	Pulmozyme			S	Respiratory (inhalation)			Not Reported	
	Singulair			S	Oral			Not Reported	
	Pyostacine			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aerius (France)			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14773360	NON-EXPEDITED			US-TEVA-2018-US-880720			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14774016	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2018151030		82 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyponatraemia	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14774020	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018151989		14 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Peripheral Swelling	Azithromycin			S	Oral	500 Mg, Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2018	14775555	NON-EXPEDITED			US-PFIZER INC-2018157622			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Benzocaine		Y	S		Unk			Pfizer
	Tetracycline Hcl			S		Unk			Pfizer
	Diphtheria Vaccine Toxoid W/Pertuss			S		Unk			Not Reported
	Monistat			S		Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Chloraseptic		S			Unk			Not Reported	
	Albuterol		S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14352708	NON-EXPEDITED				US-PFIZER INC-2017548707			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Drug Hypersensitivity	Azithromycin				S		Unk			Pfizer
	Benzocaine			Y	S		Unk			Pfizer
	Tetracycline Hcl				S		Unk			Pfizer
	Albuterol				S		Unk			Not Reported
	Chloraseptic				S		Unk			Not Reported
	Monistat				S		Unk			Not Reported
	Triple Antibiotic (Bacitracin Zinc\Neomycin Sulfate\Polymyxin B Sulfate)				S		Unk			Not Reported
	Tdap Immun				S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14779650	EXPEDITED (15-DAY)		OT		NL-PFIZER INC-2018155701		72 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Arrhythmia	Azithromycin				S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14780370	EXPEDITED (15-DAY)		OT		CO-PFIZER INC-2018158499		7 YR	Female	COL
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Bradycardia	Zitromax				S		Unk			Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2018	14848604	DIRECT		DS			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Asthenia; Asthma; Dehydration; Dizziness; Dyspnoea; Fall; Heart Rate Increased; Muscular Weakness; Syncope; Tremor	Azithromycin 250 Mg			S	Oral	Quantity:6 Tablet(S);		Pharmacy Benefits Manager (Pbm)	
	Loratidine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	13299938	NON-EXPEDITED		OT	US-PFIZER INC- 2017088063		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Palpitations; Product Complaint	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14698555	EXPEDITED (15-DAY)		DE, HO, OT	CA-ROCHE-2096948		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Xolair			S	Subcutaneous			Not Reported	
Asthma; Blood Pressure Increased; Death;	Xolair			S	Subcutaneous			Not Reported	
Decreased Appetite;	Xolair			S	Subcutaneous			Not Reported	
Dyspnoea; Forced Expiratory Volume	Xolair			S	Subcutaneous			Not Reported	
Decreased; Forced Vital	Xolair			S	Subcutaneous			Not Reported	
Capacity Decreased;	Xolair			S	Subcutaneous			Not Reported	
Heart Rate Increased;	Xolair			S	Subcutaneous			Not Reported	
Incorrect Product	Xolair			S	Subcutaneous			Not Reported	
Administration Duration;	Xolair			S	Subcutaneous			Not Reported	
Influenza; Malaise; Obstructive Airways	Azithromycin Sandoz			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Oxygen Saturation Decreased; Respiratory Failure		Xarelto		C	Oral	1 Df, Qd		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14743764	EXPEDITED (15-DAY)		OT	PHHY2018IT061731		55 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Colitis; Diarrhoea; Muscle Spasms	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14781647	EXPEDITED (15-DAY)		DS	FR-TEVA-2018-FR-882548		48 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Deafness Unilateral	Azithromycine Anhydre			S	Oral				Not Reported
	Cosentyx 150 Mg, Solution			S	Subcutaneous				Not Reported
	Injectable En Stylo Prérempli Effexor			C	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782435	NON-EXPEDITED			US-PFIZER INC-2018162060		59 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2018	14782876	NON-EXPEDITED			US-BAUSCH-BL-2017-010875		43 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tinnitus	Arestin (Minocycline Hydrochloride) Microspheres 1mg			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Arestin (Minocycline Hydrochloride) Microspheres 1mg Z-Pak		S	Unknown				Not Reported	
			S	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14783474	NON-EXPEDITED			US-TEVA-2018-US-872330			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Pain; Tinnitus	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14783690	NON-EXPEDITED			US-TEVA-2018-US-873422		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Muscle Spasms; Pain; Restlessness; Urinary Tract Infection	Azithromycin			S		250 Milligram Daily; Last Dose Administered Either On 10-Mar-2018 Or 11-Mar-2018			Not Reported
	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14786795	EXPEDITED (15-DAY)		HO	US-ACTELION-A-US2004-07603		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Nasopharyngitis; Pruritus; Rash Maculo-Papular	Tracleer			S	Oral	62.5 Mg, Bid			Actelion
	Tracleer			S	Oral	Unk			Actelion
	Zithromax			S	Unknown				Not Reported
	Remodulin			C					Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2018	14853890	DIRECT		DS, HO, LT, OT			72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Concussion; Diarrhoea; Dizziness; Fatigue; Head Injury; Loss Of Consciousness; Nausea; Pain; Syncope	Azithromycin			S			5 DAY	Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14474069	EXPEDITED (15-DAY)		OT	US-APOTEX- 2018AP006059		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Apotex	
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Apotex	
	Piperacillin & Tazobactam			S	Intravenous (not otherwise specified)	Unk		Apotex	
	Levofloxacin			S	Unknown	Unk		Apotex	
	Hydrocortisone Acetate			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14479805	EXPEDITED (15-DAY)		OT	NL-APOTEX- 2018AP005964			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Malaise; Malaise; Skin Exfoliation	Azithromycin Apotex			S	Oral	250 Mg, Every Day		Apotex	
	Filmomhulde Tabletten								
	Azithromycin Apotex			S	Oral	One Tablet Every Other Day		Apotex	
	Filmomhulde Tabletten								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14505017	EXPEDITED (15-DAY)		OT	AU-APOTEX-2018AP006261		58 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Joint Injury; Loss Of Consciousness	Azithromycin			S	Unknown	2 Df, A Day		Apotex	
	Lyrica			C	Unknown			Not Reported	
	Heparin			C	Unknown			Not Reported	
	Vitamin D /00107901/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14510821	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP006328		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Tubulointerstitial Nephritis	Azithromycin			S	Unknown			Apotex	
	Ceftriaxone For Injection, Usp			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14525347	EXPEDITED (15-DAY)		HO	US-APOTEX-2018AP006465		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S				Apotex	
	Ceftriaxone			S	Unknown	Unk		Apotex	
	Ceftriaxone			S				Apotex	
	Ceftriaxone			S				Apotex	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14571383	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP006762		70 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Sputum Discoloured	Amlodipine			S	Oral	1 Df, Qd		Apotex
	Amlodipine			S	Oral	10 Mg, Qd		Apotex
	Azithromycin Sandoz			S	Oral	3 Df, Unk		Not Reported
	Azithromycin Sandoz			S	Oral	250 Mg, Unk		Not Reported
	Xolair			S	Subcutaneous	225 Mg, One Every Two Weeks		Not Reported
	Advair			C	Other	1 Df, Bid Inhalation		Not Reported
	Asa			C	Oral	1 Df, Qd		Not Reported
	Brilinta			C	Oral	1 Df, Qd		Not Reported
	Hydrochlorothiazid			C	Oral	1 Df, Qd		Not Reported
	Mylan Pantoprazole			C	Oral	1 Df, Qd		Not Reported
	Singulair			C	Oral	1 Df, Qd		Not Reported
	Spiriva			C	Other	1 Df, Qd		Not Reported
	Ventolin /00139501/			C	Other	2 Df, Inhalation		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14576255	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006916		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased; Coccydynia; Contusion; Crying; Discomfort; Dizziness Exertional; Dry Skin; Dyspnoea; Dyspnoea Exertional; Ear Pain; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Headache; Heart Rate Increased; Myalgia; Nausea; Oxygen Saturation Decreased;	Atorvastatin			S	Unknown	Unk		Apotex
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	375 Mg, (1 Every Two Weeks)		Not Reported
	Azithromycin Sandoz			S	Unknown	Unk		Not Reported
	Fentanyl Sandoz			S	Unknown	Unk		Not Reported
	Montelukast Sandoz			S	Unknown	Unk		Not Reported
	Pantoprazole Sandoz			S	Unknown	Unk		Not Reported
	Advair			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pain In Extremity; Respiratory Rate	Reactine /00884302/	C	Unknown	Not Reported
Increased; Scratch; Vision	Spiriva	C	Unknown	Not Reported
Blurred	Ventolin /00139501/	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14602056	EXPEDITED (15-DAY)		OT	US-APOTEX- 2018AP007761		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Pulmonary Embolism	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S				Apotex	
	Ceftriaxone			S	Unknown	Unk		Apotex	
	Ceftriaxone			S				Apotex	
	Ceftriaxone			S				Apotex	
	Cefepime			S	Unknown	Unk		Apotex	
	Cefepime			S				Apotex	
	Cefepime			S				Apotex	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Vancomycin			S				Not Reported	
	Vancomycin			S				Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Meropenem			S				Not Reported	
	Meropenem			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14606159	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP007176		64 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Lower Respiratory Tract Infection; Mobility Decreased; Pain In Extremity	Azithromycin			S	Unknown	Unk		Apotex	
	Enbrel			S	Unknown	50 Mg, Q.Wk.		Not Reported	
	Bisoprolol			C	Unknown	Unk		Not Reported	
	Dexilant			C	Unknown	600 Mg, Qd		Not Reported	
	Domperidone			C	Unknown	1 Df, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Eltroxin	C	Unknown	100 Mg, Qd			Not Reported	
		Methotrexate	C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14608343	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007155		2 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Maculo-Papular	Azithromycin			S	Oral	3.75 MI, Qd		Apotex	
	Amoxicillin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14608344	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007154		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autism Spectrum	Azithromycin			S	Oral	250 Mg, Qd		Apotex	
Disorder; Blood Pressure	Xolair			S	Subcutaneous	300 Mg, Unk		Not Reported	
Decreased; Cough; Heart	Avamys			C	Unknown	Unk		Not Reported	
Rate Abnormal; Nasal	Fluoxetine			C	Unknown	Unk		Not Reported	
Congestion;	Guanfacine Hydrochloride			C	Unknown	Unk		Not Reported	
Oropharyngeal Pain;	Prozac			C	Unknown	Unk		Not Reported	
Pharyngeal Paraesthesia	Quetiapine Fumarate			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14608348	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007182		87 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Ineffective; Fatigue	Azithromycin			S	Unknown	250 Mg, Bid		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14631997	NON-EXPEDITED		OT	US-APOTEX-		23 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2018AP007988

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Azithromycin			S	Oral	1 G, Single Dose		Apotex
	Azithromycin			S	Oral	2 G, Single Dose		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14658237	NON-EXPEDITED		HO	US-APOTEX-2018AP007992		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Apotex
	Albuterol /00139501/			C	Unknown	Unk		Not Reported
	Tylenol /00020001/			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14667411	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP008690		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron Injection Usp			S	Intravenous (not otherwise specified)	4 Mg, Unk		Apotex
	Azithromycin			S	Unknown			Apotex
	Tacrolimus			S	Unknown			Not Reported
	Prochlorperazine			S	Unknown			Not Reported
	Levalbuterol /01419301/			S	Unknown			Not Reported
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14667927	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP008689		57 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron Injection Usp			S	Intravenous (not otherwise specified)	4 Mg, Unk		Apotex
	Azithromycin			S	Unknown			Apotex
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14679632	NON-EXPEDITED		OT	US-APOTEX- 2018AP008058		10 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Azithromycin			S	Oral	500 Mg Daily		Apotex
	Ceftazidime			C	Intraperitoneal	250 Mg/L, Unk		Not Reported
	Ceftazidime			C	Intraperitoneal	125 Mg/L, Unk		Not Reported
	Vancomycin			C	Intraperitoneal	1 G/L, Unk		Not Reported
	Vancomycin			C	Intraperitoneal	30 Mg/L, Unk		Not Reported
	Metronidazole			C	Oral	30 Mg/Kg, Per Day		Not Reported
	Metronidazole			C	Intravenous (not otherwise specified)	30 Mg/Kg, Per Day		Not Reported
	Piperacillin/Tazobactam			C	Intravenous (not otherwise specified)	70 Mg/Kg/Dose, Q.12h		Not Reported
	Piperacillin/Tazobactam			C	Intravenous (not otherwise specified)	25 Mg/Kg, Unk		Not Reported
	Sulfameth/Trimeth			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Cefazoline			C	Unknown	125 Mg/L, 12 Hours Only		Not Reported
	Cefepime			C	Intraperitoneal	500 Mg/L, Unk		Not Reported
	Cefepime			C	Intraperitoneal	200 Mg/L, Unk		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1 G, Per Day		Not Reported
	Imipenem			C	Intraperitoneal	500 Mg/L, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imipenem	C	Intraperitoneal	125 Mg/L, Unk	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	75 Mg/Kg (Max 2 G/Day), Per Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14688275	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP008629		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Ciprofloxacin			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Cefalexin			S	Unknown	Unk		Not Reported	
	Cefadroxil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14692267	NON-EXPEDITED		HO	US-APOTEX-2018AP008414		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14709225	NON-EXPEDITED		HO, OT	US-APOTEX-2018AP009547			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Oral	250 Mg, Unk		Apotex	
	Amikacin			S	Intravenous (not otherwise specified)	20 Mg/Kg/Dose Thrice A Week		Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	50 Mg, Every 12 Hour		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14739700	NON-EXPEDITED		OT	US-APOTEX-2018AP009897		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Vancomycin			S				Not Reported	
	Zosyn			S	Unknown	Unk		Not Reported	
	Zosyn			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2018	14741343	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP009967		2 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Ineffective; Renal Tubular Necrosis; Tubulointerstitial Nephritis	Ceftriaxone			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Piperacillin & Tazobactam			S	Unknown	100 Mg/Kg, Every 8 Hours		Apotex	
	Piperacillin & Tazobactam			S				Apotex	
	Piperacillin & Tazobactam			S				Apotex	
	Piperacillin & Tazobactam			S				Apotex	
	Vancomycin			S	Unknown	15 Mg/Kg, Every 8 Hours		Not Reported	
	Vancomycin			S	Unknown	26 Mg/Kg, Every 6 Hours		Not Reported	
	Vancomycin			S				Not Reported	
	Vancomycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14011630	EXPEDITED (15-DAY)		OT	PHHY2017IT138858		340 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia; Pharyngeal Erythema;	Azithromycin			S	Oral	Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Toxic Skin Eruption	Azithromycin	S	Oral	Unk	Novartis
	Clarithromycin	S	Oral		Not Reported
	Iron	C	Unknown	Unk	Not Reported
	Cardioaspirin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14788376	EXPEDITED (15-DAY)	HO		IT-AUROBINDO-AUR- APL-2018-021070		86 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Allergic; Rash	Meropenem			S	Intravenous (not otherwise specified)	()		Aurobindo
	Fidato			S	Intravenous (not otherwise specified)	()		Not Reported
	Zitromax			S	Oral	()		Not Reported
	Absorcol			C	Oral	()		Not Reported
	Triatec /00116401/			C	Oral	()		Not Reported
	Vimpat			S	Unknown	()		Not Reported
	Portolac			C	Oral	()		Not Reported
	Levetiracetam			C	Unknown	()		Not Reported
	Alendronate Sodium			C	Oral			Not Reported
	Eliquis			C	Unknown	()		Not Reported
	Gardenale /00023201/			C	Oral			Not Reported
	Libradin /00338001/			C	Oral			Not Reported
	Lasix /00032601/			C	Unknown	()		Not Reported
	Simvastatin			C	Oral	()		Not Reported
	Atenolol			C	Oral	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14789445	NON-EXPEDITED			US-TEVA-769746ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper; Drug Ineffective; Malaise	Nateglinide	S						Actavis
	Azithromycin	S	Unknown					Pliva
	Metformin	S	Unknown					Actavis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14789574	NON-EXPEDITED			US-TEVA-2018-US-868545			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Azithromycin			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14789875	NON-EXPEDITED			US-PFIZER INC-2018165240		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2018	14789910	NON-EXPEDITED			US-PFIZER INC-2018163701		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	13936700	NON-EXPEDITED			US-PFIZER INC-2017382553			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S		Unk			Pfizer
Nausea	Erythromycin Base			S		Unk			Not Reported
	Macrobid			S		Unk			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14678760	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2018-016122		9 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Breath Sounds Abnormal; Chest Pain; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Infectious Pleural Effusion; Inflammation; Lung Infiltration; Mobility Decreased; Mucosal Dryness; Myalgia; Pyrexia; Tachypnoea	Amoxicillin+Clavulanic Acid			S	Unknown	2 Df, Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14757074	NON-EXPEDITED			US-TEVA-2018-US-879570			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Drug Ineffective; Influenza Like Illness; Pyrexia; Rash; Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14784030	EXPEDITED (15-DAY)		HO, OT	US-009507513-1804USA008290		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Sodium Decreased; Diarrhoea; Fall; Femur Fracture; Pharyngitis Streptococcal	Fosamax			S	Oral	Unk		Merck	
	Creon (Pancreatin)			S	Oral	5 Capsule Per Day		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Levothyroxine Sodium			C		Unk		Not Reported	
	Prinivil			C		Unk		Merck	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14792671	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018163284			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Zithromax			S		Unk		Pfizer	
	Topamax			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14797553	EXPEDITED (15-DAY)		OT	US-STRIDES ARCOLAB LIMITED-2018SP003072			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Strides	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Cefepime			S	Unknown	Unk		Not Reported	
	Methylprednisolone			C	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			C	Unknown	Unk, Three Days A Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14797802	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-885822		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Confusional State; Diarrhoea; Dizziness; Malaise; Somnolence	Azithromycin			S	Oral	2000 Milligram Daily; Single Dose (8x250mg)		Not Reported	
	Truvada			C	Unknown			Not Reported	
	Imodium			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14797882	NON-EXPEDITED			US-TEVA-2018-US-884609			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Diarrhoea	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14798296	NON-EXPEDITED			US-PFIZER INC-2018159610		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Cough; Drug Ineffective; Dyspnoea; Wheezing	Azithromycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Cardizem			C		Unk		Not Reported
	Lunesta			C		Unk		Not Reported
	Albuterol			C		Unk		Not Reported
	Incruse Ellipta			C		Unk		Not Reported
	Breo Ellipta			C		Unk		Not Reported
	Augmentin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14798356	NON-EXPEDITED			US-PFIZER INC-2018163198			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14799477	NON-EXPEDITED			US-TEVA-2018-US-873820			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14800982	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018166596		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Zithromax			S	Oral	1 Df, Daily		Pfizer	
	Mabthera			S	Intravenous drip	1 Df, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2018	14802488	NON-EXPEDITED			US-TEVA-2018-US-883888			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Constipation; Malaise	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	12672052	NON-EXPEDITED			US-PFIZER INC-2016379684		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Nexium			S		Unk		Unknown	
	Fentanyl Citrate			S		Unk		Unknown	
	Tetracycline Hcl			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Norco			S		Unk		Not Reported	
	Versed			S		Unk		Not Reported	
	Clinoril			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Sulfur	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14065107	NON-EXPEDITED			US-PFIZER INC-2017428370		87 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder	Zithromax			S		Unk		Pfizer
	Vantin			S		Unk		Pfizer
	Rufen			S		Unk		Not Reported
	Oruvail			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Clinoril			S		Unk		Not Reported
	Lodine			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Lopeberin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14347118	NON-EXPEDITED			US-PFIZER INC-2017555484		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer
	Neurontin			S		100 Mg, Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Azithromycin			S		250 Mg, Unk		Pfizer
	Clindamycin Hcl			S		75 Mg, Unk		Pfizer
	Actemra			S		Unk		Not Reported
	Azathioprine			S		50 Mg, Unk		Not Reported
	Depakote			S		Unk		Not Reported
	Humira			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ketek		S		Unk		Not Reported		
	Minocycline		S		100 Mg, Unk		Not Reported		
	Remicade		S		Unk		Not Reported		
	Tegretol		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14800732	NON-EXPEDITED			US-PFIZER INC-2018166665		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14803758	EXPEDITED (15-DAY)		OT	PT-TEVA-2018-PT-885647		2 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Maculo-Papular	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14804056	NON-EXPEDITED		OT	US-PFIZER INC-2018168394		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Seizure	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Valtrex			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14804068	NON-EXPEDITED			US-PFIZER INC-2018167948		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Bacitracin	S	Unk	Pfizer
	Clindamycin Hcl	S	Unk	Pfizer
	Zithromycin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14804491	NON-EXPEDITED			US-TEVA-2018-US-867919		5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Discomfort; Tongue Erythema	Azithromycin			S		Dose Strength: 200 Mg/5 MI		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14805051	NON-EXPEDITED			US-APOTEX-2018AP007821			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Metformin			S	Unknown			Apotex	
	Paroxetine			S	Unknown			Apotex	
	Glipizide			S	Unknown			Apotex	
	Benazepril			S	Unknown			Apotex	
	Zithromax			S	Unknown			Not Reported	
	Levaquin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14806392	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018168713		31 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Faeces Soft; Haematochezia; Mucous Stools	Azithromycin			S	Oral	500 Mg, Single		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14807726	EXPEDITED (15-DAY)		OT	BE-PFIZER INC-2018164362		10 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Pallor	Azithromycin			S	Oral	250 Mg (1df), Single		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2018	14808803	EXPEDITED (15-DAY)		HO	US-CHIESI USA INC.-US-2018CHI000093		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Deafness; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Muscle Twitching; Tinnitus	Tobramycin			S	Unknown	Unk		Chiesi	
	Orkambi			S	Oral	2 Df, Bid		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14612013	EXPEDITED (15-DAY)		OT	FR-UCBSA-2018009615			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Levocetirizine Hydrochloride			S		5 Mg, Daily		Ucb	
	Montelukast			S		10 Mg, Daily		Not Reported	
	Azithromycin			S		250 Milligram,Every Other Day For 3 Months		Not Reported	
	Salbutamol			S		6 Puffs/Day		Not Reported	
	Fluticasone			S	Nasal	55 ?G/Day		Not Reported	
	Salmeterol			S		100 Mg/Day		Not Reported	
	Fluticasone			S		1000 Mg/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14815397	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018168307			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Haematochezia	Zithromac			S	Oral			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14815491	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP011925		60 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumocystis Jirovecii Pneumonia	Prednisolone			S	Unknown	2 Mg/Kg, Qd		Apotex	
	Prednisolone			S				Apotex	
	Azithromycin			S	Unknown			Apotex	
	Cefepime			S	Unknown			Apotex	
	Sirolimus			S	Unknown	0.05 Mg/Kg, Bid		Not Reported	
	Sirolimus			S				Not Reported	
	Propranolol			S	Unknown	3 Mg/Kg, Qd		Not Reported	
	Propranolol			S				Not Reported	
	Vancomycin			S				Not Reported	
	Sulfamethoxazole And Trimethoprim			S				Not Reported	
	Methylprednisolone			S				Not Reported	
	Vincristine			S	Intravenous (not otherwise specified)	0.025 Mg/Kg, Q.Wk.		Not Reported	
	Vincristine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14816624	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018165743			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Haematochezia	Zithromac			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14816730	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1027640		57 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenic Purpura	Tramadol			S	Oral	100 Mg, Unk		Not Reported	
	Helicidine			S	Oral			Mylan	
	Ordipha			S	Oral	500 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14817331	NON-EXPEDITED			US-TEVA-2018-US-885047			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2018	14892419	DIRECT		DS, HO, LT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Palpitations; Palpitations; Tachycardia	Azithromycin 250mg Zithromax			S		Quantity:6 Df Dosage Form;		Teva	
	Prednisone 20mg			S				Not Reported	
	Carbamazepine			C				Not Reported	
	Fluoxetine			C				Not Reported	
	One A Day Multivitamin			C				Not Reported	
	Baby Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	11234132	NON-EXPEDITED			US-PFIZER INC-2015217221			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythromycin	S	Unk	Pfizer
Cilium	S	Unk	Not Reported
Codeine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	12710231	NON-EXPEDITED			US-ASTRAZENECA-2016SE90046		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Nexium			S	Oral	Unk		Astrazeneca	
	Biaxin			S	Unknown	Unk		Not Reported	
	Fentanyl			S	Unknown	Unk		Not Reported	
	Norvasc			S	Unknown	Unk		Not Reported	
	Tetracycline Hydrochloride			S	Unknown	Unk		Not Reported	
	Clinoril			S	Unknown	Unk		Not Reported	
	Norco			S	Unknown	Unk		Not Reported	
	Sulfur			S	Unknown	Unk		Not Reported	
	Versed			S	Unknown	Unk		Not Reported	
	Zithromax			S	Unknown	Unk		Not Reported	
	Levaquin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14660174	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP008581		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown	Unk		Apotex	
	Nevirapine Tablets			S	Unknown	Unk		Apotex	
	Trimethoprim Sulfamethoxazole			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14818456	NON-EXPEDITED			US-TEVA-2018-US-865273			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Product Packaging Quantity Issue	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14818658	NON-EXPEDITED			US-PFIZER INC-2018173245		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14818678	NON-EXPEDITED			US-PFIZER INC-2018172797		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lopid			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14819928	EXPEDITED (15-DAY)		HO, LT	GB-AUROBINDO-AUR-APL-2018-022867			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Angina Pectoris;	Azithromycin			S	Unknown	()		Aurobindo	
Arrhythmia; Blood Iron Decreased; Dizziness;	Moxifloxacin Hcl			S	Unknown	230		Not Reported	
Electrocardiogram Qt Prolonged; Loss Of Consciousness; Nausea; Pain; Pulmonary Congestion; Syncope; Torsade De Pointes; Transferrin Saturation Decreased; Vomiting	Cefotaxime			C	Unknown	()		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14822388	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2018173509		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Amikacin Sulfate			S		Unk		Unknown	
	Amikacin Sulfate			S				Unknown	
	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Meropenem			S		Unk		Pfizer	
	Meropenem			S				Pfizer	
	Tigecycline			S		Unk		Pfizer	
	Tigecycline			S				Pfizer	
	Imipenem			S		Unk		Not Reported	
	Imipenem			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2018	14822947	NON-EXPEDITED			US-TEVA-2018-US-872663			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Feeling Abnormal	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14794992	EXPEDITED (15-DAY)		OT	UA-TEVA-2018-UA-883037		55 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cyanosis; Dyspnoea; Localised Oedema	Sumamed			S	Oral			Not Reported	
	Ofloxacin			C				Not Reported	
	Thiotriazolin			C	Intramuscular			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14804146	NON-EXPEDITED			US-PFIZER INC-2018167551		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Rash	Zithromax			S		Unk, 2x/Week (2x/Wk)		Pfizer	
	Fabior			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14826775	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-021536		19 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Agitation; Confusional State; Encephalitis; Hoffmann'S Sign; Pyrexia	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	4 Gram Daily;		Aurobindo	
	Ofloxacin 200mg			S	Oral	200 Milligram, Two Times A Day		Not Reported	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Amoxicillin			S	Unknown	Unk		Aurobindo	
	Trimethoprim Sulfamethoxazole			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14826958	EXPEDITED (15-DAY)		HO	FR-VALIDUS PHARMACEUTICALS LLC-FR-2018VAL000710		49 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Papular	Claforan			S	Intravenous (not otherwise specified)	Unk		Validus	
	Azithromycin			S	Oral	Unk		Not Reported	
	Rocephine			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

				otherwise specified)					
	Bisoce		C		Unk				Not Reported
	Oraciline /00001801/		C		Unk				Not Reported
	Mag 2 /00454301/		C		Unk				Not Reported
	Noxafil		C						Not Reported
	Alprazolam		C		Unk				Not Reported
	Cortancyl		C						Not Reported
	Calcimed /07357001/		C						Not Reported
	Pantoprazole		C		Unk				Not Reported
	Movicol		C		Unk				Not Reported
	Wellvone		C						Not Reported
	Valaciclovir		C						Not Reported
	Neoral		C						Not Reported
	Ramipril		C						Not Reported
	Entocort		C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2018	14828045	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2018173511		43 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Amikacin Sulfate			S		Unk		Unknown
	Amikacin Sulfate			S				Unknown
	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Cefoxitin Sodium			S		Unk		Unknown
	Cefoxitin Sodium			S				Unknown
	Linezolid			S		Unk		Pfizer
	Linezolid			S				Pfizer
	Clarithromycin			S		Unk		Not Reported
	Clarithromycin			S				Not Reported
	Moxifloxacin			S		Unk		Not Reported
	Moxifloxacin			S				Not Reported
	Tacrolimus			C		Unk (I.V. Or Sublingual)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14535139	EXPEDITED (15-DAY)		HO, OT	HU-MYLANLABS-2018M1002842		13 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective For Unapproved Indication; Pityriasis Lichenoides Et Varioliformis Acuta; Staphylococcal Infection	Amoxicillin			S	Oral	1500 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Dapsone			S	Unknown	50 Mg, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14818734	NON-EXPEDITED			US-PFIZER INC-2018172037			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased; Ocular Icterus; Skin Discolouration; Skin Disorder; Skin Exfoliation	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2018	14915654	DIRECT		HO			71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Cardiac Disorder; Drug Intolerance	Azithromycin	Y		S	Oral	Quantity:5 Tablet(S);		Not Reported	
	Womens Multi Vitamin			C				Not Reported	
	Vitamin C			C				Not Reported	
	Baby Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14827510	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2018175714		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Meropenem	S	Intravenous (not otherwise specified)	1 G, 3x/Day	Pfizer
	Meropenem	S			Pfizer
	Amikacin Sulfate	S	Intravenous (not otherwise specified)	500 Mg, 2x/Day	Unknown
	Amikacin Sulfate	S	Intrathecal	8 Mg, 3x/Day	Unknown
	Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Daily	Pfizer
	Azithromycin	S			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14836121	NON-EXPEDITED			US-PFIZER INC-2018174772			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Zithromax			S		500 Mg, Daily (Two 250mg Per Day)		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2018	14837448	NON-EXPEDITED			US-PFIZER INC-2018177584		28 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Humalog			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14371128	NON-EXPEDITED			US-PFIZER INC-2018010155		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14673651	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS		58 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

INC.-2018-02090

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Diarrhoea; Dizziness; Loss Of Consciousness; Nausea; Vomiting	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin
	Azithromycin Tablets Usp, 250 Mg			S	Oral	2 Df, Qd		Lupin
	Azithromycin Tablets Usp, 250 Mg			S	Oral	1 Df, Qd		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14741345	NON-EXPEDITED		HO, OT	US-APOTEX-2018AP009902		21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Apotex
	Ceftriaxone			S				Apotex
	Azithromycin			S	Unknown	Unk		Apotex
	Azithromycin			S				Apotex
	Metronidazole			S	Unknown	Unk		Not Reported
	Metronidazole			S				Not Reported
	Solunedrol			C	Unknown	Unk		Not Reported
	Hydroxychloroquine			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840402	NON-EXPEDITED		OT	US-DRREDDYS-USA/USA/17/0094611			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Moxifloxacin			S	Unknown			Not Reported
	Clofazimine			S	Unknown			Not Reported
	Voriconazole			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840888	NON-EXPEDITED			US-PFIZER INC-2018180037		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840902	NON-EXPEDITED			US-PFIZER INC-2018181040		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840954	NON-EXPEDITED			US-PFIZER INC-2018182950		49 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14840960	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-888063		82 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyponatraemia	Azithromycin (7019a)			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14841864	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2018-023494			Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Loss Of Consciousness; Vomiting	Azithromycin Film-Coated Tablets			S	Oral	250 Mg 2 Tables (One Per Day During 1 Day) Then 1 Tablet (One Per Day During 4 Days)		Aurobindo	
	Pivalone /00803802/			C	Nasal	1 Spray2 To 4 Times Per Day ()		Not Reported	
	Ibuprofen			C	Oral	1200 Milligram, Once A Day		Not Reported	
	Claradol			C	Oral	1 To 3 Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14842660	NON-EXPEDITED			US-TEVA-2018-US-889600			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2018	14843415	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-888285		50 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort	Azithromycin			S				Not Reported	
	Omeprazole			C		2 Dosage Forms Daily;		Not Reported	
	Atrovent			C	Respiratory (inhalation)	2 Puffs		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	13861904	EXPEDITED (15-DAY)		OT	PHHY2016CA178833		76 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Dyspnoea; Malaise; Pneumonia;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported	
	Valsartan Sandoz			S	Unknown	160 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Throat Irritation	Amlodipine Sandoz	S	Unknown	1 Df (10 Mg), Qd	Not Reported
	Azithro	S	Unknown	25 Mg, Unk	Not Reported
	Spiriva	C	Unknown	1 Df, Qd	Not Reported
	Symbicort	C	Unknown	4 Df, Bid	Not Reported
	Alvesco	C	Unknown	2 Df, Bid	Not Reported
	Claritin	C	Unknown	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14840837	NON-EXPEDITED			US-PFIZER INC-2018177232			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14846636	NON-EXPEDITED			US-TEVA-2018-US-888345		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S					Not Reported
	Plavix			C					Not Reported
	Eliquis			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14847410	EXPEDITED (15-DAY)		LT	CN-PFIZER INC-2018181633		32 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Increased; Chills; Feeling Cold	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Glucose			S	Intravenous drip	500 MI, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14848389	NON-EXPEDITED			US-PFIZER INC-2018184644		66 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Erythromycin Base			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14848765	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1029240		62 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hyperkalaemia; Metabolic Acidosis	Azithromycin			S	Oral	480 Mg, 12 Hour		Not Reported	
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)	Unk		Mylan	
	Cotrimoxazol, 960 Mg/10 MI, Infusion Intravenosa			S	Intravenous (not otherwise specified)	1 Df, 6 Hour		Mylan	
	Ciclosporina (406a)			S	Oral	75 Mg, 12 Hour		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14849574	NON-EXPEDITED			US-TEVA-2018-US-888864			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral	12 MI Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14849763	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018178193		52 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Rash Maculo-Papular	Zithromax			S	Oral	Unk		Pfizer	
	Lederfoline			S	Oral	Unk		Pfizer	
	Malocide (Pyrimethamine)			S	Oral	Unk		Not Reported	
	Dexamethasone			C	Ophthalmic	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Irbesartan	C	Oral	Unk	Not Reported
Atropine	C	Ophthalmic	Unk	Not Reported
Verapamil	C	Oral	Unk	Not Reported
Indapamide	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14850077	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2018-CA-887636		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Teva-Quetiapine			S	Oral			Teva
	Apo-Quetiapine			S	Oral			Not Reported
	Sandoz Azithromycin			S	Unknown			Not Reported
	Sandoz Ciprofloxacin			S	Oral			Not Reported
	Sandoz Ciprofloxacin			S				Not Reported
	Amoxicillin			C				Not Reported
	Epival			C				Not Reported
	Risperidone			C				Not Reported
	Zyprexa			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2018	14924728	DIRECT					27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Azithromycin Tablet Macrolide Antibiotics			S	Oral	Quantity:6 Capsule(S);	5 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14305722	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2017M1079535		78 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Catheter Site Haemorrhage; Drug Ineffective; Dyspnoea;	Amiodarone			S	Oral	100 Mg, 3xw		Not Reported
	Azithromycin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haemoglobin Decreased; Haemoptysis; Pneumonia Pneumococcal; Productive Cough; Pulmonary Alveolar Haemorrhage; Purulent Discharge; Pyrexia; Respiratory Failure; Streptococcus Test Positive	Apixaban	C	Unknown	5 Mg, Bid		Mylan
	Apixaban	C	Unknown	2.5 Mg, Bid		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14313758	EXPEDITED (15-DAY)		HO, OT	PHHY2017PT191008		78 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Catheter Site	Azithromycin			S	Unknown	Unk		Novartis
Haemorrhage; Drug Ineffective; Dyspnoea; Haemoglobin Decreased; Haemoptysis; Pneumonia Pneumococcal; Productive Cough; Pulmonary Alveolar Haemorrhage; Purulent Discharge; Pyrexia; Respiratory Failure; Streptococcus Test Positive	Amiodarone			S	Unknown	100 Mg, Three Times A Week		Not Reported
	Apixaban			C	Unknown	5 Mg, Bid		Not Reported
	Apixaban			C	Unknown	2.5 Mg, Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14851418	NON-EXPEDITED			US-TEVA-2018-US- 890432			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Nausea	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14852367	NON-EXPEDITED			US-PFIZER INC- 2018183519			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14852508	NON-EXPEDITED			US-PFIZER INC-2018186509		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14852510	NON-EXPEDITED			US-PFIZER INC-2018184886		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14852822	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018178067		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gynaecomastia	Zithromax			S	Oral	3 Df, Weekly		Pfizer	
	Singulair			S	Oral	1 Df, 1x/Day		Not Reported	
	Pulmozyme			S	Respiratory (inhalation)	1 Df, 1x/Day		Not Reported	
	Bactrim Forte			S	Oral	2 Df, 1x/Day		Not Reported	
	Pyostacine			S	Oral	1 Df, 1x/Day		Not Reported	
	Aerius (Desloratadine)			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14853264	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP013272		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Periorbital Swelling; Rash Erythematous; Respiratory Distress; Therapeutic Product Effect Incomplete; Ventricular Tachycardia	Azithromycin			S	Oral	Unk		Apotex	
	Diphenhydramine			S	Unknown	Unk		Apotex	
	Diphenhydramine			S				Apotex	
	Diphenhydramine			S				Apotex	
	Acetaminophen			S	Unknown	Unk		Apotex	
	Acetaminophen			S				Apotex	
	Acetaminophen			S				Apotex	
	Albuterol			S	Other	Unk, Inhalation		Apotex	
	Albuterol W/Ipratropium			C	Unknown			Not Reported	
	Albuterol W/Ipratropium			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14853999	EXPEDITED (15-DAY)		OT	PHHY2018ES002798		62 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hyperkalaemia; Metabolic Acidosis	Ciclosporin			S	Oral	75 Mg, Q12h		Novartis	
	Azitromicina			S	Oral	480 Mg, Q12h		Not Reported	
	Piperacillin+Tazobactam			S	Intravenous (not otherwise specified)			Not Reported	
	Cotrimoxazol			S	Intravenous (not otherwise specified)	1 Df, Q6h (960 Mg/10 MI)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2018	14855816	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2018182671			Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14657852	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-166901		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown	Unk		Sun	
	Sulphamethoxazole/Trimethopri m			S	Unknown	Unk		Sun	
	Nevirapine			S	Unknown	Unk		Ranbaxy	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14858064	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-171960		28 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Pruritus; Therapeutic Product Cross-Reactivity; Urticaria	Clarithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14859611	NON-EXPEDITED			US-PFIZER INC- 2018180920			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Cleocin			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14860125	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018184708		25 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Chest Discomfort; Nausea; Palpitations; Tachypnoea; Vomiting	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14860130	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018184487		4 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Eyelid Oedema; Hyperaemia; Vomiting	Azithromycin			S	Intravenous drip	0.19 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14860881	EXPEDITED (15-DAY)		HO, OT	US-QILU PHARMACEUTICAL CO.LTD.-QLU-000318-2018		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Septic Shock	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Qilu Pharmaceutical	
	Ceftriaxone			S				Qilu Pharmaceutical	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Metronidazole			S	Unknown	Unk		Not Reported	
	Metronidazole			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2018	14947220	DIRECT	Y	HO			26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hospitalisation	Tivicay 50 Mg	S	Oral	Viiv
	Zithromax	S		Not Reported
	Bactrim	C		Not Reported
	Fluconazole	C		Not Reported
	Vol-Nate	C		Not Reported
	Truvada	C		Not Reported
	Tylenol	C		Not Reported
	Vitamin B-6	C		Not Reported
	Isoniazid	C		Not Reported
	Rifampin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14852472	NON-EXPEDITED			US-PFIZER INC-2018186559			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Dynabac			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
	Norco			S		Unk		Not Reported	
	Z-Pak			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14867917	NON-EXPEDITED			US-TEVA-2018-US-890045			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Weight Increased	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14868666	NON-EXPEDITED			US-PFIZER INC-2018184617		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax	S		Pfizer
Doxycycline Hyclate	S	Unk	Pfizer
Doxycycline Hyclate	S		Pfizer
Doxycycline Hyclate	S		Pfizer
Cephalexin	S	Unk	Not Reported
Cephalexin	S		Not Reported
Cephalexin	S		Not Reported
Flonase	S	Unk	Not Reported
Flonase	S		Not Reported
Flonase	S		Not Reported
Advair	S	Unk	Not Reported
Advair	S		Not Reported
Advair	S		Not Reported
Ipratropium Bromide	S	Unk	Not Reported
Ipratropium Bromide	S		Not Reported
Ipratropium Bromide	S		Not Reported
Albuterol	S	Unk	Not Reported
Albuterol	S		Not Reported
Albuterol	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14868776	NON-EXPEDITED			US-PFIZER INC-2018189299			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14868860	NON-EXPEDITED			US-PFIZER INC-2018067105			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Route Of Product Administration; Pain	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14870584	NON-EXPEDITED			US-PFIZER INC-2018188856		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2018	14871080	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018075782		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia; Blood Pressure Increased; Hypertensive Crisis; Insomnia; Nervousness; Parosmia; Restlessness; Tachycardia	Advair Diskus			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline	
	Z-Pak			S				Glaxosmithkline	
	Cetirizine			C				Not Reported	
	Clonidine			C				Not Reported	
	Gabapentin			C				Not Reported	
	Hydroxyzine			C				Not Reported	
	Labetalol			C				Not Reported	
	Trazodone			C				Not Reported	
	Valsartan			C				Not Reported	
	Antihistamine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14804089	NON-EXPEDITED			US-PFIZER INC-2018169650			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14840856	NON-EXPEDITED			US-PFIZER INC-2018179300		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Naproxen	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14873193	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2018US021219		15 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Tacrolimus			S	Oral	Unk, Unknown Freq.		Astellas
	Atorvastatin			S	Oral	Unk, Unknown Freq.		Not Reported
	Azithromycin			S	Oral	Unk, Unknown Freq.		Not Reported
	Lansoprazole			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Mycophenolate Mofetil			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Pantoprazole			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Prednisone			S	Oral	Unk, Unknown Freq.		Not Reported
	Sulfamethoxazole W/Trimethoprim			S	Oral	Unk, Unknown Freq.		Not Reported
	Voriconazole			S	Oral	Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14873289	NON-EXPEDITED			US-PFIZER INC-2018190598		34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14873354	NON-EXPEDITED			US-PFIZER INC-2018190828		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Gait Disturbance; Loss Of Personal Independence In Daily Activities	Zithromax			S	Oral	500 Mg, 1x/Day (Two Pills, Once A Day)		Pfizer
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14873374	NON-EXPEDITED			US-PFIZER INC-2018191223		8 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14873973	EXPEDITED (15-DAY)		HO, OT	NL-SA-2018SA122596		59 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abscess Limb; Arthralgia;	Prednisolone			S	Oral			Not Reported	
Condition Aggravated;	Prednisolone			S	Oral			Not Reported	
Disease Progression;	Prednisolone			S	Oral			Not Reported	
Drug Ineffective; Infective	Prednisolone			S	Unknown			Not Reported	
Tenosynovitis; Myalgia;	Prednisolone			S	Unknown			Not Reported	
Mycobacterial Infection;	Prednisolone			S	Unknown			Not Reported	
Pain; Peripheral Swelling	Prednisolone			S	Unknown			Not Reported	
	Prednisolone			S	Oral			Not Reported	
	Prednisolone			S	Oral			Not Reported	
	Prednisolone			S	Oral			Not Reported	
	Prednisolone			S	Oral			Not Reported	
	Mycophenolate Mofetil			S	Oral	750 Mg Morning And 500 Mg Evening		Not Reported	
	Mycophenolate Mofetil			S	Oral			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Rifampicin			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14874443	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2018-025014		58 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Suicidal Ideation	Azithromycin Film Coated Tablet 250mg			S	Unknown	250 Milligram, 2.3 Day, Maandag, Woensdag, Vrijdag 250mg		Aurobindo	
	Omeprazol /00661201/			C	Unknown	20 Milligram, Once A Day (1dd1)		Not Reported	
	Salbutamol			C	Unknown	100 Microgram, As Necessary, Zn (5-10keer Per Week)		Not Reported	
	Flutiform			C	Unknown	2 Dosage Form, Two Times A Day (2dd2)		Not Reported	
	Spiriva			C	Unknown	5 Microgram, Once A Day (1dd2)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14875314	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-024502		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoxia; Periorbital Swelling; Rash Erythematous; Respiratory Distress	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2018	14875904	EXPEDITED (15-DAY)		OT	PHHY2018US077599			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Heart Rate Abnormal; Premature Baby	Azithromycin			S	Transplacental	Unk		Novartis	
	Vancomycin			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Betamethasone	S	Transplacental	Unk	Not Reported
	Ceftriaxone	S	Transplacental	Unk	Not Reported
	Meropenem	S	Transplacental	Unk	Not Reported
	Magnesium	S	Transplacental	Unk	Not Reported
	Penicillin B	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14873405	NON-EXPEDITED			US-PFIZER INC-2018187844			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus; Eye Swelling; Foot Deformity; Lip Swelling; Nail Bed Disorder; Paraesthesia Oral; Reaction To Excipient; Skin Disorder; Skin Exfoliation; Swollen Tongue; Throat Irritation; Throat Tightness	Azithromycin			S	Sublingual	250 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14879379	NON-EXPEDITED			US-PFIZER INC-2018192148			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Feldene			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Skelaxin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-May-2018	14884362	NON-EXPEDITED			US-TEVA-2018-US-890819			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower;	Azithromycin			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chromaturia; Diarrhoea;
Nausea; Pyrexia; Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14804086	NON-EXPEDITED			US-PFIZER INC-2018170219			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14889881	NON-EXPEDITED			US-TEVA-2018-US-890474			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin			S	Unknown	Dose Strength: 200 Mg/5 MI		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14889904	NON-EXPEDITED			US-TEVA-2018-US-890430		10 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14889963	NON-EXPEDITED			US-TEVA-2018-US-890777			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Back Pain	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2018	14890281	NON-EXPEDITED			US-PFIZER INC-2018193012			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Losartan			S		Unk		Not Reported	
	Reglan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14890306	NON-EXPEDITED		DS, HO	US-PFIZER INC-2018195618		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2018	14890317	NON-EXPEDITED			US-PFIZER INC-2018193240		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Hydroxyzine Pamoate			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Norco			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	12599902	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015249911		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Alanine Aminotransferase	Novatrex			S	Oral	20 Mg, Weekly		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Aplastic Anaemia; Blood Creatinine Increased; Bone Marrow Toxicity; Dermatitis Exfoliative Generalised; Leukopenia; Mouth Ulceration; Mucosal Erosion; Neutropenia	Imeth Imeth Un-Alfa Soriatane Triatec /00116401/ Speciafoldine Ostram /00183801/ Levothyrox Glucophage Betneval Amarel Atarax /00058401/	S S C C C C C C C C C C C	Oral Oral Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	20 Mg, Weekly 20 Mg, Weekly 1 Mg, Daily 25 Mg, Daily 2.5 Mg, Daily 5 Mg, Daily 1 Df, Unk 125 Mg, 1x/Day (1 Tablet Morning) 1 Df, 2x/Day (Morning And Midday) Unk, 1x/Day 4 Mg, 1x/Day (Morning) 25 Mg, 1x/Day (1 Tablet Evening)	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	14895180	NON-EXPEDITED			US-PFIZER INC- 2018194215			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Zithromax			S		250 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2018	14897432	NON-EXPEDITED			US-AKRON, INC.- 2047795			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus; Eye Swelling; Hordeolum	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14900311	EXPEDITED (15-DAY)		DS, HO, LT	US- ELI_LILLY_AND_COMP		32 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

ANY-US201805004876

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Agitation; Alopecia; Anaemia; Anogenital Warts; Atelectasis; Blood Pressure Increased; Cardiac Valve Vegetation; Cardiomegaly; Chordae Tendinae Rupture; Coagulopathy; Constipation; Cytomegalovirus Infection; Duodenitis Haemorrhagic; Electrocardiogram St Segment Elevation; Hepatic Cirrhosis; Hepatic Encephalopathy; Hepatic Failure; Hepatic Necrosis; Hepatotoxicity; Hiatus Hernia; Hyperkalaemia; Insomnia; Jaundice; Liver Disorder; Liver Function Test Increased; Liver Transplant Rejection; Lymphadenopathy; Myocardial Infarction; Oesophagitis; Pericarditis; Pleural Effusion; Rash Macular; Sinus Tachycardia; Skin Papilloma; Splenomegaly; Staphylococcal Infection; Tremor; Weight Decreased; White Blood Cell Count Decreased	Fluoxetine Hydrochloride Azithromycin Azithromycin Azithromycin Nortriptyline Ibuprofen Roxicet Zinacef /00454601/ Depakote Erythromycin Prednisone Allegra D Claritin /00917501/ Patanol Anusol /01604901/ Preparation H /00611001/			S S S S S S C C C C C C C C C	Oral Oral Oral Oral Oral Oral Unknown Unknown Unknown Unknown Unknown Unknown Unknown Ophthalmic Unknown Unknown	60 Mg, Unknown 500 Mg, Unknown Daily Dose: 500milligram Daily Dose: 500milligram 25 Mg, Unknown Unk Unk, Unknown Unk, Unknown Unk Unk, Unknown Unk, Unknown Unk, Unknown Unk, Unknown Unk, Unknown Unk Unk, Unknown Unk, Unknown Unk Unk, Unknown Unk Unk, Unknown		Eli Lilly And Co Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14901143	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-025678		10 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo	
	Salbutamol			C	Respiratory (inhalation)	2-2-2		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2018	14903556	NON-EXPEDITED			US-TAKEDA-2018TUS016512			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Diarrhoea; Respiratory Disorder	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk		Takeda	
	Z-Pak			S	Oral	Unk		Not Reported	
	Celebrex			C	Oral	100 Mg, Qd		Not Reported	
	Atenolol			C	Oral	25 Mg, Qd		Not Reported	
	Xanax			C	Oral	Unk Unk, Qd		Not Reported	
	Omeprazole			C	Oral	Unk		Not Reported	
	Ondansetron			C	Oral	Unk		Not Reported	
	Welchol			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14908567	NON-EXPEDITED			US-PFIZER INC-2018201806		91 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Aldactone			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14908666	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2018197558		243 DAY	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Osteomyelitis; Pyrexia; Sepsis	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14909002	NON-EXPEDITED			US-PFIZER INC-2018199272			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2018	14909030	NON-EXPEDITED			US-PFIZER INC-2018200709		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14804161	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018GB026999		58 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adenovirus Infection;	Cyclophosphamide			S	Unknown	150 Mg/M2, Unk		Not Reported	
Haemophilus Infection;	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
Hepatic Function Abnormal;	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
Hypogammaglobulinaemia	Fludarabine			S	Unknown			Not Reported	
; Lymphopenia; Multiple Organ Dysfunction Syndrome; Pneumonia	Co-Amoxiclav			S	Unknown	625 Mg, Tid		Not Reported	
Adenoviral; Productive Cough	Prednisolone			S	Oral	40 Mg, Qd		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Doxycycline	S	Unknown	100 Mg, Qd	Not Reported
	Acyclovir	C	Unknown	400 Mg, Bid	Not Reported
	Acyclovir	C	Unknown	800 Mg, Qd	Not Reported
	Co-Trimoxazole	C	Unknown	960 Mg, Bid (3 Times A Week)	Not Reported
	Co-Trimoxazole	C	Unknown	In Divided Doses	Not Reported
	Co-Trimoxazole	C	Unknown	1920 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14831721	NON-EXPEDITED		OT	US-PFIZER INC-2018176159		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Product Use Issue	Azithromycin			S	Oral	500 Mg, 1x/Day (Dose Of 500mg On Day 1)		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day (250mg On Days 2, 3, 4)		Pfizer	
	Azithromycin			S		50 Mg, 1x/Day (50mg On Days 5 And 7)		Pfizer	
	Medrol			C		2 Mg, Unk		Not Reported	
	Gemfibrozil			C		600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14840173	EXPEDITED (15-DAY)		CA, HO	SK-TEVA-2018-SK-886014			Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Cystic Lung; Foetal Exposure During Pregnancy; Live Birth	Azithromycin			S	Transplacental			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14911323	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2018SP001364			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Vancomycin			S	Unknown	Unk		Strides	
	Vancomycin			S				Strides	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S				Not Reported	
	Cefepime			S	Unknown	Unk		Not Reported	
	Cefepime			S				Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
Meropenem			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14912130	NON-EXPEDITED			US-PFIZER INC-2018205016		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14912694	EXPEDITED (15-DAY)		OT	NL-GLAXOSMITHKLINE-NL2018GSK086886			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Angioedema	Amoxicillin + Clavulanic Acid			S				Glaxosmithkline	
	Cefuroxime			S				Glaxosmithkline	
	Azithromycin			S				Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2018	14913067	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018203868		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rib Fracture; Sternal Fracture	Novatrex			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cosentyx			S		Subcutaneous		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-May-2018	14916508	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-026218		25 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anal Inflammation; Intertrigo; Proctalgia	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-May-2018	13807461	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20170408692		75 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Arthritis; Asthenia; Back Pain; Cardiac Disorder; Chest Discomfort; Contusion; Drug Hypersensitivity; Dysgeusia; Infected Bite; Musculoskeletal Stiffness; Nausea; Pain; Pain In Jaw; Respiratory Rate Increased; Sinusitis; Tremor	Imbruvica			S	Oral			Not Reported		
	Imbruvica			S	Oral			Not Reported		
	Synvisc One			S	Unknown			Not Reported		
	Curcumin			S	Unknown			Not Reported		
	Azithromycin			S	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-May-2018	14918613	NON-EXPEDITED			US-PFIZER INC-2018203138		67 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Constipation; Drug Hypersensitivity; Dyspnoea; Swelling	Zithromax			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-May-2018	14919917	NON-EXPEDITED			US-PFIZER INC-2018205565		9 YR	Male	USA	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2018	14920273	EXPEDITED (15-DAY)		OT	PHHY2018GB003364		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Confusional State; Diarrhoea; Dizziness; Malaise; Somnolence	Azithromycin Monohydrate			S	Oral	2000 Mg, Once/Single, Single Dose (8x250mg)		Novartis	
	Truvada			C	Unknown	Unk		Not Reported	
	Imodium			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14204497	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC- 2017498665		36 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carditis; Depression; Drug Ineffective; Dyslipidaemia; Renal Impairment; Rheumatic Fever	Methotrexate			S		25 Mg, Weekly		Pfizer	
	Azithromycin			S		75 Mg, Daily		Pfizer	
	Chloroquine			S		200 Mg, 1x/Day		Not Reported	
	Arava			S		20 Mg, 1x/Day		Not Reported	
	Minocycline			S		60 Mg, 1x/Day		Not Reported	
	Enbrel			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14817336	NON-EXPEDITED			US-TEVA-2018-US- 885465		1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Prescribing Error; Vomiting	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14918763	NON-EXPEDITED			US-PFIZER INC-2018205585		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14922556	NON-EXPEDITED			US-PFIZER INC-2018209008		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14923140	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-173512		10 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250 Mg Dia		Sun	
	Salbutamol			C	Respiratory (inhalation)	2-2-2 ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14923835	NON-EXPEDITED			US-PFIZER INC-2018207027		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Premarin			S		Unk		Pfizer	
	Tessalon			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2018	14999573	DIRECT		DS, LT			23 YR	Female	IRN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Cardiac Valve Disease; Heart Rate Irregular; Palpitations	Azithromaysin			S	Oral	Quantity:1 Capsule(S);		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	13663993	EXPEDITED (15-DAY)		DE	IT-TEVA-774078ACC		76 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholelithiasis; Hepatic Enzyme Increased; Jaundice	Azithromycin			S	Oral			Not Reported	
	Deltacortene - 25 Mg Compresse			C	Oral			Not Reported	
	Oxygen			C	Respiratory (inhalation)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14770527	EXPEDITED (15-DAY)		DE	DE-PFIZER INC-2018155484		82 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Bundle Branch Block Left; Cardiac Failure; Cardiopulmonary Failure; Drug Interaction	Cabergoline			S	Parenteral	Unk, Weekly		Pfizer	
	Azithromycin Eberth			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Optrex Actimist 2in1 Eye Spray For Dry + Irri			C		Unk		Not Reported	
	Unacid /00917901/			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Furosemid Ratiopharm /00032601/			C		Unk		Not Reported	
	Emselex /01760401/			C		3 Mg, 1x/Day		Not Reported	
	Ibuprofen			C	Oral	Unk, As Needed		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Simvastatin Ratiopharm	C		20 Mg, 1x/Day	Not Reported
Pantoprazol Tad	C		40 Mg, 1x/Day	Not Reported
Promethazin Neuraxpharm	C		25 Mg, 1x/Day	Not Reported
Hylo-Comod	C		Unk	Not Reported
Relvar Ellipta	C		180 Ug/22 Ug	Not Reported
L-Thyrox Hexal	C		100 Ug, 1x/Day	Not Reported
Atrovent	C	Respiratory (inhalation)	Unk, As Needed	Not Reported
Xarelto	C		20 Mg, 1x/Day	Not Reported
Amitriptylin Neuraxpharm	C		Unk	Not Reported
Ramipril	C		2.5 Mg, 1x/Day	Not Reported
Amitriptylin	C	Oral	25 Mg, 1x/Day	Not Reported
Bisoprolol	C		3 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14835677	EXPEDITED (15-DAY)		HO, OT	SK-TEVA-2018-SK-886013			Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Live Birth; Maternal Exposure During Pregnancy; Retroplacental Haematoma	Azithromycin			S	Unknown	In 5 Gestation Week Of Pregnancy		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14926448	EXPEDITED (15-DAY)		OT	ES-JNJFOC-20180514030			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Ibuprofen		Y	S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Amoxicillin W/Clavulanate			S	Unknown			Not Reported	
	Potassium Nitrofurantoin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14926510	EXPEDITED (15-DAY)		DE, HO, OT	AU-ALKEM LABORATORIES LIMITED-AU-ALKEM- 2018-03318			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hepatotoxicity	Isoniazid			S	Unknown	Unk		Alkem
	Diclofenac Sodium			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Rifampicin			S	Unknown	Unk		Not Reported
	Pyrazinamide			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Pyridoxine			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Cimetidine			S	Unknown	Unk		Not Reported
	Metoclopramide			S	Unknown	Unk		Not Reported
	Dexamethasone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14926641	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-173441		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma	Salbutamol			S	Unknown	Unk, Prn (As Needed)		Mutual
	Salmeterol/Fluticasone			S	Respiratory (inhalation)	Unk, Bid (One Puff Twice A Day)		Not Reported
	Azithromycin			S	Unknown	250 Mg, 3/Week		Sun
	Montelukast			S	Unknown	10 Mg, Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tiotropium Respimat	S	Respiratory (inhalation)	Unk, Bid (Two Puff Daily)	Not Reported
Budesonide	S	Respiratory (inhalation)	Unk, Bid	Not Reported
Omalizumab	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14927392	NON-EXPEDITED			US-PFIZER INC-2018210954		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14928026	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018206413			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Loss Of Consciousness; Vomiting	Azithromycin			S	Oral	500 Mg (2 Tablets), One Per Day For 1 Day		Pfizer	
	Azithromycin			S	Oral	250 Mg (1 Tablet) One Per Day For 4 Days		Pfizer	
	Pivalone (Tixocortol Pivalate)			C	Nasal	1 Spray 2 To 4 Times Per Day		Not Reported	
	Ibuprofen			C	Oral	1200 Mg, 1x/Day		Not Reported	
	Claradol			C	Oral	1 To 3 Per Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14928783	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2018GSK091919		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Dyspnoea;	Lamictal			S				Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Influenza Like Illness; Petechiae; Rash; Rash Vesicular; Respiratory Failure; Stevens-Johnson Syndrome; Stomatitis	Augmentin Azithromycin	S S		Glaxosmithkline Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	14928920	EXPEDITED (15-DAY)		OT	BE-JNJFOC- 20180526347			Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Drug Interaction; Renal Failure	Itraconazole			S	Unknown			Not Reported
	Crestor			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tildiem			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2018	15000132	DIRECT		HO, LT			17 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Colitis	Azithromycin			S	Oral	Quantity:6 Tablet(S);		Not Reported
	Remicade			C				Not Reported
	Vitamin D Nos			C				Not Reported
	Calcium			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14928022	NON-EXPEDITED			US-PFIZER INC- 2018210803		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933047	NON-EXPEDITED			US-PFIZER INC- 2018212966			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933062	NON-EXPEDITED			US-PFIZER INC-2018212699		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933774	NON-EXPEDITED			US-PFIZER INC-2018211411		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ibuprofen			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933968	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014147			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933969	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014113			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933970	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014114			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933971	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014136			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933972	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014151			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14933973	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014148			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933974	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014146			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933975	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014145			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933976	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014149			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14933977	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014150			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934367	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014078			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934368	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014089			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934369	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014099			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934370	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014090			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934371	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014100			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934616	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014155			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934617	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014157			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934618	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014154			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934619	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014156			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934620	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014159			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934621	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014158			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-May-2018	14934623	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014153			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934624	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014160			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14934625	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014152			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	14935078	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018210415		49 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Papular	Azithromycin			S	Oral	Unk		Pfizer	
	Claforan /00497602/			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rocephine			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Bisoce			C	Oral	3.75 Mg, 1x/Day		Not Reported	
	Oracilline /00001801/			C	Oral	2000000 Iu, 1x/Day		Not Reported	
	Mag 2 /00454301/			C	Oral	100 Mg, Unk		Not Reported	
	Noxafil			C	Oral	200 Mg, 1x/Day		Not Reported	
	Alprazolam			C	Oral	0.25 Mg, As Needed		Not Reported	
	Cortancyl			C		10 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Calcium Vitamine D3	C	Oral	2 Df, 1x/Day	Not Reported
Pantoprazole	C	Oral	20 Mg, 1x/Day	Not Reported
Movicol	C		Unk	Not Reported
Wellvone	C	Oral	10 Ml, 1x/Day	Not Reported
Valaciclovir	C		1000 Mg, 1x/Day	Not Reported
Neoral	C	Oral	250 Mg, 1x/Day	Not Reported
Ramipril	C		2.5 Mg, 1x/Day	Not Reported
Entocort	C	Oral	3 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2018	15004174	DIRECT		OT			34 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Heart Rate Increased; Heart Rate Irregular; Insomnia	Azithromycin Tablets Usp 250 Mg			S	Oral	Quantity:6 Tablets		Teva
	Nyquil Severe			C				Not Reported
	Dayquil			C				Not Reported
	Airborne Immune Support Supplement			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14261732	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP022162		76 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bladder Discomfort; Blood Pressure Increased; Blood Pressure Systolic Increased; Hot Flush; Urinary Tract Infection	Azithromycin			S	Unknown	250 Mg, Unk		Apotex
	Tamsulosin			S	Oral	1 Df, Qd		Not Reported
	Montelukast			S	Unknown	1 Df, Qd		Apotex
	Montelukast Sandoz			S	Unknown	1 Df, Qd		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Unk		Not Reported
	Spiriva			C	Unknown	1 Df, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Symbicort	C	Unknown	6 Df, Qd				Not Reported	
	Ventolin /00139501/	C	Unknown	6 Df, Qd				Not Reported	
	Prednisone	C	Oral	1 Df, Bid				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14519620	NON-EXPEDITED			US-PFIZER INC-2018061284		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14840739	NON-EXPEDITED			US-PFIZER INC-2018177803			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Cephalexin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Zyrtec			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14923540	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018205398		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tubulointerstitial Nephritis	Ceftriaxone Sodium			S		Unk, 9-Day Course		Pfizer	
	Azithromycin			S		Unk, 9-Day Course		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14936826	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-		25 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2018RR-173785

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Inflammation; Intertrigo; Proctalgia	Azithromycin			S	Oral			Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937544	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014103			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937549	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014104			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937550	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014105			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937551	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014102			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937552	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014101			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937835	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014168			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937836	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014169			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-May-2018	14937837	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014165			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Exposure During Pregnancy	Azithromycin		S	Unknown	Unk			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937838	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014166			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937839	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014164			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14937841	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP014167			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-May-2018	14938922	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2018M1033587		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Confusional State;	Azithromycin			S	Oral	2000 Mg, Total,Single Dose (8x250mg)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Dizziness; Malaise; Somnolence	Truvada		C			Unk			Mylan
	Imodium		C			Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-May-2018	14941551	NON-EXPEDITED			US-TEVA-2018-US-896644			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise	Azithromycin				S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2018	14943311	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014028			Female	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin				S	Unknown	Unk		Apotex
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2018	14943324	EXPEDITED (15-DAY)		DE	NP-KNIGHT THERAPEUTICS (USA) INC.-2048543		74 YR	Male	NPL
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Drug Ineffective For Unapproved Indication; Off Label Use; Oliguria; Renal Impairment	Impavido (Miltefosine) Capsules				S				Knight Therapeutics
	Amphotericin B				S				Not Reported
	Flucytosine				S				Not Reported
	Voriconazole				S				Not Reported
	Azithromycin				S				Not Reported
	Rifampicin				S				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2018	14944206	EXPEDITED (15-DAY)		OT	PHHY2018GB009698		50 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort	Azithromycin				S	Unknown			Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omeprazole		C	Unknown	2 Df, Qd	Not Reported				
Atrovent		C	Respiratory (inhalation)	2 Puffs Up To Four Times A Day	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944731	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014130			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944733	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014140			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944734	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014129			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944735	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014132			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pregnancy

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944736	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014108			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944737	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014084			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944742	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014083			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944748	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014134			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944749	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014087			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944750	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014135			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944751	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014107			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944752	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014106			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944753	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014131			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944754	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014086			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944756	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014139			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944757	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014133			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944758	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014085			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944778	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014123			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944779	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014127			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14944780	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014120			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944781	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014128			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944997	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014119			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14944999	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014121			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945000	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014125			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945001	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014126			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945002	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014122			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945003	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014124			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945119	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014170			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945567	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014079			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945568	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014082			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945573	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014088			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945574	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014091			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945578	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014109			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945580	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014092			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945586	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014081			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945623	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014111			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945624	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014112			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945625	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014138			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945626	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014098			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945627	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014094			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945628	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014093			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945630	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014080			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945634	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014110			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945635	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014137			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945636	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014097			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945637	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014141			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945638	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014095			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945639	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014096			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945641	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014174			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945642	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014143			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945643	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014175			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945644	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014177			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945645	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014172			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945646	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014176			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945647	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014178			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14945651	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014173			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945652	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014142			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945653	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014171			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14945654	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014144			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
29-May-2018	14946123	NON-EXPEDITED			PHEH2018US020675			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise	Ilaris			S	Subcutaneous	360 Mg, Qmo		Novartis	
	Z-Pak			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947472	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014163			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947473	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014076			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947474	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014116			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947475	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014118			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947484	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014077			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947485	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014075			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947486	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014073			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947487	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014070			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947488	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014161			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947489	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014071			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947490	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014117			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947491	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014072			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947492	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014115			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947493	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014162			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14947497	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP014074			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14948572	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018213971		47 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Oedema; Urticaria	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Augmentin /00756801/			S	Oral	1 Df, 1x/Day		Not Reported	
	Synflex /00256202/			S	Oral	1 Df, Single		Not Reported	
	Cefodox			S	Oral	200 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eutirox			C		75 Ug, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14948717	EXPEDITED (15-DAY)		HO	AU-PFIZER INC-2018212994		7 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain In Extremity	Zithromax			S	Oral	320 Mg, Daily		Pfizer	
	Everolimus			S	Oral	10 Mg, Daily		Not Reported	
	Everolimus			S				Not Reported	
	Lamictal			C		Unk		Not Reported	
	Keppra			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14949043	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018214617		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Laryngeal Obstruction; Malaise; Tachycardia	Zithromax			S	Oral	1 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14949140	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1034784			Unknown	PNG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance; Treatment Failure	Azithromycin			S	Oral	30 Mg/Kg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14949151	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2018M1034783		11 YR	Male	PNG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pathogen Resistance; Treatment Failure	Azithromycin	S	Oral	30 Mg/Kg, Total Dose: 1.5 G	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	14949216	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS- 2018M1035091		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Wall	Azithromycin			S	Unknown			Not Reported
Haematoma; Brain	Levofloxacin			S	Unknown			Not Reported
Herniation; Cerebral	Ceftriaxone			S	Unknown			Mylan
Haemorrhage; Factor V	Meropenem			S	Unknown			Mylan
Inhibition; Subdural								
Haematoma								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2018	15011833	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Azithromycin			S				Not Reported
	Ciprofloxacin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	12933541	EXPEDITED (15-DAY)		HO	US-ACTELION-A- NJ2016-145393		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure;	Upravi			S	Oral	600 Mcg, Bid		Actelion
Bronchial Hyperreactivity;	Upravi			S	Oral	Unk		Actelion
Bronchial Secretion	Opsumit			C		Unk		Actelion
Retention; Drug	Zithromycin			S	Unknown			Not Reported
Hypersensitivity; Fluid	Revatio			C		Unk		Not Reported
Overload; Folliculitis;	Lactobacillus			C		Unk		Not Reported
Hypoxia; Pain;	Hydrochlorothiazide			C		Unk		Not Reported
Palpitations; Pneumonia;	Methylprednisolone			C		125 Mg, Tid		Not Reported
Pneumonia Bacterial;								
Pneumonia Viral; Pruritus;								
Right Ventricular Failure;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sepsis; Upper Respiratory Tract Infection	Lasix Ceftriaxone	C C	Intravenous (not otherwise specified)	1 G, Single	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	13861108	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2017345937		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Demyelination	Novatrex			S	Unknown	10 Mg, Weekly		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, Cyclic: Every Twelve Weeks		Not Reported	
	Nisisco			C		Unk		Not Reported	
	Speciafoldine			C		Unk		Not Reported	
	Tramadol			C		Unk		Not Reported	
	Amlor			C		Unk		Not Reported	
	Propranolol			C		Unk		Not Reported	
	Alodine			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14941062	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018211275		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Weight Increased	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14950686	EXPEDITED (15-DAY)		OT	PHHY2018IT009528		14 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain; Muscle	Azithromycin			S	Oral	500 Mg		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swelling

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14951265	EXPEDITED (15-DAY)		OT	PHHY2018US006736		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Renal Tubular Necrosis; Tubulointerstitial Nephritis	Azithromycin			S	Unknown	Unk		Novartis	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14952542	NON-EXPEDITED			US-PFIZER INC-2018220643			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14952628	NON-EXPEDITED			US-PFIZER INC-2018216348		182 DAY	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Azithromycin			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14952965	EXPEDITED (15-DAY)		LT	IT-ASTRAZENECA-2018SE69620		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Toxic Epidermal Necrolysis	Quetiapine Fumarate			S	Oral			Zeneca	
	Diazepam			S	Oral	20.0gtt Intermittent		Not Reported	
	Rocefin			S	Parenteral			Not Reported	
	Azithromycin Dihydrate			S	Oral			Not Reported	
	Zolpidem Tartrate			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14953618	NON-EXPEDITED			US-PFIZER INC-2018221091		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S				Not Reported	
	Cymbalta			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2018	14954818	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-898393		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azitromicina (7019a)			S	Oral	Dosis Única		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	13610947	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-1943388		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Atrial Fibrillation; Back Pain; Blood Disorder; Blood Pressure Increased; Body Temperature Decreased; Diarrhoea; Dyspnoea; Fatigue; Infection; Osteoarthritis; Pneumonia Pseudomonal; Pneumonia Streptococcal; Pulmonary Oedema; Wheezing	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Bisoprolol Sandoz			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azithromycin	S	Unknown	(For 1 Year)	Not Reported
	Spiriva	C	Unknown		Not Reported
	Zenhale	C	Unknown		Not Reported
	Qvar	C	Unknown		Not Reported
	Singulair	C	Unknown		Not Reported
	Claritin	C	Unknown		Not Reported
	Ventolin	C	Unknown	Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14318733	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2017-45333		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Venooclusive Disease	Azithromycin			S	Oral	Unk ()		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14606967	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP007158		22 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Biopsy	Azithromycin			S	Unknown	Unk		Apotex	
Colon Abnormal; Blood Pressure Decreased; C-Reactive Protein	Azithromycin			S	Unknown	Unk, Once		Apotex	
Increased; Diarrhoea; Dysbiosis; Enteritis; Frequent Bowel Movements; Gastroenteritis	Ciprofloxacin			S	Oral	Unk		Apotex	
Staphylococcal; Gastrointestinal Mucosa Hyperaemia; Haematochezia; Heart Rate Increased; Nausea; Purulence; Staphylococcal Infection; Weight	Moxifloxacin			S	Unknown	Unk		Apotex	
	Cefixime			S	Unknown	Unk, Once		Not Reported	
	Pms Azithromycin			S	Unknown	Unk		Not Reported	
	Pms Azithromycin			S				Not Reported	
	Pms Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14642961	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018108523		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestatic Liver Injury;	Azithromycin			S		Unk		Pfizer	
Granuloma;	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
Granulomatous Liver Disease; Vanishing Bile Duct Syndrome	Nevirapine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14798432	NON-EXPEDITED			US-PFIZER INC-2018165468		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14956408	NON-EXPEDITED			US-PFIZER INC-2018220432		5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14956498	NON-EXPEDITED			US-PFIZER INC-2018222878		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Bacitracin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14956505	NON-EXPEDITED			US-PFIZER INC-2018222986		53 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14957785	NON-EXPEDITED			US-TEVA-2018-US-898527			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Chills; Decreased Appetite; Headache; Hyperhidrosis; Nausea; Paraesthesia; Weight Decreased	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958001	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018221313		2 YR	Female	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Electrocardiogram Q Wave Abnormal; Extrasystoles; Inappropriate Schedule Of Product Administration	Zithromax			S	Oral	0.15 G, 3x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2018	14958440	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-028406		63 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Fluconazole			S	Oral	200 Milligram, Once A Day		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Perindopril	C	Unknown	4 Milligram		Not Reported			
	Lansoprazole	C	Unknown	20 Milligram		Not Reported			
	Eutirox	C	Unknown	1 Dosage Form		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2018	14958629	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK201806154		12 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia; Vomiting; Weight Decreased	Cytarabine Injection			S	Intrathecal	30 Mg/Cure		Fresenius Medical Care	
	Prednisolone			S	Intrathecal	15 Mg/Cure		Not Reported	
	Methotrexate Mylan			S	Intrathecal	12 Mg/Cure		Not Reported	
	Purinethol			S	Oral			Not Reported	
	Novatrex			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14840890	NON-EXPEDITED			US-PFIZER INC-2018179265			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14873392	NON-EXPEDITED			US-PFIZER INC-2018192346		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Z-Pak			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14940905	EXPEDITED (15-DAY)		DE, HO, OT	CN-IMPAX LABORATORIES, INC-2018-IPXL-01743			Female	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Dysgenesis; Cerebral Haemorrhage; Cerebral Ventricle Dilatation; Epilepsy; Haemorrhage Intracranial; Hydrocephalus; Phenylketonuria; Product Administered To Patient Of Inappropriate Age; Product Use Issue; Refusal Of Treatment By Relative; Retinal Haemorrhage	Omeprazole Delayed Release			S	Unknown	Unk		Impax
	Divalproex Sodium Er			S	Unknown	Unk		Impax
	Levetiracetam			S	Unknown	Unk		Not Reported
	Augmentin			S	Unknown	Unk		Not Reported
	Cefoperazona/Sulbactam			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Fluconazole			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Heparin			S	Unknown	Unk, Low-Molecular Weight		Not Reported
	Etamsylate			S	Unknown	Unk		Not Reported
	Glucuronolactone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14961929	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR- 899588		31 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Faeces Soft; Haematochezia; Mucous Stools	Azithromycine Anhydre			S	Oral			Not Reported
	Azithromycine Anhydre			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14962639	NON-EXPEDITED			US-PFIZER INC- 2018225186		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14962839	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI-FK201806266		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma;	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care	
Antiphospholipid Antibodies Positive; Blood Fibrinogen Increased;	Azithromycin (Manufacturer Unknown)			S				Fresenius Medical Care	
Brain Herniation;	Levofloxacin In 5% Dextrose (Manufacturer Unknown)			S	Unknown	Unknown		Not Reported	
Coagulation Factor Decreased; Coagulation Time Prolonged; Factor V Inhibition; Haemorrhage Intracranial; Intracranial Mass; Prothrombin Time Prolonged; Respiratory Disorder; Subdural Haematoma; Subdural Haematoma; Subdural Haematoma	Levofloxacin In 5% Dextrose (Manufacturer Unknown)			S				Unknown	
	Ceftriaxone For Injection (Manufacturer Unknown)			S	Unknown	Unknown		Not Reported	
	Ceftriaxone For Injection (Manufacturer Unknown)			S				Not Reported	
	Meropenem (Manufacturer Unknown)			S	Unknown	Unknown		Not Reported	
	Meropenem (Manufacturer Unknown)			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14963515	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018215314			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Gluten Sensitivity; Infection; Metabolic Disorder; Systemic Lupus Erythematosus	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14964808	NON-EXPEDITED			US-TEVA-2018-US-897430			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Abdominal Pain; Diarrhoea; Nausea; Vomiting	Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	14964843	EXPEDITED (15-DAY)		DE	PHHY2018US011901		76 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cerebral Haemorrhage;	Azithromycin			S	Unknown			Novartis
Confusional State;	Ceftriaxone			S	Unknown			Not Reported
Headache; Muscular	Levofloxacin			S	Unknown			Not Reported
Weakness; Subdural	Meropenem			S	Unknown			Not Reported
Haematoma								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2018	15020739	DIRECT		HO, OT			1 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Seizure	Azithromycin 100mg/5ml Susp			S	Oral	Quantity:15 ML;		Not Reported
	15ml							
	Multi Vitamin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2018	15023570	DIRECT					2 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Gingival	Azithromycin			S	Oral			Teva
Bleeding; Pain In	Flintstone			C				Not Reported
Extremity; Stomatitis	Vitamin With Iron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14505919	NON-EXPEDITED		DS, HO, LT, OT	US-PFIZER INC-2018028237		52 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Administered; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Zithromax			S	Oral	1 Df, 1x/Day (One Tablet Once A Day)		Pfizer	
	Centrum Silver			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14967421	EXPEDITED (15-DAY)		DE	US-ORCHID HEALTHCARE-2048909		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Factor V Inhibition	Levofloxacin			S	Unknown			Orchid	
	Ceftriaxone			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14967646	EXPEDITED (15-DAY)		DE, OT	US-ZYDUS-020295		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Brain Herniation; Coagulation Time Prolonged; Condition Aggravated; Confusional State; Factor V Inhibition; Haemorrhage Intracranial; Headache; Intra-Abdominal Haematoma; Muscular Weakness; Subdural Haematoma	Levofloxacin			S	Unknown			Zydus Pharm	
	Ceftriaxone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	14969734	EXPEDITED (15-DAY)		LT, OT	IT-APOTEX-2018AP015101		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythema; Toxic Epidermal Necrolysis	Quetiapine	S	Oral	200 Mg, Daily	Apotex
	Zolpidem	S	Oral	10 Mg, Daily	Apotex
	Diazepam	S	Oral	As Necessary	Not Reported
	Rocefin	S	Parenteral	1 G/10 ML	Not Reported
	Azithromycin Dihydrate	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2018	15057035	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Choking Sensation; Constipation; Cough	Azithromycin			S		Quantity:R I - . I L;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14057860	EXPEDITED (15-DAY)		LT, OT	US-BAUSCH-BL-2017-028503		5 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Interleukin-2 Receptor Increased	Dexamethasone			S	Unknown			Valeant	
	Methotrexate			S	Unknown			Not Reported	
	Mercaptopurine			S	Unknown			Not Reported	
	Vincristine			S	Unknown	1 Dose		Not Reported	
	Azithromycin			S	Unknown	Monday, Wednesday, And Friday		Not Reported	
	Immunoglobulin (Ivig)			S	Intravenous (not otherwise specified)	2 Doses		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14971818	NON-EXPEDITED			US- ELI_LILLY_AND_COMP ANY-US201805006714		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cough; Fungal Infection;	Trulicity 0.75mg	S	Subcutaneous	0.75 Mg, Unknown	Eli Lilly And Co
Hypoacusis;	Trulicity 1.5mg	S	Subcutaneous	1.5 Mg, Unknown	Eli Lilly And Co
Nasopharyngitis;	Z-Pak	S	Unknown	Unk, Unknown	Not Reported
Temperature Intolerance	Z-Pak	S			Not Reported
	Jardiance	C		25 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972401	NON-EXPEDITED			US- FOUNDATIONCONSUM ERHC-2018-US-004673		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Back Pain; Breast Tenderness; Menstruation	Plan B One-Step (Non-Specific)			S	Oral	1.5mg		Foundation Consumer Healthcare	
Delayed; Vaginal Discharge; Vaginal Haemorrhage	Plan B One-Step (Non-Specific)			S	Oral	1.5mg		Foundation Consumer Healthcare	
	Azithromycin			S				Not Reported	
	Unspecified Vegan Protein Shake			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972735	NON-EXPEDITED			US-PFIZER INC- 2018227606			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972743	NON-EXPEDITED			US-PFIZER INC- 2018229079			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14972981	NON-EXPEDITED			US-WEST-WARD PHARMACEUTICALS		76 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

CORP.-US-H14001-18-00

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Throat; Nausea; Rash Pruritic; Urticaria	Doxycycline Hyclate			S	Oral			Hikma
	Doxycycline Hyclate			S				Hikma
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14973867	EXPEDITED (15-DAY)		HO	CZ-TEVA-2018-CZ-902267		46 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption	Azitromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14974427	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK201806164		71 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Purpura	Ropivacaine Fresenius Kabi 7.5mg/ML			S	Ophthalmic	7,5 Mg/ML Form Strength		Not Reported
	Tetracaine Thea			S	Ophthalmic			Not Reported
	Miochole			S	Ophthalmic			Not Reported
	Midazolam Mylan			S	Intravenous (not otherwise specified)	0,5 Milligram		Not Reported
	Eupressyl			S	Intravenous (not otherwise specified)			Not Reported
	Betadine			S	Ophthalmic			Not Reported
	Aprokam			S	Ophthalmic			Not Reported
	Azyter			S	Ophthalmic			Not Reported
	Aspirine			C	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Lasilix		C	Oral					Not Reported
	Tahor		C	Oral					Not Reported
	Lodoz		C						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	14974742	EXPEDITED (15-DAY)		OT	GH-PFIZER INC-2018228419			Unknown	GHA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gangrene; Pain In Extremity; Peripheral Swelling; Tenderness	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2018	15065426	DIRECT		OT			32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Anxiety; Depression; Dizziness; Hypoaesthesia; Loss Of Employment; Pain; Poisoning; Quality Of Life Decreased; Syncope; Unevaluable Event	Zithromax Azithromycin			S	Oral	Quantity:1 Capsule(S);			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14972736	NON-EXPEDITED			US-PFIZER INC-2018226694		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14977724	NON-EXPEDITED			US-TEVA-2018-US-900857			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14977949	NON-EXPEDITED			US-PFIZER INC-2018229264		70 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14978005	NON-EXPEDITED			US-PFIZER INC-2018230126		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Aubagio			C	Oral	14 Mg, Daily		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14978098	NON-EXPEDITED			US-PFIZER INC-2018229664		26 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2018	14978541	EXPEDITED (15-DAY)		LT	IT-AUROBINDO-AUR-APL-2018-028683			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Erythema; Toxic Epidermal Necrolysis	Diazepam Oral Drops Solution			S	Oral	As Necessary		Not Reported	
	Quetiapine Film-Coated Tablet			S	Oral	200 Milligram, Once A Day		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Azithromycin Film-Coated Tablets	S	Oral	Unk			Aurobindo	
		Zolpidem Film-Coated Tablet	S	Oral	10 Milligram, Once A Day			Aurobindo	
		Rocefin	S	Parenteral	()			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	14979188	EXPEDITED (15-DAY)		DE, OT	CL-PFIZER INC-2018228559		60 YR	Female	CHL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Renal Failure	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2018	15068344	DIRECT		HO			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Dyspnoea; Headache; Poisoning	Azithromycin 250 Mg Tablet			S	Oral	Quantity:6 Tablet(S);	5 DAY	Pliva	
	Generic For Zithromax			C				Not Reported	
	Levothyroxine			C				Not Reported	
	Tramadol			C				Not Reported	
	Losarten			C				Not Reported	
	Magnesium			C				Not Reported	
	Allopurinol			C				Not Reported	
	Ibuprofen			C				Not Reported	
	Kaopectate			C				Not Reported	
Imodium			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	11580790	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2015US-103237		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Azithromycin			S	Unknown	1 G, Qd (1 Gram On Day One)		Sun	
	Azithromycin			S	Unknown	500 Milligrams Daily For		Sun	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

The Next Four Days

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	13317256	EXPEDITED (15-DAY)		OT	PT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-135616		88 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Ranbaxy	
	Azithromycin			S	Unknown	Unk		Sun	
	Bisoprolol			C	Unknown	Unk		Not Reported	
	Bromazepam			C	Unknown	Unk		Not Reported	
	Pentoxifylline			C	Unknown	Unk		Not Reported	
	Triflusal			C	Unknown	Unk		Not Reported	
	Furosemide			C	Unknown	Unk		Not Reported	
	Cyamemazine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	13485041	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-139024		35 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy	Vancomycin			S	Unknown	1 G, Q3h		Not Reported	
	Azithromycin			S	Unknown	500 Mg, Bid		Sun	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Insulin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	13790297	EXPEDITED (15-DAY)		HO, OT	GB-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017R1-146082		69 YR	Male	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Cholestatic	Azithromycin			S	Unknown	500 Mg, Qd		Sun	
	Azithromycin			S				Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	13795553	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017US-135049		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug-Induced Liver Injury	Azithromycin			S	Oral	Unk		Sun	
	Salbutamol			C	Unknown	Unk, Prn		Not Reported	
	Dextromethorphan, Promethazine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14333306	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2017RR-158131		48 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fixed Eruption	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14465478	EXPEDITED (15-DAY)		HO, OT	TW-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-161746		30 YR	Female	TWN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Exposure During Pregnancy	Azithromycin			S	Unknown	500 Mg, Loading Dose		Sun	
	Azithromycin			S	Unknown	250 Mg, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14679224	NON-EXPEDITED			US-PFIZER INC-			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2018121281

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14982402	EXPEDITED (15-DAY)		DE, OT	GR-BAUSCH-BL-2018-015939		65 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Death; Hepatic Cirrhosis	Doxycycline Monohydrate			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported	
	Piperacillin, Tazobactam			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14982494	NON-EXPEDITED			US-PFIZER INC-2018231827		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Pregabalin			S		Unk		Pfizer	
	Pantoprazole			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Amitriptyline			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14983624	EXPEDITED (15-DAY)		OT	MY-PFIZER INC-2018229241		2 YR	Unknown	MYS

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis Bacterial; Treatment Failure	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14985149	EXPEDITED (15-DAY)		HO	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018014156			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Aripiprazole Tablet			S	Oral	210 Milligram, Total		Macleods	
	Escitalopram Tablet			S	Oral	140 Milligram, Total, Abuse / Misuse		Macleods	
	Alprazolam			S	Oral	15 Milliliter, Total		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Milligram, Total, 25 Mg Covered Tablets, Abuse / Misuse		Not Reported	
	Zitromax			S	Oral	1500 Milligram, Total, 500 Mg Coated Tablets With Film		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14985245	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR- 903558		42 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling	Azimed			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2018	14985577	EXPEDITED (15-DAY)		DE, OT	US-TEVA-2018-US- 900731		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Brain	Ceftriaxone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Herniation; Factor V Inhibition; Haemorrhage Intracranial; Subdural Haematoma	Meropenem	S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985747	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2018M1037664		50 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chest Discomfort	Azithromycin			S				Not Reported	
	Omeprazole			C		2 Df, Qd		Mylan	
	Atrovent			C	Respiratory (inhalation)	2 Puffs Up To Four Times A Day		Mylan	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985836	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1037953		14 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Muscle Swelling	Azithromycin			S	Oral	500 Mg, Unk		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Jun-2018	14985940	EXPEDITED (15-DAY)		OT	PHHY2018BE017192		10 YR	Female	BEL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Pallor	Azithromycin			S	Oral	1 Df Total		Novartis	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jun-2018	14328277	NON-EXPEDITED			US-PFIZER INC-2017548796		59 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Celecoxib			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S		Unk			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14989265	EXPEDITED (15-DAY)		OT	AU-NAPPMUNDI-GBR-2018-0056520		67 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower;	Oxycodone Hydrochloride			S	Oral	5 Mg, Qid		Purdue	
Abdominal Pain Upper;	Targin			S	Oral	1 Df, Bid [Strength 10/5 Mg]		Purdue	
Anaemia; Anisocytosis;									
Arrhythmia; Atrial	Allopurinol			S	Oral	300 Mg, Daily		Not Reported	
Fibrillation; Chronic Kidney	Augmentin /00756801/			S	Unknown			Not Reported	
Disease; Chronic									
Myelomonocytic	Azithromycin			S	Unknown			Not Reported	
Leukaemia; Decubitus	Ceftriaxone			S	Unknown			Not Reported	
Ulcer; Deep Vein	Coloxyl With Senna			S	Oral	2 Df, Bid		Not Reported	
Thrombosis; Diarrhoea;	Duodart			S	Oral	1 Df, Daily [Strength 0.5/0.4 Mg]		Not Reported	
Duodenitis; Dysplasia;									
Dyspnoea Exertional;	Enoxaparin			S	Subcutaneous	120 Mg, Daily		Not Reported	
Early Satiety; Fluid	Frusemide /00032601/			S	Oral	80 Mg, Daily		Not Reported	
Overload; Leukostasis									
Syndrome; Macrocytosis;	Hydroxyurea			S	Oral	1.5 G, Daily		Not Reported	
Mastocytosis;	Magmin			S	Oral	2 Df, Tid		Not Reported	
Monocytosis; Obstruction	Metoprolol			S	Unknown	25 Mg, Bid		Not Reported	
Gastric; Pleural Effusion;	Progout			S	Unknown			Not Reported	
Pleurisy; Pulmonary	Roxithromycin			S	Unknown			Not Reported	
Oedema; Renal	Spirolactone			S	Oral	25 Mg, Bid		Not Reported	
Impairment; Respiratory	Tazocin			S	Unknown			Not Reported	
Failure; Splenic Infarction;	Movicol /01625101/			C	Unknown			Not Reported	
Splenomegaly;									
Tachypnoea;	Vitamin K Nos			C	Unknown			Not Reported	
Thrombocytopenia;									
Tumour Lysis Syndrome;									
Ventricular Tachycardia;									
Vomiting; Weight									
Decreased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14991454	NON-EXPEDITED			US-GLAXOSMITHKLINE-			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

US2018GSK099225

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Nucala Powder For Injection			S		100 Mg, Unk		Glaxosmithkline
	Zithromax			S				Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14991916	NON-EXPEDITED			US-AKRON, INC.-2049190			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation; Eye Pain; Instillation Site Pain; Instillation Site Pain; Vision Blurred	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jun-2018	14992274	EXPEDITED (15-DAY)		HO	DE-TEVA-2018-DE-903126		68 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2018	14993324	EXPEDITED (15-DAY)		HO	PHHY2018US015030		38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Oedema	Azithromycin			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14616443	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS		74 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

INC.-2018-00730

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper; Dehydration; Diarrhoea; Nausea	Azithromycin Tablets Usp, 250 Mg			S	Oral	Took Two 250mg Tablets Around Noon		Lupin	
	Azithromycin Tablets Usp, 250 Mg			S				Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14675027	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-015537		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Granuloma; Hepatitis; Hepatomegaly; Jaundice; Myalgia; Skin Abrasion; Vanishing Bile Duct Syndrome	Azithromycin			S	Unknown	()		Aurobindo	
	Azithromycin			S		()		Aurobindo	
	Nevirapine			S				Aurobindo	
	Trimethoprim+Sulfamethoxazole			S	Unknown	()		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14993584	NON-EXPEDITED			US-TEVA-2018-US- 902075			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994316	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-03173		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin Tablets Usp, 250 Mg			S	Oral	2 Df, Qd		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994317	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02931			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Product Prescribing Error	Azithromycin Tablets Usp, 250 Mg			S	Unknown	2 Df, Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994318	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-01533			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin Tablets			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994319	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02482			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Limb Injury; Product Package Associated Injury; Product Packaging Issue	Azithromycin Tablets			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994320	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-03175		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Headache	Azithromycin Tablets Usp, 250 Mg			S	Oral	2 Df, Qd (500 Mg)		Lupin	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994321	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02721			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Erythema	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994322	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02845		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Feeling Abnormal; Lymphadenopathy; Night Sweats	Azithromycin Tablets			S	Oral	Unk, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994323	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-01777			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994324	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-03379		88 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin Tablets Usp, 250 Mg			S	Oral	500 Mgx1d, 250 Mgx4d (Instructions To Take 2 On Day 1, Then 1 Tab On Days 2-5)		Lupin	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994325	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02892			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Malaise	Azithromycin Tablets			S	Unknown	Unknown		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994326	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-01774		82 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Extra Dose Administered	Azithromycin Tablets			S	Oral	Took Two Tablets Of 250 Mg Together		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994327	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02280		72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S	Unknown	Unk		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994328	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-03174		61 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Anosmia	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994336	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-03050		69 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Gingival Disorder; Gingival Pain	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Bid (500 Mg On Day One)		Lupin	
	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Single		Lupin	
	Multivitamin /00097801/			C	Oral	Unk (Daily)		Not Reported	
	Magnesium /00082501/			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994337	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-01476		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
	Oseltamivir			C	Oral	75 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994338	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-03810			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin Tablets			S	Unknown	Unknown		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14994339	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-02406		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
	Medrol Dosepak			C	Oral	Unk Unk, Prn		Not Reported	
	Promethazine			C	Oral	Unk Unk, Prn		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994763	NON-EXPEDITED			US-PFIZER INC-2018233836			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994797	NON-EXPEDITED			US-PFIZER INC-2018235990		74 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14994919	NON-EXPEDITED			US-PFIZER INC-2018237997		65 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jun-2018	14995582	EXPEDITED (15-DAY)		DE	MY-PFIZER INC-2018235501		19 YR	Male	MYS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Meropenem			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cloxacillin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Normal Saline	C		Unk (At A Rate Of 20ml/Kg Bolus)	Not Reported
Oseltamivir	C		Unk	Not Reported
Oseltamivir	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	14997204	NON-EXPEDITED			US-TEVA-2018-US-903633			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dosage Administered; Rash	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2018	15103241	DIRECT					74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Erythema; Feeling Hot; Flushing; Incorrect Dose Administered; Swelling Face	Methylprednisolone Tablets, Usp 4 Mg (Generic For Medrol)			S	Oral	Quantity:21 Df Dosage Form;	6 DAY	Sandoz	
	Azithromycin 250 Mg Tablet (Generic For Zithromax)			S	Oral	Quantity:1 Df Dosage Form;	6 DAY	Teva	
	Azelastine Nasal Spray			C				Not Reported	
	Raloxifene			C				Not Reported	
	Multivitamin			C				Not Reported	
	Calcium-Vitamin D			C				Not Reported	
	Omega-3			C				Not Reported	
	Aspirin			C				Not Reported	
	Diphenhydramine			C				Not Reported	
	Loperamide			C				Not Reported	
	Biotin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14465810	EXPEDITED (15-DAY)		HO, OT	US-CIPLA LTD.-2018US02399			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alternaria Infection; Diffuse Large B-Cell Lymphoma Refractory; Distributive Shock; Mental Status Changes; Phaeohyphomycosis; Pneumonia Moraxella; Respiratory Failure; Thrombosis	Carboplatin			S	Unknown	Unk, Cycle 1		Cipla
	Etoposide			S	Unknown	Unk, Cycle 1		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Cefepime			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Ifosfamide			S	Unknown	Unk, Cycle 1		Not Reported
	Rituximab			S	Unknown	Unk, Cycle 1		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14609962	EXPEDITED (15-DAY)		LT	CN-PFIZER INC- 2018087811		3 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Breath Sounds Abnormal; Drug Hypersensitivity; Hyperhidrosis; Irregular Breathing; Pallor; Product Use Issue; Rales	Azithromycin			S	Intravenous drip	140 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14959070	EXPEDITED (15-DAY)		HO	TR-IGSA-SR10006425			Male	TUR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Skin Mass; Tissue Infiltration	Gamunex-C			S	Subcutaneous	10 G, Q.Wk.		Grifols
	Gamunex-C			S	Subcutaneous	Unk		Grifols
	Gamunex-C			S	Subcutaneous	Unk		Grifols
	Azitro			S	Oral	500 Mg, Q.Wk.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	14999526	EXPEDITED (15-DAY)		DE, OT	GR-AXELLIA-001726		65 YR	Male	GRC

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Death; Hepatic Cirrhosis	Vancomycin			S				Xellia Pharmaceuticals
	Azithromycin			S				Not Reported
	Doxycycline			S				Not Reported
	Sulfamethoxazole/Trimethoprim			S				Not Reported
	Piperacillin Sodium/Tazobactam			S				Not Reported
	Sodium							
	Meropenem/Meropenem Trihydrate			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15001274	EXPEDITED (15-DAY)		OT	GB-PERRIGO-18GB006135			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Arthropathy; Blood Creatinine Increased; Blood Urea Increased; Drug Interaction; Dyspepsia; Hypophagia; Influenza Like Illness; Polyarthritis; Vomiting; Weight Decreased	Ibuprofen			S	Oral	Unk		Perrigo
	Ibuprofen			S				Perrigo
	Azithromycin			S	Unknown	Unknown		Not Reported
	Tobramycin			S	Intravenous (not otherwise specified)	8mg/Kg/Day = 120mg Tds		Not Reported
	Colomycin /00013203/			S	Intravenous (not otherwise specified)	2 Million lu, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15001468	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-904803		49 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Papular	Azithromycin			S	Oral			Not Reported
	Claforan			S				Not Reported
	Rocephine			S				Not Reported
	Bisoce			C	Oral	3.75 Milligram Daily;		Not Reported
	Oracilline			C	Oral	2000000 lu (International Unit) Daily;		Not Reported
	Mag 2			C	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Noxafil	C	Oral	200 Milligram Daily;	Not Reported
Alprazolam	C	Oral		Not Reported
Cortancyl	C		10 Milligram Daily;	Not Reported
Calcium Vitamine D3 Calcimed	C	Oral		Not Reported
Pantoprazole	C	Oral	20 Milligram Daily;	Not Reported
Movicol	C	Unknown		Not Reported
10wellvone	C	Oral	10 MI Daily;	Not Reported
Valaciclovir	C		1000 Milligram Daily;	Not Reported
Neoral	C	Oral	250 Milligram Daily;	Not Reported
Ramipril	C		2.5 Milligram Daily;	Not Reported
Entocort	C	Oral	3 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15001597	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2018232432			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Pneumonia	Zithromac			S	Oral	2 Tablets, Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2018	15002580	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1039191		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Weight Increased	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	11918001	EXPEDITED (15-DAY)		OT	PHHY2016IT001960		43 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hepatotoxicity	Azithromycin			S	Unknown			Novartis
	Voriconazole			S	Intravenous (not otherwise specified)	450 Mg, Bid		Not Reported
	Voriconazole			S	Intravenous (not otherwise specified)	300 Mg, Bid		Not Reported
	Voriconazole			S	Oral	250 Mg, Bid		Not Reported
	Voriconazole			S	Oral	200 Mg, Bid		Not Reported
	Voriconazole			S	Oral	100 Mg, Bid		Not Reported
	Haloperidol			S	Oral	1 Mg, Tid		Not Reported
	Delorazepam			S	Oral	1 Mg, Qd		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Tramadol			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Raltegravir			S	Unknown			Not Reported
	Emtricitabine W/Tenofovir			S	Unknown			Not Reported
	Atovaquone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14685193	EXPEDITED (15-DAY)		OT	US-DRREDDYS- USA/USA/18/0097009		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Tacrolimus			S	Unknown			Not Reported
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Not Reported
	Prochlorperazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Sulfamethoxazole/Trimethoprim			C	Unknown			Not Reported
	Levalbuterol			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14687211	EXPEDITED (15-DAY)		OT	US-DRREDDYS- USA/USA/18/0097010		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Tacrolimus			S	Unknown			Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Sulfamethoxazole/Trimethoprim			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14836609	NON-EXPEDITED			US-PFIZER INC- 2018177231			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	14919564	NON-EXPEDITED			US-PFIZER INC- 2018202948		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Malaise; Nausea	Azithromycin			S		2 Pills On Day 1 And Then 1 Pill Daily For 4 More Days		Pfizer	
	Azithromycin			S		2 Pills On Day 1 And Then 1 Pill Daily For 4 More Days		Pfizer	
	Benadryl			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15003270	EXPEDITED (15-DAY)		OT	PHHY2018ZA018395		36 YR	Male	ZAF

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Carditis; Depression; Dyslipidaemia; Renal Impairment; Rheumatic Fever	Minocycline			S	Unknown	60 Mg, Qd		Novartis
	Azithromycin			S	Unknown	75 Mg, Qd		Not Reported
	Methotrexate Sodium			S	Unknown	25 Mg, Qw		Not Reported
	Chloroquine			S	Unknown	200 Mg, Qd		Not Reported
	Arava			S	Unknown	20 Mg, Qd		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15003490	EXPEDITED (15-DAY)		DE, OT	DE-TEVA-2018-DE-904975		82 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiopulmonary Failure; Drug Interaction	Cabergolin Teva 0.5mg			S	Oral	1x/Woche Sonntag		Ivax
	Cabergolin Teva 0.5mg			S	Parenteral			Ivax
	Azithromycin Dr. Eberth 500 Mgpowder For The Production Of A Infusions			S	Intravenous (not otherwise specified)			Not Reported
	L-Thyrox Hexal 100			C	Unknown	100 Microgram Daily; 1-0-0		Not Reported
	Amitriptylin			C	Oral	25 Milligram Daily; 0-0-1		Not Reported
	Optrex			C	Unknown			Not Reported
	Xarelto			C		20 Milligram Daily; 0-1-0 17.30 Uhr		Not Reported
	Emselex			C	Unknown	7.5 Milligram Daily; 1-0-0		Not Reported
	Saline For Inhalation			C		If Necessary		Not Reported
	Unacid (Sultamicillin Tosilate)			C	Intravenous (not otherwise specified)			Not Reported
	Pantoprazol Tad 40mg			C	Unknown	40 Milligram Daily; 1-0-0		Not Reported
	Ibuprofen			C	Oral	If Necessary		Not Reported
	Bisoprolol			C	Unknown	1-0-0		Not Reported
	Furosemid-Ratiopharm 40			C	Unknown	40 Milligram Daily; 1-0-0		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Promethazin-Neuraxpharm 25	C	Unknown	25 Milligram Daily; 0-0-1	Not Reported
Atrovent	C	Unknown	If Necessary	Not Reported
Hylo-Comod Eye Drops	C	Unknown		Not Reported
Relvar Ellipta 180 Ug/22ug Inhalationspulver	C	Unknown	1 Dosage Forms Daily; 1-0-0	Not Reported
Ramipril	C	Unknown	2.5 Milligram Daily; 1-0-0	Not Reported
Simvastatin-Ratiopharm 40 Mg	C		20 Milligram Daily; 0-0-1/2	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15004134	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-175651		21 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sopor	Aripiprazole			S	Oral	In Total		Not Reported
	Zitromax 500 Mg Compresse			S	Oral	In Total		Not Reported
	Rivestite Con Film							
	Prozin 25 Mg Compresse			S	Oral	In Total		Not Reported
	Rivestite							
	Escitalopram			S	Oral	In Total		Not Reported
	Alprazolam			S	Oral	In Total		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2018	15004223	NON-EXPEDITED			US-PFIZER INC- 2018237243			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Lipitor			S	Unknown	Unk		Pfizer
	Azithromycin			S	Unknown	Unk		Pfizer
	Doxycycline Monohydrate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15010586	NON-EXPEDITED			US-PFIZER INC- 2018241593			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2018	15127158	DIRECT		OT			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tooth Fracture	Zithromax			S	Oral	Quantity:6 Tablet(S);	5 DAY	Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	13378098	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2017SE31615		21 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Pulmicort			S	Respiratory (inhalation)			Astrazeneca	
	Terbutaline Sulfate			S	Respiratory (inhalation)			Not Reported	
	Hydrocortisone			S	Oral	Non-Az Product		Not Reported	
	Alprazolam			S	Oral			Not Reported	
	Hizentra			S	Subcutaneous			Not Reported	
	Ventoline			S	Respiratory (inhalation)			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Bactrim			S	Oral			Not Reported	
	Calcium Folate			S	Oral			Not Reported	
	Neoral			S	Oral			Not Reported	
	Oracilline			S	Oral			Not Reported	
	Pantoprazole			S	Oral			Not Reported	
	Seresta			S	Oral			Not Reported	
	Vfend			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zelitrex			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014260	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-907543		10 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250 Milligram Daily; 250 Mg Dia			Not Reported
	Salbutamol (2297a)			C	Respiratory (inhalation)	2-2-2			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15014632	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-904404			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia; Reaction To Excipient	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016217	NON-EXPEDITED			US-PFIZER INC-2018243381		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Skin Irritation	Zithromax			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016510	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1041101		30 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	2 G			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15016786	EXPEDITED (15-DAY)		OT	BE-PFIZER INC-2018242082			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Renal Failure	Azithromycin			S		500 Mg, Unk		Pfizer	
	Tildiem			S		60 Mg, Unk		Not Reported	
	Crestor			S		Unk		Not Reported	
	Itraconazole			S		100 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2018	15018430	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2049505			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Azithromycin Tablets			S				Wockhardt	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jun-2018	15135212	DIRECT		OT			61 YR	Female	ALA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Haemorrhagic	Azithromycin Tablets Usp			S	Oral	Quantity:2 Tablet(S);		Teva	
	Aspirin 81 Mg			C				Not Reported	
	Bone Strength Calcium Supplement			C				Not Reported	
	Vitamin D3			C				Not Reported	
	K2			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	14623007	EXPEDITED (15-DAY)		HO	PHHY2018PL032688		2 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Auscultation; Blood Lactate	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dehydrogenase
Increased; Cough; Drug
Ineffective; Dry Mouth;
Electrolyte Imbalance;
Hyponatraemia; Mucosal
Dryness; Pneumonitis;
Pyrexia; Renal Failure;
Streptococcus Test
Positive

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	14781290	EXPEDITED (15-DAY)		OT	US-GILEAD-2018-0328903		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Hernia;	Idelalisib			S	Oral	150 Mg, Bid		Gilead
Abdominal Pain Upper;	Idelalisib			S				Gilead
Abdominal Pain Upper;	Idelalisib			S				Gilead
Chromaturia; Cough; Ear	Azithromycin			S	Oral	By Mouth For Five Days		Not Reported
Infection; Fungal	Vitamin B			C		Unknown		Not Reported
Oesophagitis; Gastritis;	Rituxan			C	Intravenous (not	Unk		Not Reported
Gastroenteritis Viral;					otherwise specified)			
Gastrooesophageal Reflux	Rituxan			C		Unknown		Not Reported
Disease; Immune System								
Disorder; Lower								
Respiratory Tract								
Infection; Nasopharyngitis;								
White Blood Cell Count								
Abnormal								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15020320	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-175871		36 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Blood Bilirubin	Azithromycin			S	Oral	500 Mg, Unk		Sun
Increased; Blood Lactate	Paracetamol			C	Oral	1 G, Unk		Not Reported
Dehydrogenase	Omeprazole			C	Oral	20 Mg, Unk		Not Reported
Increased; Chills;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Haemoglobin
Decreased; Haemolytic
Anaemia; Hepatocellular
Injury; Jaundice

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15022685	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018246112		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Inflammation; Proctalgia; Skin Candida	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2018	15026756	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-175846		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Decreased Appetite; Dysgeusia; Haemoptysis	Azithromycin			S	Oral	250 Mg, Daily		Sun	
	Arikayce (Atu)			S	Respiratory (inhalation)	Unk		Not Reported	
	Lamprene, Capsule Molle			S	Oral	100 Mg, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	13369326	EXPEDITED (15-DAY)		HO	FR- GLAXOSMITHKLINE- FR2017GSK039722		21 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Zelitrex			S	Oral	Unk		Glaxosmithkline	
	Ventoline			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Pantoprazole			S	Oral	Unk		Glaxosmithkline	
	Hydrocortisone			S	Oral	Unk		Glaxosmithkline	
	Seresta			S	Oral	Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neoral	S	Oral	Unk	Glaxosmithkline
Bactrim	S	Oral	Unk	Glaxosmithkline
Folinoral	S	Oral	Unk	Glaxosmithkline
Oracilline	S	Oral	Unk	Glaxosmithkline
Azithromycine	S	Oral	Unk	Glaxosmithkline
Pulmicort	S	Respiratory (inhalation)	Unk	Glaxosmithkline
Hizentra	S	Subcutaneous	Unk	Not Reported
Alprazolam	S	Oral	Unk	Not Reported
Vfend	S	Oral	Unk	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14573338	EXPEDITED (15-DAY)		LT	PT-PFIZER INC-2018078203		57 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14951669	EXPEDITED (15-DAY)		DE, OT	GR-PFIZER INC-2018215627		65 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Death; Hepatic Cirrhosis	Azithromycin			S		Unk		Pfizer	
	Doxycycline Monohydrate			S		Unk		Pfizer	
	Piperacillin/Tazobactam			S		Unk		Unknown	
	Vancomycin Hcl			S		Unk		Pfizer	
	Trimethoprim Sulfamethoxazole			S		Unk		Not Reported	
	Meropenem			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	14981366	EXPEDITED (15-DAY)		HO	IT-OTSUKA-2018_013993		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Intentional Self-Injury; Partner Stress; Prescribed Overdose; Product Administration Error; Product Use In Unapproved Indication; Sopor	Aripiprazole			S	Oral	210 Mg, Unk		Otsuka	
	Zitromax			S	Oral	1500 Mg, Unk		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Mg, Unk		Not Reported	
	Escitalopram Oxalate			S	Oral	140 Mg, Unk		Not Reported	
	Alprazolam			S	Oral	15 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15027800	NON-EXPEDITED			US-PFIZER INC-2018247102			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Stadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15027810	NON-EXPEDITED			US-PFIZER INC-2018249081		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15028101	NON-EXPEDITED			US-TEVA-2018-US-907737		3 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression	Azithromycin			S	Unknown	Dose Strength: 200 Mg/5		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

MI

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15028117	NON-EXPEDITED			US-PFIZER INC-2018246661			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; Therapeutic Product Effect Incomplete	Azithromycin			S		250 Mg, Unk (For 5 Days)		Pfizer	
	Azithromycin			S		250 Mg, Unk (For 14 Days)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15028118	NON-EXPEDITED			US-PFIZER INC-2018247380		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Phosphate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Vicodin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15028604	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-911682		85 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bronchospasm; Rash	Azithromycina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15028630	EXPEDITED (15-DAY)		OT	HR-TEVA-2018-HR-909874		28 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Ocular Hyperaemia; Oral Mucosal Erythema	Sumamed			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15029310	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2018M1040140		57 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Haemoptysis; Necrosis; Nocardiosis; Pleural Effusion; Pneumonia; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoxicillin/Potassium Clavulanate			S	Unknown	Unk		Not Reported	
	Amoxicillin/Potassium Clavulanate			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030044	NON-EXPEDITED			US-AKRON, INC.-2049634			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Pain; Ocular Hyperaemia	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030159	NON-EXPEDITED			US-AKRON, INC.-2049635			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030175	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1040174		60 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Dyspnoea; Productive Cough; Rhinorrhoea; Sputum Retention; Wheezing	Erdosteine			S	Unknown	Unk		Not Reported	
	Fluticasone Propionate/Salmeterol Xinafoate			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fluticasone	S	Nasal	Unk	Mylan
Lansoprazole	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030214	EXPEDITED (15-DAY)		DE	BY-PFIZER INC-2018243650		91 DAY	Female	BLR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Linezolid			S		30 Mg/Kg, Daily		Pfizer
	Meropenem			S	Intravenous (not otherwise specified)	60 Mg/Kg, 3x/Day		Pfizer
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg, 1x/Day		Not Reported
	Clarithromycin			S		15 Mg/Kg, Daily (In 2 Divided Doses)		Not Reported
	Oseltamivir			S		6 Mg/Kg, Daily		Not Reported
	Ganciclovir			S	Intravenous drip	10 Mg/Kg, 2x/Day		Not Reported
	Octagam			S	Intravenous drip	Unk (0.4g/Kg)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030246	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018242998		12 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Asthenia; Vomiting; Weight Decreased	Novatrex			S	Oral	Variable Over The Period		Pfizer
	Prednisolone			S	Intrathecal	15 Mg/Treatment		Not Reported
	Cytarabine Kabi			S	Intrathecal	30 Mg/Treatment		Not Reported
	Methotrexate Mylan			S	Intrathecal	12 Mg/Treatment		Not Reported
	Purinethol			S	Oral	Variable Over The Period		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030663	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018246391		60 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Arterial Hypertension	Zithromax			S	Oral	250 Mg, Alternate Day		Pfizer	
	Sprycel			S	Oral	1 Df, 1x/Day		Not Reported	
	Ultibro Breezhaler			S	Respiratory (inhalation)	1 Dose Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15030752	NON-EXPEDITED			US-AKRON, INC.-2049642			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eyelid Margin Crusting	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15031240	NON-EXPEDITED			US-AKRON, INC.-2049645			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2018	15032246	NON-EXPEDITED		OT	US-TEVA-2018-US-910383		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; Weight Increased	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	14709254	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1019656		80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pneumonia	Azithromycin	S	Oral	3.5 Mg, Cycle	Not Reported
	Digox /00017701/	C		Unk	Mylan
	Pepcid /00706001/	C		Unk	Mylan
	Proscar	C		Unk	Mylan
	Mevacor	C		Unk	Mylan
	Lopressor	C		Unk	Mylan
	Zolof	C		Unk	Mylan
	Zocor	C		Unk	Mylan
	Multivitamins /00116001/	C		Unk	Mylan
	Diovan	C		Unk	Mylan
	Coumadin	C		Unk	Mylan
	Claritin /00413701/	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	14778473	NON-EXPEDITED			US-PFIZER INC-2018160505		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Anosmia	Zithromax			S		Unk (Prescribed On The Package For 5 Days)		Pfizer
	Armour Thyroid			C		Unk (30)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15034497	EXPEDITED (15-DAY)		HO	FR-MACLEODS PHARMACEUTICALS US LTD-MAC2018014300			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Myoclonus; Paraesthesia	Pantoprazole			S	Oral	Unk, Non Communique		Macleods
	Azithromycin			S	Oral	Unk		Not Reported
	Ventoline			S	Respiratory (inhalation)	Unk, Non Communique		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactrim	S	Oral	Unk	Not Reported
Folinoral	S	Oral	Unk	Not Reported
Terbutaline Sulfate	S	Respiratory (inhalation)	Unk	Not Reported
Oracilline	S	Oral	Unk	Not Reported
Neoral	S	Oral	Unk	Not Reported
Vfend	S	Oral	Unk	Not Reported
Hizentra	S	Subcutaneous	Unk	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Alprazolam	S	Oral	Unk	Not Reported
Zelitrex	S	Oral	Unk	Not Reported
Seresta	S	Oral	Unk	Not Reported
Pulmicort	S	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15035062	NON-EXPEDITED			US-PFIZER INC-2018248854		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15035444	NON-EXPEDITED			US-PFIZER INC-2018248874		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lorcet 10/650			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15035447	NON-EXPEDITED			US-PFIZER INC-2018249187		77 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Lyrica			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Skelaxin			S		Unk		Pfizer	
	Hydroxychloroquine			S		Unk		Not Reported	
	Robaxin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	
	Allegra			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15035739	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018245718		85 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bronchospasm; Rash	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15035754	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2018248271		58 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Product Use Issue; Suicidal Ideation	Azithromycin			S	Other	250 Mg, 1x/Day On Monday/Wednesday/Friday		Pfizer	
	Salbutamol Novoliz			C	Respiratory (inhalation)	100 Ug, As Needed (5-10 Times Per Week)		Not Reported	
	Spiriva			C	Other	5 Ug, 1x/Day		Not Reported	
	Omeprazol			C		20 Mg, 1x/Day		Not Reported	
	Flutiform			C	Other	2 Df, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15035922	EXPEDITED (15-DAY)		DE	IN-009507513-1806IND006169		51 YR	Male	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Imipenem (+) Cilastatin Sodium			S		Unk		Merck	
	Caspofungin Acetate			S		Unk		Merck	
	Azithromycin			S		Unk		Not Reported	
	Doxycycline			S		Unk		Not Reported	
	Oseltamivir			S		Unk		Not Reported	
	Meropenem			S		Unk		Not Reported	
	Teicoplanin			S		Unk		Not Reported	
	Sulfamethoxazole (+) Trimethoprim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2018	15037583	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1043235		47 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Melaena; Nausea	Azithromycin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	14687850	EXPEDITED (15-DAY)		HO, OT	PHHY2017CA174027		40 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchospasm;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported	
Bronchospasm; Candida Infection; Cerebrovascular Accident; Dyspnoea;	Xolair			S	Subcutaneous	Unk		Not Reported	
Dyspnoea; Heart Rate Increased; Hemiplegia;	Xolair			S	Subcutaneous	Unk		Not Reported	
Inappropriate Schedule Of	Xolair			S	Subcutaneous	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Administration;	Xolair	S	Subcutaneous	Unk	Not Reported
Oxygen Saturation	Xolair	S	Subcutaneous	Unk	Not Reported
Decreased; Peritonsillar	Xolair	S	Subcutaneous	Unk	Not Reported
Abscess; Pharyngeal	Xolair	S	Subcutaneous	Unk	Not Reported
Inflammation; Pilonidal	Xolair	S	Subcutaneous	Unk	Not Reported
Cyst; Postoperative	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Wound Complication;	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Productive Cough;	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Productive Cough;	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Pulmonary Pain;	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Pulmonary Pain;	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Respiratory Rate	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Increased; Rhonchi;	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Therapy Partial	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
Responder; Wheezing	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
	Azithromycin	S	Unknown		Novartis
	Potassium Acetate	S	Unknown		Not Reported
	Zenhale	C	Respiratory (inhalation)	3 Df, Bid	Not Reported
	Zenhale	C	Respiratory (inhalation)	8 Inhalations A Day	Not Reported
	Spiriva	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
	Singulair	C	Oral	1 Df, Qd	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Ventolin	C	Unknown	Unk	Not Reported
	Ventolin	C	Respiratory (inhalation)	2-3 Inhalations A Day	Not Reported
	Levaquin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15037418	NON-EXPEDITED			US-PFIZER INC-2018246858			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S		For 5 Days		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042184	NON-EXPEDITED			US-PFIZER INC-2018252387		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042431	EXPEDITED (15-DAY)		HO	PHHO2016US015690		2 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pseudomonas Infection	Blinded Azithromycin			S	Respiratory (inhalation)	Code Not Broken		Not Reported	
	Blinded No Treatment Received			S	Respiratory (inhalation)	Code Not Broken		Not Reported	
	Blinded Placebo			S	Respiratory (inhalation)	Code Not Broken		Not Reported	
	Tobi			S	Respiratory (inhalation)	300 Mg, Bid		Not Reported	
	Albuterol			C	Respiratory (inhalation)	2 Df (Puff), Bid		Not Reported	
	Zyrtec			C	Oral	5 Ml, Prn		Not Reported	
	Zenpep			C	Oral	1 Df (5000) (Capsule), With Meals		Not Reported	
	Zenpep			C	Oral	1 Df (10000) (Capsule), With Meals And Snacks		Not Reported	
	Miralax			C	Oral	As Needed		Not Reported	
	Salt			C	Oral	1/8 Tsp, Once Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042540	EXPEDITED (15-DAY)		DE, OT	PHHY2018PT021622		56 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Haemoptysis	Amoxicillin Sodium+Potassium	S	Unknown	Novartis
	Clavulanate	S	Unknown	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15042829	NON-EXPEDITED			US-TEVA-2018-US-909282		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15043719	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1041449		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thoracic Cavity Drainage Test Abnormal	Azithromycin			S	Unknown	Unk			Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15044012	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2018GSK107901			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Product Prescribing Error; Product Use Issue	Seretide			S		1 Df, Bid			Glaxosmithkline
	Seretide			S					Glaxosmithkline
	Seretide			S					Glaxosmithkline
	Clenil			S	Respiratory (inhalation)	2 Df, Bid			Glaxosmithkline
	Clenil			S					Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	4 Df, Qid			Glaxosmithkline
	Salbutamol			S					Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisolone	S	Respiratory (inhalation)	3 MI, Bid	Glaxosmithkline
Prednisolone Singulair	S	Respiratory (inhalation)	1 Df, Qd	Glaxosmithkline Glaxosmithkline
Singulair Symbicort	S		2 Df, Bid	Glaxosmithkline Not Reported
Symbicort Montelair	S	Respiratory (inhalation)	1 Df, Qd	Not Reported Not Reported
Montelair Azitromicin	S	Respiratory (inhalation)	13.5 MI, Qd	Not Reported Not Reported
Azitromicin	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15044191	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2018M1041570		10 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Pallor	Azithromycin			S	Oral	1 Df, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2018	15167619	DIRECT		OT			62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Vomiting	Zithromax			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	14752322	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2018-002310		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Balance Disorder; Deafness; Infection; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Muscle Twitching; Tinnitus	Orkambi Tobramycin Azithromycin	S S S	Oral Unknown Unknown	2 Dosage Form, Bid	Vertex Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15047942	EXPEDITED (15-DAY)		OT	CA-BAXTER- 2018BAX017516			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Procytox (Cyclophosphamide)			S	Unknown			Baxter
	2000mg/Vial							
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Xeljanz			S	Oral			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Arava			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Celebrex			S	Oral			Not Reported
	Levofloxacin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Imuran			S	Unknown			Not Reported
	Cimzia			S	Unknown			Not Reported
	Humira			S	Unknown			Not Reported
	Simponi			S	Unknown			Not Reported
	Demerol			S	Unknown			Not Reported
	Benadryl			S	Unknown			Not Reported
	Ezetrol			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15048200	NON-EXPEDITED			US-TEVA-2018-US-897935			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Product Prescribing Error	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15049749	EXPEDITED (15-DAY)		OT	PHHY2018PT021578		60 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Respiratory Failure	Piperacillin+Tazobactam			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2018	15053834	NON-EXPEDITED			US-PFIZER INC-2018253335			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	14950945	EXPEDITED (15-DAY)		OT	US-GILEAD-2018-0341131		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Nausea; Pneumonia	Ambrisentan			S	Unknown	10 Mg, Qd		Gilead	
	Orenitram			S	Unknown	0.125 Mg, Tid		Not Reported	
	Digoxin			S	Unknown			Not Reported	
	Z-Pak			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	14965719	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-029034		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis; C-Reactive Protein Increased; Chills; Dermatitis; Eosinophilia; Erythema; Leukocytosis; Neutrophilia; Oedema Peripheral; Pustule; Swelling; Weight Increased	Azithromycin			S	Unknown	()		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	14971092	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1036082			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma;	Salbutamol			S		6 Puffs/Day		Not Reported	
Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Azithromycin			S		250 Milligram,Every Other Day For 3 Months		Not Reported	
	Montelukast			S		10 Mg, Qd		Not Reported	
	Levocetirizine			S		5 Mg, Qd		Not Reported	
	Salmeterol /00954702/			S		100 ?G/Day		Mylan	
	Fluticasone /00972202/			S	Nasal	55 ?G/Day		Mylan	
	Fluticasone /00972202/			S		1000 ?G/Day		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15058115	NON-EXPEDITED			US-PFIZER INC-2018254985		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Nausea; Vomiting		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15058468	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT023127		35 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Ineffective; Pulmonary Tuberculosis; Pyrexia	Azithromycin			S	Unknown	Unk			Not Reported
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15058943	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2018251665		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Sopor	Alprazolam			S	Oral	15 MI, Single (Total)			Pfizer
	Zitromax			S	Oral	1500 Mg, Total			Pfizer
	Aripiprazole			S	Oral	210 Mg, Single (Total)			Not Reported
	Prozin /00011902/			S	Oral	1200 Mg, Single (Total)			Not Reported
	Escitalopram Oxalate			S	Oral	140 Mg, Single (Total)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15060843	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2018253225			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Facial Paralysis	Zithromac 250mg			S	Oral	500 Mg, 1x/Day			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15061030	EXPEDITED (15-DAY)		LT	IT-PFIZER INC- 2018254427		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythema; Toxic Epidermal Necrolysis	Azithromycin	S	Oral	Unk	Pfizer
	Diazepam	S	Oral	20 Gtt, As Needed	Not Reported
	Rocefin	S	Parenteral	Unk	Not Reported
	Quetiapine Fumarate	S	Oral	200 Mg, 1x/Day	Not Reported
	Zolpidem Tartrate	S	Oral	10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2018	15063584	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT023184		68 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyanosis; Disorientation; Hypotension; Pneumonia Necrotising; Pneumothorax; Rales; Staphylococcal Sepsis; Tachypnoea	Azithromycin			S	Unknown	Unk		Novartis
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Piperacillin, Tazobactam			S	Unknown	Unk		Not Reported
	Linezolid			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	11432212	NON-EXPEDITED			US-PFIZER INC- 2015285918			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Dilantin			S		Unk		Pfizer
	Sumatriptan Succinate			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trileptal	S	Unk	Not Reported
Anaprox	S	Unk	Not Reported
Relafen	S	Unk	Not Reported
Pyridium	S	Unk	Not Reported
Lovastatin	S	Unk	Not Reported
Mestinon	S	Unk	Not Reported
Tegretol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	14533281	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2070222		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchospasm;	Xolair			S	Subcutaneous			Not Reported
Candida Infection;	Xolair			S	Subcutaneous			Not Reported
Cerebrovascular Accident;	Xolair			S	Subcutaneous	Unk		Not Reported
Dyspnoea; Heart Rate	Xolair			S	Subcutaneous	Unk		Not Reported
Increased; Hemiplegia;	Xolair			S	Subcutaneous	Unk		Not Reported
Inappropriate Schedule Of	Xolair			S	Subcutaneous	Unk		Not Reported
Product Administration;	Xolair			S	Subcutaneous	Unk		Not Reported
Oxygen Saturation	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Peritonsillar	Xolair			S	Subcutaneous	Unk		Not Reported
Abscess; Pharyngeal	Xolair			S	Subcutaneous	Unk		Not Reported
Inflammation; Pilonidal	Xolair			S	Subcutaneous	Unk		Not Reported
Cyst; Postoperative	Xolair			S	Subcutaneous	Unk		Not Reported
Wound Complication;	Xolair			S	Subcutaneous			Not Reported
Productive Cough;	Xolair			S	Subcutaneous			Not Reported
Pulmonary Pain;	Xolair			S	Subcutaneous			Not Reported
Respiratory Rate	Xolair			S	Subcutaneous			Not Reported
Increased; Rhonchi;	Xolair			S	Subcutaneous			Not Reported
Therapy Partial	Xolair			S	Subcutaneous			Not Reported
Responder; Wheezing	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Potassium Acetate	S	Unknown		Not Reported
Zenhale	C	Respiratory (inhalation)	3 Df, Bid	Not Reported
Zenhale	C	Respiratory (inhalation)	8 Inhalations A Day Dose Increased	Not Reported
Spiriva	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
Spiriva	C	Oral		Not Reported
Singulair	C	Oral	1 Df, Qd	Not Reported
Prednisone	C	Unknown	Unk	Not Reported
Ventolin	C	Unknown	Unk	Not Reported
Ventolin	C	Respiratory (inhalation)	2-3 Inhalations A Day	Not Reported
Levaquin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	14837051	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018175682		18 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Pruritus; Throat Irritation	Zitromax			S	Oral	500 Mg, As Needed		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	14860524	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018187438		22 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Hepatitis Acute; Hepatocellular Injury	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	14948143	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018212086		62 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Macroglossia; Palatal Oedema	Zitromax			S	Oral	1 Df, 1x/Day		Pfizer	
	Brufen			S	Oral	Unk		Not Reported	
	Colchicine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15065063	NON-EXPEDITED			US-TEVA-2018-US-913481			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Functional Gastrointestinal Disorder	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15065117	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-912912		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Decreased Appetite; Dysgeusia; Haemoptysis	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	
	Arikayce (Atu) (Amikacin)			S	Respiratory (inhalation)			Not Reported	
	Lamprene 100 Mg, Capsule Molle(Clofazimine)			S	Oral	100 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15065182	NON-EXPEDITED			US-TEVA-2018-US-912435		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Dyspnoea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2018	15066186	NON-EXPEDITED			US-TEVA-2018-US-915613		89 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dysphagia; Dyspnoea; Azithromycin S Unknown Not Reported
Therapeutic Product Effect
Incomplete

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	14757026	EXPEDITED (15-DAY)		HO	PL-PFIZER INC-2018145523		2 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Auscultation; Blood Lactate Dehydrogenase Increased; Cough; Drug Ineffective; Dry Mouth; Electrolyte Imbalance; Hypokalaemia; Hyponatraemia; Mucosal Dryness; Pneumonitis; Pyrexia; Renal Failure; Streptococcus Test Positive	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15014556	EXPEDITED (15-DAY)		OT	NL-TEVA-2018-NL-906764		58 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Suicidal Ideation	Azitromycine Tablet 250mg Tablet, 250 Mg (Milligram)			S	Unknown	Monday, Wednesday, Friday		Not Reported
	Omeprazol 20mg			C	Unknown	20 Milligram Daily; 1dd1		Not Reported
	Salbutamol 100mzg Novolizer			C	Unknown	Zn (5-10times A Week)		Not Reported
	Flutiform Da 250/10 Mcg			C	Unknown	2dd2		Not Reported
	Spiriva Respimat 2.5 Mcg			C	Unknown	5 Microgram Daily; 1dd2		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15073047	NON-EXPEDITED		OT	US-TEVA-2018-US-914107			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Platelet Count Decreased; Productive Cough; Thrombocytopenia; Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15073532	NON-EXPEDITED			US-PFIZER INC- 2018259103		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Accupril			S		Unk		Pfizer	
	Quinapril Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15074441	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2018-032556		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Amoxicillin			S	Oral	Unk		Aurobindo	
	Azithromycin			S	Oral	Unk		Aurobindo	
	Clarithromycin			S	Oral	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15076060	EXPEDITED (15-DAY)		OT	NL-MYLANLABS- 2018M1044741		47 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Condition Aggravated; Therapeutic Response Unexpected	Azithromycin			S		1x Per Dag 1		Not Reported	
	Vitamin B12			C		Unk		Mylan	
	Fluticasone Propionate			C		Unk		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15076974	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018256047		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Bilirubin Increased; Blood Lactate Dehydrogenase Increased; Chills; Dyspnoea; Haemoglobin Decreased; Haemolytic Anaemia; Hepatocellular Injury; Jaundice	Azithromycin			S	Oral	500 Mg, Unk		Pfizer	
	Paracetamol			C	Oral	1 G, Unk		Not Reported	
	Omeprazole			C	Oral	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2018	15078669	NON-EXPEDITED			PHEH2018US025610			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	14611853	EXPEDITED (15-DAY)		HO, OT	DE-TORRENT-00007890		1 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial; Product Use Issue	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Unknown	
	Dexamethasone			S	Unknown	10 Mg/M2 For 21 Days Then Tapering		Unknown	
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Unknown	
	Liposomal Amphotericin B			S	Unknown	4 Mg/Kg/Day		Unknown	
	Pegylated Asparaginase			S	Unknown			Unknown	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Unknown
Sodium Chloride	S	Nasal	0.9% Nose Spray
Voriconazole	S	Other	Unknown
Daunorubicin	C	Unknown	Unknown
Methotrexate	C	Intrathecal	Unknown
Vincristine	C	Unknown	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	14896647	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018195653		86 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Allergic; Rash	Zitromax			S	Oral	Unk		Pfizer
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Fidato			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Absorcol			C	Oral	Unk		Not Reported
	Triatec (Ramipril)			C	Oral	Unk		Not Reported
	Vimpat			C		Unk		Not Reported
	Portolac			C	Oral	Unk		Not Reported
	Levetiracetam			C		Unk		Not Reported
	Alendronate Sodium			C	Oral	70 Mg, Unk		Not Reported
	Eliquis			C		Unk		Not Reported
	Gardenale			C	Oral	2 Df, Unk		Not Reported
	Libradin			C	Oral	1 Df, Unk		Not Reported
	Lasix			C		Unk		Not Reported
	Simvastatin			C	Oral	Unk		Not Reported
	Atenolol			C	Oral	Unk		Not Reported
	Zir Fos			C		Unk		Not Reported
	Vitamin360			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15010999	EXPEDITED (15-DAY)		DS, OT	PT-PFIZER INC-2018236899		69 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Drug	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
Hypersensitivity; Fatigue;	Zithromax			S	Oral	Half Tablet		Pfizer	
Feeling Hot; Gait Inability;	Brufen			C		Unk		Not Reported	
Hand Deformity; Joint	Morfex			C		15 Mg, Unk		Not Reported	
Swelling; Oedema	Triticum			C		Unk		Not Reported	
Peripheral; Peripheral									
Swelling; Peripheral									
Swelling; Peripheral									
Swelling									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15080738	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-914862		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Bilirubin	Azithromycine Anhydre			S	Oral			Not Reported	
Increased; Blood Lactate	Paracetamol			C	Oral			Not Reported	
Dehydrogenase	Omeprazole			C	Oral			Not Reported	
Increased; Chills;									
Dyspnoea; Haemoglobin									
Decreased; Haemolytic									
Anaemia; Hepatocellular									
Injury; Jaundice									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15081729	NON-EXPEDITED			US-PFIZER INC-2018262085		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer	
Headache	Doxycycline Hyclate			S		Unk		Pfizer	
	Medrol			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Prednisone		S		Unk		Not Reported	
		Trazodone		S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2018	15083388	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018257276			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Colitis Ischaemic; Diarrhoea; Melaena	Zithromac			S	Oral	2 Df, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	14870052	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018187485		58 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Petechiae; Pruritus; Purpura	Zitromax			S	Oral	500 Mg, As Needed		Pfizer	
	Aulin			C	Oral	100 Mg, Unk		Not Reported	
	Aulin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15092370	NON-EXPEDITED			US-PFIZER INC-2018264733			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Muscle Spasms	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jun-2018	15093509	EXPEDITED (15-DAY)		HO	AU-PFIZER INC-2018221164		1 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pseudomonas Infection	Blinded Azithromycin			S		3x Week Mon, Wed, Fri		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blinded Azithromycin	S		3x Week Mon, Wed, Fri	Pfizer
Blinded Placebo	S		3x Week Mon, Wed, Fri	Pfizer
Blinded Placebo	S		3x Week Mon, Wed, Fri	Pfizer
Salt	C	Oral	1 Teaspoon, 1x/Day	Not Reported
Vitabdeck	C	Oral	1/2 Capsule, 1x/Day	Not Reported
Salbutamol	C	Respiratory (inhalation)	4 Puffs, 2x/Day Pre Physio	Not Reported
Fluticasone Propionate (Glucocorticoid)	C	Respiratory (inhalation)	1 Puff, 1x/Day, Post Physio	Not Reported
Zinc Oxide	C	Topical	Smear Topically As Needed	Not Reported
Pancrelipase 20000	C		10000 Units, As Needed With Food	Not Reported
Dornase Alfa Recombinant	C	Respiratory (inhalation)	2.5 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2018	14945938	NON-EXPEDITED			US-TEVA-2018-US-897225			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Nausea; Penile Discharge	Azithromycin			S	Oral	4 Tablets		Not Reported	
	Azithromycin			S	Oral	2 Tablets		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2018	15094101	EXPEDITED (15-DAY)		OT	HU-TEVA-2018-HU-916510		35 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Photophobia; Photopsia	Sumamed			S	Oral	500 Milligram Daily;		Not Reported	
	Acc			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2018	15094497	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2018-033796		68 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Disorientation; Hypotension; Pneumonia Necrotising; Pneumothorax; Rales; Staphylococcal Sepsis; Tachypnoea	Azithromycin			S	Unknown	Unk ()		Aurobindo	
	Ceftriaxone			S	Unknown	Unk ()		Aurobindo	
	Clindamycin			S	Unknown	Unk ()		Aurobindo	
	Linezolid			S	Unknown	Unk ()		Aurobindo	
	Piperacillin+Tazobactam			S	Unknown	Unk ()		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	14777871	NON-EXPEDITED			US-PFIZER INC- 2018161286		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Abnormal; Drug Interaction; Heart Rate Increased	Azithromycin			S		Unk		Pfizer	
	Lexapro			S		20 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15081418	NON-EXPEDITED			US-TEVA-2018-US- 915671			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Anxiety; Headache; Restlessness; Tinnitus; Vomiting	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15095519	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT- 917705		38 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Abdominal Pain; Azithromycin S Unknown Not Reported
 Abdominal Pain;
 Diarrhoea; Dyspnoea;
 Nausea; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15096308	NON-EXPEDITED			US-PFIZER INC- 2018264565			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Humira			S		Unk		Not Reported
	Ambien			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15096400	NON-EXPEDITED			US-PFIZER INC- 2018264918		60 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15096473	EXPEDITED (15-DAY)		HO, LT	PHHY2018US033948			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Angina Pectoris;	Azithromycin			S	Unknown			Not Reported
Arrhythmia; Blood Iron	Moxifloxacin			S	Unknown			Novartis
Decreased; Dizziness;	Cefotaxime			C	Unknown			Not Reported
Electrocardiogram Qt								
Prolonged; Loss Of								
Consciousness; Nausea;								
Pain; Pulmonary								
Congestion; Syncope;								
Torsade De Pointes;								
Transferrin Saturation								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2018	15099282	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018261640		88 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Bradycardia; Dizziness; Ventricular Extrasystoles	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Diamicon			C		Unk		Not Reported	
	Metformine			C		Unk		Not Reported	
	Temesta (Lorazepam)			C		Unk		Not Reported	
	Tahor			C		Unk		Not Reported	
	Levothyrox			C		Unk		Not Reported	
	Januvia			C		Unk		Not Reported	
	Cardensiel			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15005146	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2018GSK101248			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Overdose; Product Prescribing Issue; Product Use In Unapproved Indication; Product Use Issue; Underdose	Seretide			S	Respiratory (inhalation)	2 Df, Bid,Application(S)		Glaxosmithkline	
	Aerolin			S	Respiratory (inhalation)	5 Df, Z,Application(S)		Glaxosmithkline	
	Flixotide			S	Respiratory (inhalation)	1 Df, Bid,Application(S)		Glaxosmithkline	
	Prednisolone			S	Oral	3.5 MI, Unk		Glaxosmithkline	
	Azitromycine			S	Oral	2.5 MI, Unk		Glaxosmithkline	
	Oseltamivir			C	Oral	1 Df, Bid,Tablet		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15100968	NON-EXPEDITED			US-PFIZER INC-		63 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2018266867

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Swelling	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15101021	EXPEDITED (15-DAY)		OT	PHEH2018US026942			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Sputum Decreased; Toxicity To Various Agents; Visual Impairment	Azithromycin			S	Unknown			Novartis	
	Rifampicin			S	Unknown			Not Reported	
	Ethambutol			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15103754	EXPEDITED (15-DAY)		OT	PHHY2018FR034635		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rib Fracture; Sternal Fracture	Cosentyx			S	Subcutaneous	Unk		Novartis	
	Novatrex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2018	15105049	NON-EXPEDITED			US-TEVA-2018-US-918041			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Reaction	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15105596	NON-EXPEDITED			US-TEVA-2018-US-919578		6 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Reaction To Excipient; Behaviour Disorder	Azithromycin			S	Unknown	Oral Suspension, 200 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15105795	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-918281		14 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain; Muscle Swelling	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15105811	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR-APL-2018-033454		69 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphthous Ulcer; Haemoglobin Decreased; Leukopenia; Thrombocytopenia; Tonsillitis	Azithromycin			S	Unknown	Unk, Administered After Tonsillitis As Ae Treatment		Aurobindo	
	Leflunomide Medac			S	Oral	20 Milligram, Unk		Not Reported	
	Meloxicam			C	Oral	15 Milligram, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15106125	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-177213		29 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance	Azithromycin			S	Unknown			Sun	
	Doxycycline			S	Unknown			Sun	
	Meropenem			S	Unknown			Not Reported	
	Nitazoxanide			S	Unknown			Not Reported	
	Tigecycline			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chloramphenicol			S		Endocervical			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15107669	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-919647		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Inflammation; Intertrigo; Proctalgia	Azithromycin			S	Oral	500 Milligram Daily;			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2018	15107855	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-918862		12 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dizziness; Headache; Hot Flush; Insomnia; Nervousness; Oropharyngeal Pain; Palpitations; Paraesthesia; Pharyngitis Mycoplasmal; Pyrexia	Azithromycin Dihydrate			S	Oral	300 Milligram Daily;			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	14285355	NON-EXPEDITED			US-PFIZER INC-2017531371			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
	Morphine Sulfate			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	14423487	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-846461		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Throat Tightness	Azithromycin			S	Oral	1 Df, Total (1 Ug/Litre)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin Omeprazole			S C		Oral		Unk		Not Reported Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	14871616	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2018189057		76 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Guillain-Barre Syndrome	Meropenem			S	Intravenous drip	Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Ceftriaxone Sodium			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	14878517	EXPEDITED (15-DAY)		OT	US-CIPLA (EU) LIMITED-2018US17330			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Levofloxacin			S	Unknown	Unknown		Cipla	
	Adalimumab			S	Unknown	40 Mg		Not Reported	
	Azithromycin			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15110549	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2018266335		1 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Crying; Diarrhoea	Zithromax			S	Oral	100 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15110720	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2018266025		31 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Papule; Pruritus; Rash Erythematous	Zithromax			S	Oral	0.5 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15111577	EXPEDITED (15-DAY)		LT	IT-TEVA-2018-IT-921052		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Toxic Epidermal Necrolysis	Quetiapine			S	Oral	200 Milligram Daily;		Teva	
	Diazepam			S	Oral			Barr	
	Azithromycin			S	Oral			Not Reported	
	Zolpidem			S	Oral	10 Milligram Daily;		Actavis	
	Rocefin 1 G/10 MI Polvere E Solvente Per Soluzione Iniettabile Per Uso			S	Parenteral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2018	15112144	EXPEDITED (15-DAY)		HO, OT	PT-BAUSCH-BL-2018-018198		68 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Disorientation; Hypotension; Pneumonia Necrotising; Pneumothorax; Rales; Staphylococcal Sepsis; Tachypnoea	Clindamycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Linezolid			S	Unknown			Not Reported	
	Piperacillin, Tazobactam			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	6430813	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2007078321		51 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Creatinine Renal Clearance Decreased; Drug Interaction; Drug Level Increased;	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Tobramycin			S	Intravenous (not otherwise specified)	Daily		Unknown	
	Tobramycin			S				Unknown	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eosinophilia	Colomycin /00013203/	S	Intravenous (not otherwise specified)	2000000 Iu, 3x/Day	Not Reported
	Colomycin /00013203/ Tobi	S C	Nasal	Unk	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	13190257	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2016255147		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blindness; Depression; Diarrhoea; Glaucoma; Injection Site Pain; Joint Swelling; Nasopharyngitis; Neuropathy Peripheral; Osteoporosis; Pain; Peripheral Swelling; Product Dose Omission; Product Quality Issue; Psoriasis; Rash; Somnolence; Vertigo	Enbrel			S	Subcutaneous	50 Mg, Weekly		Unknown	
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Unknown	
	Enbrel			S	Unknown	50 Mg, Qwk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Armour Thyroid			C		Unk		Not Reported	
	Istalol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	14817047	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018163299		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hodgkin'S Disease Nodular Sclerosis	Inflectra			S	Intravenous (not otherwise specified)	200 Mg Every 8 Weeks		Not Reported	
	Novatrex			S	Oral	15 Mg, Unk		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	200 Mg Every 8 Weeks		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jul-2018	15113721	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-920994		21 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Sopor	Aripiprazole			S	Oral			Teva	
	Alprazolam			S	Oral			Actavis	
	Escitalopram Oxalate			S	Oral			Ivax	
	Zitromax 500 Mg Comprese			S	Oral			Not Reported	
	Rivestite Con Film								
	Prozin 25 Mg Comprese			S	Oral			Not Reported	
	Rivestite								
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15113792	NON-EXPEDITED			US-PFIZER INC-2018273871		61 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15114991	EXPEDITED (15-DAY)		OT	PHHY2018FR037021			Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Loss Of Consciousness; Vomiting	Azithromycin			S	Oral	250 Mg2 Tables (Oneper Day During1 Day) Then 1tablet (Oneper Day During4 Days)		Novartis	
	Pivalone (Tixocortol Pivalate)			C	Nasal	1 Spray2 To 4 Times Per Day		Not Reported	
	Ibuprofen			C	Oral	1200 Mg, Qd		Not Reported	
	Claradol			C	Oral	1 To 3 Per Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116395	EXPEDITED (15-DAY)		DE, OT	PT-AUROBINDO-AUR-APL-2018-034099		56 YR	Male	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Haemoptysis	Amoxicillin+Clavulanic Acid	S	Unknown	Unk	Aurobindo
	Azithromycin	S	Unknown	Unk	Aurobindo
	Itraconazole	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116526	EXPEDITED (15-DAY)		HO, OT	CZ-SAKK- 2018SA171247AA		69 YR	Female	CZE

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Aphthous Ulcer; Haemoglobin Decreased; Leukopenia; Thrombocytopenia; Tonsillitis	Azithromycin			S		Administered After Tonsillitis As Ae Treatment		Not Reported
	Leflunomide			S	Oral			Sanofi
	Meloxicam			C	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15116538	NON-EXPEDITED			US-TEVA-2018-US- 920291		64 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15226285	DIRECT	Y	HO			83 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Anaphylactic Reaction	Azithromycin			S	Oral			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jul-2018	15228748	DIRECT					49 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ageusia; Deafness;	Azithromycin 500 Mg Tablets			S		Quantity:6 Tablet(S);		Wockhardt

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tinnitus	Azithromycin 500 Mg Tablets	S	Quantity:6 Tablet(S);	Teva
	Singular	C		Not Reported
	Serevent	C		Not Reported
	Zyrtec D	C		Not Reported
	Losartin	C		Not Reported
	Triamterene	C		Not Reported
	Multi Vitamin	C		Not Reported
	Probiotic	C		Not Reported
	Vitamin B	C		Not Reported
	Vitamin C	C		Not Reported
	Vitamin D Nos	C		Not Reported
	Vitamin E	C		Not Reported
	Calcium	C		Not Reported
	Lutein	C		Not Reported
	Ocuvite	C		Not Reported
	Iron	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2018	14937013	EXPEDITED (15-DAY)		OT	US-AMGEN- USASL2018070073		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Contusion;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
Diarrhoea; Dyspepsia;	Z-Pak			S	Unknown	Unk		Not Reported	
Gait Disturbance; Ill- Defined Disorder; Nausea;	Methotrexate			C		Unk		Not Reported	
Oral Pain; Pain In Extremity; Rash; Renal Neoplasm; Tooth Infection; Vision Blurred	Remicade			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jul-2018	15117900	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2018-034736		60 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Respiratory Failure	Azithromycin			S	Unknown	Unk		Aurobindo	
	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo	
	Oseltamivir			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	9981109	NON-EXPEDITED			US-PFIZER INC-2014062284			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Zithromax			S		Unk		Pfizer	
	Mobic			S		Unk		Not Reported	
	Maxalt			C		Unk		Not Reported	
	Imitrex			C		Unk		Not Reported	
	Levaquin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15119063	EXPEDITED (15-DAY)		DE, OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18-05		56 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Haemoptysis	Amoxicillin Sodium+Potassium Clavulanate			S	Unknown	()		Hikma	
	Itraconazole			S	Intravenous (not otherwise specified)	()		Not Reported	
	Azithromycin			S	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2018	15121823	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018271527		64 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury; Liver Disorder	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15113580	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-919062		22 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Hepatitis Acute; Hepatocellular Injury	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15124388	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-04879		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Skin Burning Sensation; Skin Disorder	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15124963	EXPEDITED (15-DAY)		HO	PHHY2018FR039182		49 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Papular	Azithromycin			S	Oral	Unk		Novartis	
	Rocephine			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Claforan			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Bisoce			C	Oral	3.75 Mg, Qd		Not Reported	
	Oracilline			C	Oral	2000000 Iu, Qd		Not Reported	
	Mag 2			C	Oral	100 Mg, Unk		Not Reported	
	Noxafil			C	Oral	200 Mg, Qd		Not Reported	
	Alprazolam			C	Oral	0.25 Mg, Prn (Si Besoin)		Not Reported	
	Cortancyl			C	Unknown	10 Mg, Qd		Not Reported	
	Calcimed D3			C	Oral	2 Ot, Qd		Not Reported	
	Pantoprazole			C	Oral	20 Mg, Qd		Not Reported	
	Movicol			C	Unknown	Unk		Not Reported	
	Wellvone			C	Oral	10 MI, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Valaciclovir	C	Unknown	1000 Mg, Qd	Not Reported
	Neoral	C	Oral	250 Mg, Qd	Not Reported
	Ramipril	C	Unknown	2.5 Mg, Qd	Not Reported
	Entocort	C	Oral	3 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2018	15127588	EXPEDITED (15-DAY)		DE	FR-PRINSTON PHARMACEUTICAL INC.-2018PRN00369		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Hepatotoxicity	Voriconazole			S	Unknown			Prinston Pharmaceutical	
	Ponatinib			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	14285447	NON-EXPEDITED			US-PFIZER INC- 2017531868			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Rash Erythematous; Rash Pruritic	Zithromax			S		Unk		Pfizer	
	Furosemide			C	Oral	10-20mg At The Time Each Day		Not Reported	
	Potassium			C	Oral	10 Meq, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	14587090	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018082825		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Diarrhoea; Muscle Spasms	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	14648755	EXPEDITED (15-DAY)		OT	GB-SA-2018SA062834		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Levocetirizine			S	Unknown	5 Mg,Qd		Sanofi	
	Azithromycin			S	Unknown	250 Mg, Bid		Not Reported	
	Salbutamol Sulfate			S	Unknown	6 Df, Qd		Not Reported	
	Montelukast			S	Unknown	10 Mg,Qd		Not Reported	
	Fluticasone			S	Nasal	Unk (55g/Day)		Not Reported	
	Fluticasone			S	Nasal	1000 Ug,Qd		Not Reported	
	Salmeterol			S	Unknown	Unk (6 Puffs/Day; 100 ?G/Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15129041	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-034913		35 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Ineffective; Pulmonary Tuberculosis; Pyrexia	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2018	15129985	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018269960		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Pulmonary Fibrosis	Azithromycin			S	Oral	0.5 Df, Daily (Half A Pill)		Pfizer	
	Xeljanz			C	Oral	5 Mg, 1x/Day		Not Reported	
	Xeljanz			C	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	14447969	EXPEDITED (15-DAY)		OT	GB-TAKEDA-2017TUS018391			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Arthralgia; Large Intestinal Stenosis; Oral Herpes; Rash; Tonsillitis	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk		Takeda	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15030065	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2018M1040157		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pleural Effusion; Pneumonia; Pyrexia	Azithromycin			S	Unknown			Not Reported	
	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15084506	EXPEDITED (15-DAY)		HO	US-TEVA-2018-US-912506			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Fatigue; Neuralgia; Vertigo	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15132444	EXPEDITED (15-DAY)		HO	PT-ALVOGEN-2018-ALVOGEN-096746		65 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Pneumonia; Respiratory Failure; Therapeutic Response Decreased	Lisinopril			S	Oral			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Indapamide/Perindopril			S	Unknown			Not Reported	
	Erbumine								
	Alendronate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sodium/Colecalciferol Amoxicillin Trihydrate/Clavulanate Potassium Indapamide/Perindopril	S	Unknown		Not Reported
	S	Unknown	Dose Of Perindopril Had Been Doubled	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15132900	EXPEDITED (15-DAY)		HO, OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18- 05		68 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Disorientation; Hypotension; Pneumonia Necrotising; Pneumothorax; Rales; Staphylococcal Sepsis; Tachypnoea	Ceftriaxone			S	Unknown	Unk ()		Hikma	
	Azithromycin			S	Unknown	Unk ()		Not Reported	
	Clindamycin			S	Unknown	Unk ()		Not Reported	
	Linezolid			S	Unknown	Unk ()		Not Reported	
	Piperacillin, Tazobactam			S	Unknown	Unk ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15133357	NON-EXPEDITED			US-TEVA-2018-US- 921173			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Arthralgia; Arthralgia; Back Pain; Muscle Spasms; Muscle Spasms; Pain In Extremity; Restlessness	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15133661	EXPEDITED (15-DAY)		DE	FR-AJANTA PHARMA USA INC.-2051851		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure;	Voriconazole			S				Ajanta Pharma	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Hepatotoxicity; Toxicity To Various Agents		Ponatinib Azithromycin Monohydrate		S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15133765	EXPEDITED (15-DAY)		HO	ES-TEVA-2018-ES-924083		82 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypotension; Rash; Stridor	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg / 24 H		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2018	15243634	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Avenova Novabay Azithromycin			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14610069	EXPEDITED (15-DAY)		DE, OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2017-121330			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Hepatic Failure; Hepatitis; Off Label Use	Hydrea			S	Oral	500 Mg, Bid		Bristol Myers Squibb	
	Trimebutine Arrow			S	Oral	200 Mg, Qd		Not Reported	
	Vfend			S	Unknown	400 Mg, Qd		Not Reported	
	Vfend			S	Intravenous (not otherwise specified)	800 Mg, Bid		Not Reported	
	Bisoce			S	Oral	5 Mg, Qd		Not Reported	
	Iclusig			S	Oral	45 Mg, Qd		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported	
	Ceftriaxone			S	Intravenous (not	100 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Zyloric	S	Oral	200 Mg, Qd		Not Reported
Zyloric	S	Oral	100 Mg, Qd		Not Reported
Zyloric	S	Oral	100 Mg, Qd		Not Reported
Hydrocortisone	S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported
Lasilix /00032601/	S	Oral	40 Mg, Qd		Not Reported
Lasilix /00032601/	S	Oral	20 Mg, Qd		Not Reported
Polaramine	S	Intravenous (not otherwise specified)	5 Mg, Qd		Not Reported
Zithromax	S	Unknown	500 Mg, Single		Not Reported
Zithromax	S	Oral	250 Mg, Qd		Not Reported
Cortancyl	C	Unknown	40 Mg, Qd		Not Reported
Fasturtec	C	Intravenous (not otherwise specified)	7.5 Mg, Single		Not Reported
Stilnox	C	Unknown	10 Mg, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	14978716	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2018-028985		21 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sopor	Aripiprazole Tablets			S	Oral	210 Milligram, In Total		Aurobindo
	Escitalopram Film-Coated Tablets			S	Oral	140 Milligram, In Total		Aurobindo
	Alprazolam			S	Oral	15 Milliliter, In Total		Not Reported
	Prozin /00011902/			S	Oral	1200 Milligram, In Total		Not Reported
	Zitromax			S	Oral	1500 Milligram, In Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15138150	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-035162		58 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatitis; Hyperbilirubinaemia; Liver Disorder	Azithromycin 500 Mg	S	Oral	500 Milligram, Daily, 1 Cp Dia	Aurobindo
	Amoxicillin Clavulanic Acid	C	Oral	Unk, 1-1-1	Not Reported
	Pravastatina Alter	C	Unknown	Unk, 0-0-1	Not Reported
	Cymbalta	C	Oral	Unk, 1 Cp Dia	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138212	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-035580		39 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Rash; Swelling Face	Azithromycin			S	Oral	Unk		Aurobindo	
	Amoxicillin+Clavulanic Acid			S	Oral	Unk		Aurobindo	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138217	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2018-035069		85 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anaphylactic Reaction; Bronchospasm; Rash	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138219	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2018-035179		11 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Hyperhidrosis; Nausea; Peripheral Coldness; Somnolence	Azithromycin			S	Oral	In Total		Aurobindo	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jul-2018	15138238	EXPEDITED (15-DAY)		HO	ES-AUROBINDO-AUR- APL-2018-035287		82 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Hyponatraemia	Azithromycin	S	Unknown	Unk				Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15138612	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-924581		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Amoxicilline			S	Oral			Teva	
	Clarithromycine			S	Oral			Not Reported	
	Azithromycine Anhydre			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15139196	NON-EXPEDITED			US-PFIZER INC-2018280417			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atenolol			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Doxepin Hcl			S		Unk		Pfizer	
	Spironolactone			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	
	Arimidex			S		Unk		Not Reported	
	Ceftin			S		Unk		Not Reported	
	Ethacrynic Acid			S		Unk		Not Reported	
	Januvia			S		Unk		Not Reported	
	Lasix			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Losartan			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lovenox	S	Unk	Not Reported
Mavik	S	Unk	Not Reported
Metformin Hcl	S	Unk	Not Reported
Prandin	S	Unk	Not Reported
Topamax	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15139642	EXPEDITED (15-DAY)		HO, OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18-05		35 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Ineffective; Pulmonary Tuberculosis; Pyrexia	Amoxicillin/Clavulanic Acid			S	Unknown	Unk ()		Hikma	
	Azithromycin			S	Unknown	Unk ()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15141141	EXPEDITED (15-DAY)		DE, OT	PT-PFIZER INC-2018282880		56 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Haemoptysis; Superinfection	Azithromycin			S		Unk		Pfizer	
	Amoxicillin Clavulanic Acid			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15143645	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018279388		57 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Metabolic Acidosis	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Sulfamethoxazole And Trimethoprim			S	Intravenous (not otherwise specified)	480 Mg, 4x/Day (Every 6 Hours)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15144097	NON-EXPEDITED			US-TEVA-2018-US-878524			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2018	15144995	NON-EXPEDITED			US-TEVA-2018-US-923748			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Incorrect Dose Administered	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2018	15248393	DIRECT					63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Decreased Appetite; Dehydration; Diarrhoea; Heart Rate Increased; Insomnia; Malaise; Vomiting	Azythromycin			S	Oral	Quantity:2 Tablet(S);Other Frequency:Once;		Teva	
	Klonapin			C				Not Reported	
	Diltiazem			C				Not Reported	
	Naltrexone			C				Not Reported	
	Multi Vitamin			C				Not Reported	
	Selenium			C				Not Reported	
	Co Q 10			C				Not Reported	
	Fish Oil			C				Not Reported	
	Vitamin D3			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	12210159	NON-EXPEDITED			US-PFIZER INC-2016140189			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product	Zithromax			S		2 Df, Daily		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Administered; Diarrhoea; Drug Hypersensitivity; Nausea		Zithromax	S	1 Df, Daily		Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	14354782	EXPEDITED (15-DAY)		HO, OT	PL-LUPIN PHARMACEUTICALS INC.-2017-07667		35 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Resistance; Opportunistic Infection; Periodontitis; Pyogenic Granuloma	Ceftriaxone			S	Unknown	1000 Mg, Qd		Lupin	
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
	Cefadroxil			S	Unknown	500 Mg, Bid		Not Reported	
	Amoxicillin			C	Unknown	1000 Mg, Tid		Not Reported	
	Clavulanate Potassium			C	Unknown	200 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	14656283	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2018108855		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperaemia; Pruritus	Zitromax			S	Oral	500 Mg, Total		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15030229	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC- 2018241976		58 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption; Pneumonia	Minomycin			S	Oral	100 Mg, 1x/Day		Pfizer	
	Azithromycin			S		500 Mg, 1x/Day		Pfizer	
	Ceftriaxone Sodium			S		2000 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15147716	NON-EXPEDITED			US-PFIZER INC- 2018284032			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Asa			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15148307	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1050382		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250 Mg, Total,250mg Dosis Unica		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15149001	EXPEDITED (15-DAY)		HO	PHHY2018SK045975			Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Live Birth; Maternal Exposure During Pregnancy; Retroplacental Haematoma	Azithromycin			S	Unknown	In 5 Gestation Week Of Pregnancy		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15150146	EXPEDITED (15-DAY)		DE, LT	FR-FRESENIUS KABI-FK201807852		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Hepatic Failure; Hepatocellular Injury	Azithromycin (Manufacturer Unknown)			S	Unknown	D2: 500 Mg/Day, D3: 250 Mg/Day, D4 To D9: 250 Mg/Day		Fresenius Medical Care	
	Voriconazole (Manufacturer Unknown)			S	Unknown	D3: 400 Mg/Day At Night, D4 To D7: 400 Mg Morning-Night, D8: 400 Mg Morning, 200 Mg Night, D9: 200 M		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ponatinib	S	Unknown	D1 To D9: 45 Mg/Day At Noon	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15150502	EXPEDITED (15-DAY)		DE	FR-MYLANLABS-2018M1051519		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Drug Interaction; Hepatocellular Injury	Voriconazole			S	Unknown	On Day 3		Not Reported
	Voriconazole			S	Unknown	From Day 4 To Day 7		Not Reported
	Voriconazole			S	Unknown	On Day 8: 400 Mg Morning 200 Mg Night		Not Reported
	Voriconazole			S	Unknown	On Day 9: Administered Only In The Morning		Not Reported
	Azithromycin			S	Unknown	On Day 2		Not Reported
	Azithromycin			S	Unknown	From Day 3 To Day 9		Not Reported
	Ponatinib			S	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15150561	EXPEDITED (15-DAY)		CA, HO	PHHY2018SK045961			Female	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Cystic Lung; Foetal Exposure During Pregnancy; Live Birth	Azithromycin			S	Transplacental			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2018	15150787	EXPEDITED (15-DAY)		DE	FR-AKORN PHARMACEUTICALS-2018AKN00999		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Drug Interaction; Hepatotoxicity	Voriconazole			S	Unknown			Akorn
	Ponatinib			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	9434732	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2013218706		51 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Condition Aggravated; Cytopenia; Diarrhoea; Folate Deficiency; Hyperlipidaemia; Hyperuricaemia; Lymphadenitis; Mycobacterium Avium Complex Infection; Nausea; Osteoporosis; Periarthritis; Pneumonia; Renal Impairment	Mycobutin			S	Oral	150 Mg, 3x/Week		Pfizer
	Zithromac 600mg			S	Oral	1200 Mg, Weekly		Pfizer
	Zithromac 600mg			S	Oral	600 Mg, Daily		Pfizer
	Zithromac 250mg			S		500 Mg, 2 Tablets Of 250 Mg, Once Per Day		Pfizer
	Zithromac 250mg			S				Pfizer
	Valixa			S		900 Mg, 2x/Day		Not Reported
	Valixa			S		450 Mg, 2x/Day		Not Reported
	Valixa			S		450 Mg, 1x/Day		Not Reported
	Valixa			S		900 Mg, 2x/Day		Not Reported
	Valixa			S		450 Mg, 2x/Day		Not Reported
	Valixa			S		450 Mg, 2x/Day		Not Reported
	Valixa			S		450 Mg, 2x/Day		Not Reported
	Baktar			S		1 Df, 2x/Day		Not Reported
	Baktar			S		1 Df, 1x/Day		Not Reported
	Esanbutol			S		625 Mg, Daily		Not Reported
	Esanbutol			S		500 Mg, 1x/Day		Not Reported
	Norvir			S		100 Mg, Daily		Not Reported
	Truvada			S		1 Df, Daily		Not Reported
	Prezista			S		800 Mg, 1x/Day		Not Reported
	Epzicom			S		1 Df, 1x/Day		Not Reported
Fosamac			S		35 Mg, Weekly		Not Reported	
Bezato Sr			S	Oral	200 Mg, 2x/Day		Not Reported	
Sawacillin			C		1000 Mg, 3x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sawacillin	C	1000 Mg, 3x/Day	Not Reported
Risumic	C	10 Mg, 2x/Day	Not Reported
Maglax	C	330 Mg, 3x/Day	Not Reported
Cephadol	C	25 Mg, 3x/Day	Not Reported
Vfend	C	100 Mg, 2x/Day	Not Reported
Talion (Bepotastine Besylate)	C	10 Mg, 2x/Day	Not Reported
Fluconazole	C	100 Mg, 1x/Day	Not Reported
Enteronon R	C	1 G, 3x/Day	Not Reported
Omeptorol	C	20 Mg, 1x/Day	Not Reported
Lopemin [Loperamide Hydrochloride]	C	1 Mg, 2x/Day	Not Reported
Myonal [Eperisone Hydrochloride]	C	50 Mg, 3x/Day	Not Reported
Loxonin	C	60 Mg, 3x/Day	Not Reported
Tannalbin	C	1 G, 3x/Day	Not Reported
Nauzelin	C	10 Mg, 3x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2018	15155015	EXPEDITED (15-DAY)		DE	FR-EPIC PHARMA LLC-2018EPC00336		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure;	Azithromycin			S	Unknown			Epic Pharm
Drug Interaction;	Ponatinib			S	Unknown			Not Reported
Hepatotoxicity	Voriconazole			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15158535	EXPEDITED (15-DAY)		HO, LT	GB-MYLANLABS-2018M1051341			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Angina Pectoris; Arrhythmia; Blood Iron Decreased; Bundle	Moxifloxacin			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Branch Block Left; Cardiac Arrest; Cardio-Respiratory Arrest; Dizziness; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Nausea; Pain; Pulmonary Congestion; Pulse Absent; Syncope; Torsade De Pointes; Transferrin Saturation Decreased; Ventricular Fibrillation; Ventricular Tachycardia; Vomiting	Azithromycin	S	Unk	Not Reported
	Famotidine	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15159194	NON-EXPEDITED			US-TEVA-2018-US-926471			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15160666	EXPEDITED (15-DAY)		OT	PHHY2018IT049313		25 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Inflammation; Intertrigo; Proctalgia	Azithromycin Dihydrate			S	Oral	500 Mg, Qd			Novartis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2018	15255709	DIRECT						Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S					Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	14921951	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-893086		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Diarrhoea; Muscle Spasms	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15099065	NON-EXPEDITED			US-PFIZER INC-2018266765		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15163460	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-929090		39 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Swelling Face	Azithromycin			S	Oral			Not Reported	
	Amoxicillin W/Clavulanic Acid			S	Oral			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15163603	NON-EXPEDITED			US-TEVA-2018-US-927763			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Storage Error	Azithromycin			S		Form Strength: 200mg/5ml		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15166123	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018288326		87 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dermatitis Bullous; Purpura	Zithromax	S	Oral	3 Df, Unk	Pfizer
	Incruse	C	Respiratory (inhalation)	1 Df, 1x/Day	Not Reported
	Relvar Ellipta	C	Respiratory (inhalation)	1 Df, 1x/Day	Not Reported
	Rilmenidine	C	Oral	1 Df, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2018	15166690	EXPEDITED (15-DAY)		HO	CZ-MYLANLABS-2018M1052124		46 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption	Azithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	12311710	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2016228005			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Electrocardiogram Qt Prolonged	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15168985	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-036185		55 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mixed Liver Injury	Azithromycin			S	Oral	Unk		Aurobindo
	Meiact			S	Oral	200 Milligram, 8 Hour(200 Mg 1-1-1 For 6 Days, Then 1-0-1)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15170561	EXPEDITED (15-DAY)		HO, OT	PT-WEST-WARD PHARMACEUTICALS		65 YR	Female	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

CORP.-PT-H14001-18-05

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Cough; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Therapeutic Response Decreased	Amoxicillin+Clavulanic Acid			S	Unknown	()		Hikma
	Azithromycin			S	Unknown	()		Not Reported
	Perindopril+Indapamide			S	Unknown	()		Not Reported
	Alendronate+Cholecalciferol			S	Unknown	()		Not Reported
	Lisinopril			S	Unknown	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15172265	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018283068			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abdominal Pain Upper; Diarrhoea; Feeling Cold; Gastroenteritis Norovirus; Gastroenteritis Viral; Melaena; Nausea; Pharyngitis; Product Use In Unapproved Indication; Somnolence; Sputum Discoloured; Vomiting Projectile	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer
	Loxonin			C	Oral	Unk Unk, 3x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15172355	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018242872			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pathogen Resistance	Azithromycin			S		Unk		Pfizer
	Ceftriaxone Sodium			S		1 G, Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spectinomycin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2018	15174917	EXPEDITED (15-DAY)		LT	US-PFIZER INC-2018293086		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		250 Mg, Unk		Pfizer	
	Levaquin			S		750 Mg, Unk		Not Reported	
	Augmentin			S		Unk (875-125 Mg)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jul-2018	15178301	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-036418		19 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Oral	1 Gram, Stat Dose ; In Total		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2018	15178777	EXPEDITED (15-DAY)		OT	PHHY2018ES048284		10 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azitromicina			S	Oral	250 Mg, Qd		Novartis	
	Salbutamol			C	Respiratory (inhalation)	Unk, Tid (2-2-2)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2018	15264219	DIRECT	Y	HO			44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Pneumonia	Enbrel Mini 50mg/MI			S	Subcutaneous			Not Reported	
	Z- Pak			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	14439705	EXPEDITED (15-DAY)			CH-TEVA-2018-CH-852133		30 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Product Prescribing Error	Azithromycin-Mepha			S	Unknown	Drug Not Taken		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15179127	EXPEDITED (15-DAY)		DE, OT	FR-TEVA-2018-FR-926361		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Drug Interaction; Hepatocellular Injury	Voriconazole			S	Unknown	400 Milligram Daily; On Day 3		Teva	
	Voriconazole			S	Unknown	800 Milligram Daily; From Day 4 To Day 7		Teva	
	Voriconazole			S	Unknown	On Day 8: 400 Mg Morning 200 Mg Night		Teva	
	Voriconazole			S	Unknown	200 Milligram Daily; On Day 9: Administered Only In The Morning		Teva	
	Azithromycin			S	Unknown	500 Milligram Daily; On Day 2		Not Reported	
	Azithromycin			S	Unknown	250 Milligram Daily; From Day 3 To Day 9		Not Reported	
	Ponatinib			S	Unknown	45 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15180329	EXPEDITED (15-DAY)		HO, OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18-05		17 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy;	Clarithromycin			S	Unknown	()		Westward	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Conjunctival Hyperaemia;	Clarithromycin	S				Westward
Enanthema; Eye	Nimesulide	S	Unknown	()		Not Reported
Discharge; Genital	Nimesulide	S	Unknown	()		Not Reported
Ulceration; Lip Erythema;	Azithromycin	S	Unknown	()		Not Reported
Lip Oedema; Lung	Azithromycin	S	Unknown	()		Not Reported
Infiltration; Nasal Mucosal	Azithromycin	S	Unknown	()		Not Reported
Disorder; Off Label Use;	Bilastine	C	Unknown	()		Not Reported
Oral Mucosa Erosion;	Bilastine	C				Not Reported
Pyrexia; Rash	Brivudine	C	Unknown	()		Not Reported
Maculovesicular; Rash						Not Reported
Papular; Stevens-Johnson Syndrome						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2018	15181101	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2018292783		14 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Supraventricular Tachycardia	Azithromycin			S		Unk		Pfizer
	Fexofenadine			S		Unk		Not Reported
	Fluticasone			C	Nasal	Unk		Not Reported
	Fluticasone W/Salmeterol			C	Respiratory (inhalation)	Unk Unk, 2x/Day (100/50 Ug)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	10419168	NON-EXPEDITED			US-PFIZER INC-2014236236			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Ultram			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	10527864	NON-EXPEDITED			US-PFIZER INC-2014281535			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Meperidine Hcl			S		Unk		Unknown	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	14603445	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL036744		9 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Atelectasis; Breath Sounds Abnormal; Chest Pain; Cough; Drug Ineffective; Dry Mouth; Dyspnoea; Empyema; General Physical Health Deterioration; Hypokalaemia; Hyponatraemia; Inflammation; Lung Infiltration; Mobility Decreased; Myalgia; Pneumonia Pneumococcal; Renal Failure; Tachypnoea	Amoxicillin Trihydrate+Potassium Clavulanate			S	Unknown	2 Df (2 Ug/Litre)		Novartis	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	14618799	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2018039543		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Salmeterol	S	Unknown	Unk (6 Puffs/Day; 100 ?G/Day	Glaxosmithkline
	Montelukast	S	Unknown	10 Mg,Qd	Glaxosmithkline
	Levocetirizine	S	Unknown	5 Mg,Qd	Glaxosmithkline
	Azithromycin	S	Unknown	250 Mg, Bid	Glaxosmithkline
	Fluticasone	S	Nasal	1000 Ug,Qd	Glaxosmithkline
	Fluticasone	S	Nasal	Unk (55g/Day)	Glaxosmithkline
	Salbutamol Sulphate	S	Unknown	6 Df, Qd	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	14669374	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES- 870012		69 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Bronchospasm; Palatal Oedema	Acetilcisteína 200 Mg Solución/Suspensión Oral 30 Sobres			S	Oral	600 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	14790879	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018160530		56 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Flushing; Skin Reaction	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15131479	EXPEDITED (15-DAY)		DE, OT	FR-TAKEDA- 2017TUS024698		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Hepatic Failure; Hepatitis; Off Label Use	Iclusig			S	Oral	45 Mg, Qd		Takeda	
	Zyloric			S	Oral	200 Mg, Qd		Not Reported	
	Zyloric			S	Oral	100 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zyloric	S	Oral	100 Mg, Qd	Not Reported
Bisoce	S	Oral	5 Mg, Qd	Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, Qd	Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
Hydrea	S	Oral	500 Mg, Bid	Not Reported
Lasilix /00032601/	S	Oral	40 Mg, Qd	Not Reported
Lasilix /00032601/	S	Oral	20 Mg, Qd	Not Reported
Polaramine	S	Intravenous (not otherwise specified)	5 Mg, Qd	Not Reported
Hydrocortisone	S	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
Trimebutine Arrow	S	Oral	100 Mg, Bid	Not Reported
Zithromax	S	Unknown	500 Mg, Unk	Not Reported
Zithromax	S	Oral	250 Mg, Qd	Not Reported
Vfend	S	Intravenous (not otherwise specified)	400 Mg, Bid	Not Reported
Vfend	S	Unknown	200 Mg, Bid	Not Reported
Fasturtec	C	Intravenous (not otherwise specified)	7.5 Mg, Unk	Not Reported
Cortancyl	C	Unknown	40 Mg, Qd	Not Reported
Movicol /08437601/	C	Unknown	Unk	Not Reported
Spasfon /00934601/	C	Unknown	80 Mg, Unk	Not Reported
Topalgic /00599202/	C	Unknown	50 Mg, Unk	Not Reported
Stilnox	C	Unknown	10 Mg, Unk	Not Reported
Atarax /00058401/	C	Unknown	12.5 Mg, Qd	Not Reported
Renagel /01459901/	C	Unknown	800 Mg, Bid	Not Reported
Polyethylene Glycol 3350	C	Unknown	Unk	Not Reported
Sodium Bicarbonate	C	Unknown	Unk	Not Reported
Potassium Chloride	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15187701	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-06824			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Faeces Discoloured	Azithromycin Tablets			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15189522	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-037070		31 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Faeces Soft; Haematochezia; Mucous Stools	Azithromycin			S	Oral	500 Milligram, In Total		Aurobindo	
	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15189942	EXPEDITED (15-DAY)		LT	PHHY2018IT053315		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Toxic Epidermal Necrolysis	Diazepam			S	Oral	20 Gtt, Unk		Not Reported	
	Quetiapine Fumarate			S	Oral	200 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	Unk		Novartis	
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported	
	Rocefin			S	Parenteral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15190419	NON-EXPEDITED			US-PFIZER INC- 2018295174		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Productive Cough; Pyrexia	Zithromax			S	Oral	2 Pills On The First Day And 1 Pill For The Last 4		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax		S		Days By Mouth)/5 Day Dose Pack		Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15190442	EXPEDITED (15-DAY)		DE	US-PFIZER INC- 2018294449		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Meropenem			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Piperacillin/Tazobactam			S		Unk		Unknown	
	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Ampicillin Sodium/Sulbactam Sodium			S		Unk		Pfizer	
	Voriconazole			S		Unk		Pfizer	
	Cefazolin			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Ceftazidime			S		Unk		Unknown	
	Cefepime Hcl			S		Unk		Unknown	
	Ampicillin Sodium			S		Unk		Unknown	
	Gentamicin Sulfate			S		Unk		Unknown	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Aztreonam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15191874	EXPEDITED (15-DAY)		OT	PHHY2018BE052059			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Renal Failure	Azithromycin 500 Mg			S	Unknown			Novartis	
	Itraconazole			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Tildiem		S	Unknown				Not Reported
		Crestor		S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2018	15191920	NON-EXPEDITED		OT	US-SA-2018SA192218		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Multaq			S		400 Mg, Bid		Sanofi	
	Azithromycin			S		250 Mg, Bid		Not Reported	
	Azithromycin			S		250 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	14310103	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017537686		182 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15142161	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-036036		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Amoxicillin+Clavulanic Acid			S	Oral	2 Dosage Form, Daily		Aurobindo	
	Azithromycin			S	Oral	1 Dosage Form, Daily		Aurobindo	
	Lyrice			C	Oral	1 Dosage Form		Not Reported	
	Pantorc			C	Oral	1 Dosage Form		Not Reported	
	Gentalyn Beta			C	Cutaneous	1 Dosage Form		Not Reported	
	Norvasc			C	Oral	1 Dosage Form		Not Reported	
	Cymbalta			C	Oral	1 Dosage Form		Not Reported	
	Zyllt			C	Oral	1 Dosage Form		Not Reported	
	Lasix /00032601/			C	Oral	1 Dosage Form		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Simvastatin	C	Oral	1 Dosage Form	Not Reported				
	Lexotan	C	Oral	1 Dosage Form	Not Reported				
	Norapril	C	Oral	1 Dosage Form	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15192917	EXPEDITED (15-DAY)		DS	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-179397		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Neuropathy Peripheral; Paraesthesia; Paraesthesia	Azithromycin			S	Oral	500 Mg, Daily		Sun	
	Zyvoxid 600 Mg, Comprime Pellicule			S	Oral	600 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15194247	EXPEDITED (15-DAY)		DE	US-HORIZON-PRE- 0320-2018		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection	Prednisone			S				Not Reported	
	Tacrolimus			S				Not Reported	
	Imuran			S				Not Reported	
	Valgancyclovir			S				Not Reported	
	Azithromycin			S				Not Reported	
	Bactrim			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2018	15195739	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2018291908			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Oedema; Product Administration Error; Renal Impairment	Zithromac 250mg			S		2 Df, Unk		Pfizer	
	Neoral			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15196206	NON-EXPEDITED		OT	US-TEVA-2018-US-932552			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Erythema; Skin Reaction	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15197053	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-931100		55 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Mixed Liver Injury	Azitromicina			S	Oral				Not Reported
	Meiact			S	Oral	200 Mg 1-1-1 For 6 Days, Then 1-0-1			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15198290	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018291909			Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chlamydial Infection	Zithromac 250mg			S		2 Df, Unk			Pfizer
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jul-2018	15198444	EXPEDITED (15-DAY)		OT	PHHY2018GB055062			Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pathogen Resistance	Azithromycin			S	Unknown	Unk			Not Reported
	Ceftriaxone			S	Unknown	Unk			Novartis
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15169559	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-928654		82 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Oedema Peripheral; Pruritus	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Amoxicillin W/Clavulanic Acid			S	Oral	2 Dosage Forms Daily;		Teva	
	Lyrica			C	Oral			Not Reported	
	Pantorc 20 Mg Compresse Gastroresistenti			C	Oral			Not Reported	
	Gentalyn Beta			C	Cutaneous			Not Reported	
	Norvasc 5 Mg Compresse			C	Oral			Not Reported	
	Cymbalta 30 Mg Hard Gastro- Resistant Capsules			C	Oral			Not Reported	
	Zyllt 75 Mg Film-Coated Tablets			C	Oral			Not Reported	
	Lasix 25 Mg Compresse			C	Oral			Not Reported	
	Simvastatin			C	Oral			Not Reported	
	Lexotan 2,5 Mg/MI Gocce Orali Soluzione			C	Oral			Not Reported	
	Norapril 2,5 Mg Compresse			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201043	EXPEDITED (15-DAY)		DE, OT	FR-TEVA-2018-FR- 931093			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Drug Level Increased; Hepatic Failure; Hepatitis; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	100 Milligram Daily;		Not Reported	
	Trimebutine			S	Oral	200 Milligram Daily;		Not Reported	
	Bisoprolol Fumarate			S	Oral	5 Milligram Daily;		Duramed	
	Lasilix			S	Oral	20 Milligram Daily;		Not Reported	
	Lasilix /00032601/			S	Oral	40 Milligram Daily;		Not Reported	
	Polaramine			S	Intravenous (not otherwise specified)	5 Milligram Daily;		Not Reported	
	Hydrocortisone			S	Intravenous (not	100 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Zithromax	S	Oral	250 Milligram Daily;	Not Reported	
Vfend	S		400 Milligram Daily;	Not Reported	
Vfend	S	Intravenous (not otherwise specified)	800 Milligram Daily;	Not Reported	
Lasilix	S	Oral	40 Milligram Daily;	Not Reported	
Zyloric	S	Oral	100 Milligram Daily;	Not Reported	
Zithromax	S		500 Mg, Once	Not Reported	
Iclusig	S	Oral	45 Milligram Daily;	Not Reported	
Hydrea	S	Oral	1000 Milligram Daily;	Not Reported	
Zyloric	S	Oral	100 Milligram Daily;	Not Reported	
Zyloric	S	Oral	200 Milligram Daily;	Not Reported	
Topalgic [Tramadol Hydrochloride]	C		50 Mg, Prn	Not Reported	
Stilnox	C		10 Mg, Prn	Not Reported	
Atarax [Hydroxyzine Hydrochloride]	C		12.5 Milligram Daily;	Not Reported	
Fasturtec	C	Intravenous (not otherwise specified)	7.5 Mg, Once	Not Reported	
Cortancyl	C		40 Mg, Qd	Not Reported	
Movicol	C		2 Df, Qd	Not Reported	
Renagel [Sevelamer Hydrochloride]	C		800 Mg, Unk	Not Reported	
Polyethylene Glycol 3350	C			Not Reported	
Phloroglucinol	C		80 Mg, Prn	Not Reported	
Sodium Bicarbonate	C			Not Reported	
Potassium Chloride	C			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2018	15201175	NON-EXPEDITED			US-PFIZER INC-2018300284		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15203003	EXPEDITED (15-DAY)		DS, OT	FR-PFIZER INC-2018296468		61 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypoaesthesia; Neuropathy Peripheral; Paraesthesia	Zyvoxid			S	Oral	600 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jul-2018	15204730	EXPEDITED (15-DAY)		HO	PHHY2018ES054379		85 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anaphylactic Reaction; Bronchospasm; Rash	Azitromicina			S	Oral	500 Mg, Qd		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15180172	NON-EXPEDITED			US-PFIZER INC-2018295745		64 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Dyspnoea; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15206820	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-931256		19 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Oral	Stat Dose		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Jul-2018	15207593	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP017588		58 YR	Male	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardioversion; Chest Discomfort; Dizziness; Drug Interaction; Palpitations; Similar Reaction On Previous Exposure To Drug; Tachycardia	Apo-Sotalol - Tab 160mg			S	Oral	80 Mg, Bid		Apotex	
	Jamp Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Jamp Azithromycin			S	Oral	2 Df, Once		Not Reported	
	Apo Mometasone			C	Unknown			Not Reported	
	Acetylsalicylic Acid Enteric Coated			C	Unknown	Unk		Not Reported	
	Ran Rosuvastatin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15208441	EXPEDITED (15-DAY)		OT	PHHY2018NL055445			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Angioedema	Amoxicillin+Clavulanic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Cefuroxime			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2018	15209183	EXPEDITED (15-DAY)		DS	FR-TEVA-2018-FR-931087		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Neuropathy Peripheral; Paraesthesia; Paraesthesia	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
	Zyvoxid 600 Mg, Comprimé			S	Oral	600 Milligram Daily;		Not Reported	
	Pelliculé								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2018	15211068	NON-EXPEDITED		OT	PHEH2018US030618			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Computerised Tomogram Abnormal; Drug	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Renal Failure		Rifampin	S	Unknown	Unk	Not Reported			
		Amikacin	S	Unknown	Unk	Not Reported			
		Ethambutol	S	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2018	15211934	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-933110			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis; Sudden Hearing Loss	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15128234	NON-EXPEDITED			US-AMGEN-USASL2018092948		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ill-Defined Disorder; Rash	Enbrel			S	Subcutaneous	50 Mg, Qwk			Amgen
	Z-Pak			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15213596	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-038118			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Arthralgia; Large Intestinal Stenosis; Oral Herpes; Rash; Tonsillitis	Azithromycin			S	Unknown	Unk			Aurobindo
	Entyvio			S	Intravenous (not otherwise specified)	300 Milligram			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15215519	EXPEDITED (15-DAY)		HO, OT	ES-BAUSCH-BL-2018-020192		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Tobramycin			S	Unknown				Bausch And Lomb

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaemia; Mycobacterium	Moxifloxacin	S	Oral	Not Reported
Cheloniae Infection;	Sivextro	S	Oral	Not Reported
Neuropathy Peripheral;	Tigecycline	S	Unknown	Not Reported
Pancreatitis Acute;	Azithromycin	S	Unknown	Not Reported
Pulmonary Embolism	Acenocoumarol	C		Not Reported
	Amoxicillin, Potassium Clavulanate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15216171	EXPEDITED (15-DAY)		HO	PHHY2018US052808		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea;	Ziprasidone			S	Unknown			Novartis
Hypersensitivity	Azithromycin			S	Unknown			Not Reported
Pneumonitis; Malaise;	Ceftriaxone			S	Unknown			Not Reported
Pyrexia; Respiratory Failure; Tachypnoea; Wheezing								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2018	15216609	NON-EXPEDITED			US-PFIZER INC-2018306454			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	13382068	EXPEDITED (15-DAY)		HO	PHHY2017FR043786		21 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Myoclonus; Paraesthesia	Neoral			S	Oral	Unk		Novartis
	Azithromycin			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Pantoprazole			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Terbutaline	S	Respiratory (inhalation)	Unk	Not Reported
Hizentra	S	Oral	Unk	Not Reported
Hizentra	S	Subcutaneous	Unk	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Seresta	S	Oral	Unk	Not Reported
Bactrim	S	Oral	Unk	Not Reported
Folinoral	S	Oral	Unk	Not Reported
Zelitrex	S	Oral	Unk	Not Reported
Oracilline	S	Oral	Unk	Not Reported
Vfend	S	Oral	Unk	Not Reported
Ventoline	S	Respiratory (inhalation)	Unk	Not Reported
Pulmicort	S	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	14553524	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-857628		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure; Venocclusive Disease	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15001588	EXPEDITED (15-DAY)		DE, OT	DE-MYLANLABS-2018M1038512		82 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiopulmonary Failure	Cabergoline			S	Parenteral	1 Df, 1x/Woche		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Mylan
	Optrex /01376401/			C				Mylan
	Unacid /00903602/			C	Intravenous (not			Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					otherwise specified)				
	Furosemid /00032601/	C			40 Mg,1-0-0				Mylan
	Emselex /01760401/	C			7.5 Mg, 1-0-0				Mylan
	Ibuprofen	C	Oral		Bei Bedarf				Mylan
	Simvastatin	C			20 Mg, 0-0-1/2				Mylan
	Pantoprazol /01263201/	C			40 Mg, 1-0-0				Mylan
	Promethazin	C			25 Mg, 0-0-1				Mylan
	Hylo-Comod	C							Mylan
	Relvar Ellipta	C			1 Df, 1-0-0				Mylan
	L Thyrox	C			100 G, 1-0-0				Mylan
	Atrovent	C			Bei Bedarf				Mylan
	Xarelto	C			20 Mg, 0-1-0 17.30 Uhr				Mylan
	Amitriptylene	C			25 Mg, 0-0-1				Mylan
	Ramipril	C			2.5 Mg, 1-0-0				Mylan
	Bisoprolol	C			5 Mg, 1-0-0				Mylan
	Kochsalz	C			Bei Bedarf				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220208	NON-EXPEDITED		HO, OT	US-APOTEX-2018AP018155		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Apotex	
	Cefepime			S	Unknown	Unk		Apotex	
	Cefepime			S				Apotex	
	Vancomycin Hcl			S	Unknown	Unk		Not Reported	
	Vancomycin Hcl			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220283	EXPEDITED (15-DAY)		DE, OT	US-APOTEX-2018AP017945		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Piperacillin & Tazobactam	S	Unknown	Unk	Apotex
	Azithromycin	S	Unknown	Unk	Apotex
	Cefazolin	S	Unknown	Unk	Apotex
	Cefuroxime	S	Unknown	Unk	Apotex
	Ciprofloxacin	S	Unknown	Unk	Apotex
	Cefepime	S	Unknown	Unk	Apotex
	Meropenem	S	Unknown	Unk	Not Reported
	Vancomycin Hcl	S	Unknown	Unk	Not Reported
	Ampicillin Sodium And Sulbactam Sodium	S	Unknown	Unk	Not Reported
	Voriconazole	S	Unknown	Unk	Not Reported
	Ceftazidime	S	Unknown	Unk	Not Reported
	Ampicillin Sodium	S	Unknown	Unk	Not Reported
	Gentamicin Sulfate	S	Unknown	Unk	Not Reported
	Trimethoprim Sulfamethoxazole	S	Unknown	Unk	Not Reported
	Aztreonam	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220563	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1055347			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Loss Of Consciousness; Vomiting	Azithromycin			S	Oral	250 Mg^2 Tables (One^Per Day During^1 Day) Then 1^Tablet (One^Per Day During^4 Days)		Not Reported	
	Pivalone /00803802/			C	Nasal	1 Spray 2 To4 Times Per Day		Mylan	
	Ibuprofen			C	Oral	1200 Mg, Qd		Mylan	
	Claradol			C	Oral	Unk, Qd		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220790	EXPEDITED (15-DAY)		OT	PHEH2018US029886		22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypogammaglobulinaemia ; Mycoplasma Infection	Everolimus			S	Unknown	Unk		Novartis	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Sirolimus			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220846	EXPEDITED (15-DAY)		LT	PHHY2018US052757		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response Decreased	Azithromycin			S	Unknown			Novartis	
	Vancomycin			S	Unknown			Not Reported	
	Zosyn			S	Unknown			Not Reported	
	Heparin			C	Intravenous drip			Not Reported	
	Lovenox			C	Unknown			Not Reported	
	Decadron			C	Unknown	1 Mg, Unk		Not Reported	
	Micafungin			C	Unknown			Not Reported	
	Bactrim			C	Unknown	Unk		Not Reported	
	Cefepime			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15220862	EXPEDITED (15-DAY)		HO	PHHY2018FR055574		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Decreased Appetite; Dysgeusia; Haemoptysis	Lamprene			S	Oral	100 Mg, Qd		Novartis	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15221303	EXPEDITED (15-DAY)		DE	US-QILU PHARMACEUTICAL CO.LTD.-QLU-000577- 2018		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Resistance	Cefepime Hydrochloride			S	Unknown	Unk		Qilu Pharmaceutical
	Cefazolin			S	Unknown	Unk		Qilu Pharmaceutical
	Ampicillin Sodium			S	Unknown	Unk		Not Reported
	Gentamicin Sulfate			S	Unknown	Unk		Not Reported
	Trimethoprim, Sulfamethoxazole			S	Unknown	Unk		Not Reported
	Aztreonam			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Cefuroxime			S	Unknown	Unk		Not Reported
	Voriconazole			S	Unknown	Unk		Not Reported
	Ampicillin Sodium, Sulbactam Sodium			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Piperacillin, Tazobactam			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Vancomycin Hcl			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15221513	EXPEDITED (15-DAY)		HO, OT	US-SUNOVION- 2018SUN002969			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Arterial Hypertension	Indacaterol And Glycopyrrolate			S	Respiratory (inhalation)	1 Df, Unk (Par Jour)		Sunovion
	Zithromax			S	Oral	250 Mg, Q48h		Not Reported
	Sprycel			S	Oral	1 Df, 100 Mg Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2018	15222636	EXPEDITED (15-DAY)		HO	PHHY2018IT058213		64 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cell Death; Cholestasis; Liver Disorder	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	14908898	EXPEDITED (15-DAY)		HO, LT, OT	BG-MYLANLABS- 2018M1019363		63 YR	Male	BGR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous;	Azithromycin			S	Unknown	Unk		Not Reported	
Hypoproteinaemia;	Azithromycin			S				Not Reported	
Hypotension;	Azithromycin			S				Not Reported	
Leukocytosis; Mucosal Necrosis; Nikolsky'S Sign; Oral Mucosa Erosion; Oral Mucosal Exfoliation; Pain In Extremity; Penile Blister; Penile Erosion; Penile Haemorrhage; Peripheral Swelling; Rales; Rash; Skin Necrosis; Stevens- Johnson Syndrome; Tachycardia; Toxic Epidermal Necrolysis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15218837	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-179832		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Oedema	Amoxicillin/Clavulanic Acid			S	Oral	2 Df, Daily		Ranbaxy	
Peripheral; Pruritus	Azithromycin			S	Oral	1 Df, Daily		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Lyrica	C	Oral	1 Df, Unk	Not Reported
	Pantorc 20 Mg Compresse	C	Oral	1 Df, Unk	Not Reported
	Gastroresistenti				
	Gentalyn Beta	C	Cutaneous	1 Df, Unk	Not Reported
	Norvasc 5 Mg Compresse	C	Oral	1 Df, Unk	Not Reported
	Cymbalta 30 Mg Hard Gastro-Resistant Capsules	C	Oral	1 Df, Unk	Not Reported
	Zyllt 75 Mg Film-Coated Tablets	C	Oral	1 Df, Unk	Not Reported
	Lasix 25 Mg Compresse	C	Oral	1 Df, Unk	Not Reported
	Simvastatin	C	Oral	1 Df, Unk	Not Reported
	Lexotan 2,5 Mg/MI Gocce Orali Soluzione	C	Oral	1 Df, Unk	Not Reported
	Norapril 2,5 Mg Compresse	C	Oral	1 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15226129	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-05374		33 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Respiratory Failure	Azithromycin			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Vancomycin			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15226589	EXPEDITED (15-DAY)		HO, OT	PHHY2018JP053578		39 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Hypoxia; Pneumonia Mycoplasmal	Azithromycin			S	Unknown	2 G, Unk		Not Reported
	Prednisolone			S	Unknown	40 Mg, Qd		Novartis
	Methylprednisolone			S	Unknown	1 Mg, Qd		Not Reported
	Ampicillin + Sulbactam			S	Unknown	6 G, Qd		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15227629	EXPEDITED (15-DAY)		HO	IT-BAUSCH-BL-2018-020262		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Erythromycin			S	Cutaneous			Bausch And Lomb	
	Augmentin			S	Oral			Not Reported	
	Zitromax			S	Oral			Not Reported	
	Moxifloxacin Hydrochloride			S	Oral			Not Reported	
	Metformin Hydrochloride			C	Oral			Not Reported	
	Diamicron			C	Oral			Not Reported	
	Cotareg			C	Oral	80/12.5mg		Not Reported	
	Lyrica			C	Oral			Not Reported	
	Targin			C	Oral	10/5 Mg		Not Reported	
	Tareg			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2018	15228136	EXPEDITED (15-DAY)		OT	PHHY2018FR056624		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Bilirubin Increased; Blood Lactate Dehydrogenase Increased; Chills; Dyspnoea; Haemoglobin Decreased; Haemolytic Anaemia; Hepatocellular Injury; Jaundice	Azithromycin			S	Oral	500 Mg, Unk		Novartis	
	Paracetamol			C	Oral	1 G, Unk		Not Reported	
	Omeprazole			C	Oral	20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	14602747	EXPEDITED (15-DAY)		HO, OT	PHHY2017PL201439		10 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cryptosporidiosis Infection; Diarrhoea; Immunosuppressant Drug Level Increased; Off Label Use; Varicella; Weight Decreased	Mycophenolate Mofetil	S	Unknown	Unk		Not Reported
	Mycophenolate Mofetil	S				Not Reported
	Tacrolimus	S	Unknown	Unk		Novartis
	Tacrolimus	S				Novartis
	Sirolimus	S	Unknown	Unk		Not Reported
	Sirolimus	S				Not Reported
	Sirolimus	S				Not Reported
	Azithromycin	S	Unknown	Unk		Not Reported
	Azithromycin	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15230553	NON-EXPEDITED			US-TEVA-2018-US-936217			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15231384	NON-EXPEDITED			US-PFIZER INC-2018311084		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15231849	NON-EXPEDITED			US-PFIZER INC-2018307780		15 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2018	15233115	EXPEDITED (15-DAY)		LT, OT	CN-PFIZER INC-2018308014		6 YR	Female	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Dyspnoea	Zithromax			S	Oral	200 MI, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	13548896	NON-EXPEDITED			US-PFIZER INC-2017024408		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Inappropriate Schedule Of Product Administration; Product Administration Error	Zmax			S	Oral	2 G, Single (One Time)		Pfizer	
	Zmax			S				Pfizer	
	Zmax			S				Pfizer	
	Zmax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15125038	NON-EXPEDITED			US-PFIZER INC-2018278586		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Acetaminophen			S		Unk		Not Reported	
	Aspirin			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15235157	EXPEDITED (15-DAY)		HO, LT, OT	CN-ALKEM LABORATORIES LIMITED-CN-ALKEM-2018-00098		24 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Cefuroxime Axetil			S	Unknown	Unk		Alkem	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Moxifloxacin	S	Unknown	Unk	Not Reported
Cefotaxime	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Not Reported
Cilastatin Sodium, Imipenem	S	Unknown	Unk	Not Reported
Cefminox Sodium	S	Unknown	Unk	Not Reported
Oseltamivir	S	Unknown	Unk	Not Reported
Oseltamivir	S	Unknown	Unk	Not Reported
Vancomycin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15235193	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-180385		39 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Drug Ineffective; Pathogen Resistance	Azithromycin			S	Unknown	2 G, Unk		Sun
	Ampicillin/Sulbactam			S	Unknown	6 G, Daily		Not Reported
	Prednisolone			S	Unknown	40 Mg, Daily		Taro
	Methylprednisolone			S	Unknown	1 G, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15235400	NON-EXPEDITED			US-PFIZER INC- 2018311435		59 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15235510	NON-EXPEDITED			US-PFIZER INC- 2018313340		64 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity		Azithromycin		S				Pfizer	
		Morphine Sulfate		S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15238089	EXPEDITED (15-DAY)		HO	US-GLENMARK PHARMACEUTICALS- 2018GMK036843		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Systemic Candida	Tacrolimus			S	Unknown	Unk		Glenmark	
	Tacrolimus			S				Glenmark	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S				Not Reported	
	Imuran /00001501/			S	Unknown	Unk		Not Reported	
	Imuran /00001501/			S				Not Reported	
	Valganciclovir			S	Unknown	Unk		Not Reported	
	Valganciclovir			S				Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Bactrim			S	Unknown	Unk		Not Reported	
	Bactrim			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15238451	EXPEDITED (15-DAY)		HO	PHHY2018CZ062609		69 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphthous Ulcer; Haemoglobin Decreased; Leukopenia; Thrombocytopenia; Tonsillitis	Azithromycin			S	Unknown	Administered After Tonsillitis As Ae Treatment		Novartis	
	Leflunomide Medac			S	Oral	20 Mg, Unk		Not Reported	
	Meloxicam			C	Oral	15 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15239528	NON-EXPEDITED			US-PFIZER INC- 2018309783			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2018	15239573	NON-EXPEDITED			US-PFIZER INC-2018313772			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2018	14709047	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-017576		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pleural Effusion; Pneumonia; Pyrexia	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2018	15241431	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR-APL-2018-038988		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	13142553	NON-EXPEDITED			US-PFIZER INC-2017025097		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect	Zithromax			S		500 Mg, 1x/Day (The First		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Incomplete									
	Zithromax		S			Day)			Pfizer
						250 Mg, 1x/Day (The Next Day)			
	Zithromax		S						Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	13497614	EXPEDITED (15-DAY)		DE, HO	DE-TEVA-761836GER		60 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Cardiovascular Disorder; Diarrhoea; Multiple Organ Dysfunction Syndrome; Pseudomembranous Colitis; Sepsis; Vomiting	Azithromycin			S	Oral			Teva
	Ramipril			C	Oral			Not Reported
	Amlodipin			C	Oral	Long-Term Medication		Not Reported
	Novalgin (Metamizole Sodium)			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15243205	EXPEDITED (15-DAY)		HO, OT	NL-TEVA-2018-NL-933682		65 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Appetite Disorder; Back Pain; Bone Pain; Chronic Obstructive Pulmonary Disease; Dehydration; Dizziness; Fatigue; Headache; Hypersensitivity; Malaise; Myalgia; Nausea; Pneumonia; Sense Of Oppression; Vomiting; Weight Decreased	Azithromycin			S	Unknown			Not Reported
	Teriparatide			S	Subcutaneous	20 Microgram Daily;		Not Reported
	Teriparatide			S	Subcutaneous	20 Microgram Daily;		Not Reported
	Teriparatide			S	Subcutaneous	20 Microgram Daily;		Not Reported
	Teriparatide			S	Subcutaneous	20 Microgram Daily;		Not Reported
	Nebusal			S	Respiratory (inhalation)	2 Dosage Forms Daily;		Not Reported
	Adenuric			S	Unknown			Not Reported
	Spironolacton			C	Oral	1 Dosage Forms Daily;		Not Reported
	Beclometasone Dipropionate W/Formoterol Fumar			C	Oral	6 Dosage Forms Daily; Aerosol (Spray And Inhalation)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Budesonide	C	Oral	Inhaler	Not Reported
Pantoprazol	C	Oral	2 Dosage Forms Daily;	Not Reported
Itraconazol	C	Oral	2 Dosage Forms Daily;	Not Reported
Macrogol	C	Oral		Not Reported
Benzbromaron	C	Oral	1 Dosage Forms Daily;	Not Reported
Benzbromaron	C	Oral	.5 Dosage Forms Daily;	Not Reported
Levothyroxine	C	Oral	3 Dosage Forms Daily;	Not Reported
Levothyroxine	C		1 Dosage Forms Daily;	Not Reported
Paracetamol	C	Oral	4 Dosage Forms Daily; 1 Df, Qid	Not Reported
Paracetamol	C	Oral	3 Dosage Forms Daily; 1 Df, Tid	Not Reported
Hidroxocobalamina	C	Subcutaneous		Not Reported
Kaliumchloride	C	Oral	3d1t	Not Reported
Oxicodona	C	Oral	8 Dosage Forms Daily; 2 Df, Qid	Not Reported
Colchicine	C	Oral	2 Dosage Forms Daily;	Not Reported
Codeine	C	Oral	3 Dosage Forms Daily;	Not Reported
Azitromycine	C	Oral	1 Df, 3/W	Not Reported
Sodium Chloride	C	Subcutaneous	1 Df, Monthly (1/M)	Not Reported
Paracetamol Codeine	C	Rectal		Not Reported
Acetylcysteine	C	Oral	1 Dosage Forms Daily;	Not Reported
Calciumcarbonaat	C	Oral	2 Dosage Forms Daily;	Not Reported
Ipratropium W/Salbutamol	C	Oral		Not Reported
Algeldrate W/Magnesium Hydroxide	C	Oral	30 MI Daily; Suspension	Not Reported
Fentanyl	C	Topical		Not Reported
Oxycodon	C	Oral		Not Reported
Labetalol	C	Oral	1 Dosage Forms Daily;	Not Reported
Sumatriptan	C	Oral		Not Reported
Desloratadine	C	Oral	2 Dosage Forms Daily;	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycine	C	Oral	1 Df, 3/W	Not Reported
Metoclopramide	C	Oral	1 Df, Prn	Not Reported
Metoclopramide	C	Rectal	1 Df, Pm	Not Reported
Colistine	C	Oral	2 Dosage Forms Daily;	Not Reported
Ezetimibe W/Simvastatin	C	Oral	1 Dosage Forms Daily;	Not Reported
Pregabalin	C	Oral	6 Dosage Forms Daily; 3 Df, Bid	Not Reported
Salbutamol	C	Respiratory (inhalation)		Not Reported
Nystatine	C	Oral	20 MI Daily; Suspension	Not Reported
Colecalciferol	C	Oral	2 Df, Unk, Liquid	Not Reported
Moxifloxacin	C	Oral	1 Dosage Forms Daily;	Not Reported
Carbasalatcalcium	C	Oral	1 Dosage Forms Daily;	Not Reported
Metformin	C	Oral	2 Dosage Forms Daily;	Not Reported
Prednisolon	C		1 Dosage Forms Daily;	Not Reported
Tiotropium	C	Oral	2 Dosage Forms Daily;	Not Reported
Nortriptyline	C	Oral		Not Reported
Bumetanide	C	Oral	2 Dosage Forms Daily;	Not Reported
Fluticasone Furoate	C	Nasal	2 Dosage Forms Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15243560	NON-EXPEDITED			US-PFIZER INC-2018313272		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Gentamycin			S		Unk		Unknown
	Zithromax			S		Unk		Pfizer
	Daypro			S		Unk		Pfizer
	Zomig			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245335	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018314497		82 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Pruritus	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer
	Amoxicillin/Clavulanic Acid			S	Oral	2 Df, 1x/Day		Not Reported
	Cymbalta			C	Oral	1 Df, Unk		Not Reported
	Pantorc			C	Oral	1 Df, Unk		Not Reported
	Gentalyn Beta			C	Cutaneous	1 Df, Unk		Not Reported
	Lexotan			C	Oral	1 Df, Unk		Not Reported
	Lasix /00032601/			C	Oral	1 Df, Unk		Not Reported
	Zyllt			C	Oral	1 Df, Unk		Not Reported
	Lyrica			C	Oral	1 Df, Unk		Not Reported
	Norvasc			C	Oral	1 Df, Unk		Not Reported
	Norapril			C	Oral	1 Df, Unk		Not Reported
	Simvastatin			C	Oral	1 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245417	NON-EXPEDITED			US-PFIZER INC-2018314921		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245515	EXPEDITED (15-DAY)		HO	PHHY2018FR061964		75 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pancreatitis Acute	Amoxicillin	S	Oral	Unk	Novartis				
	Clarithromycin	S	Oral	Unk	Not Reported				
	Azithromycin	S	Oral	Unk	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245534	NON-EXPEDITED			US-TEVA-2018-US-939372			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15245943	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018311612		1 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiomyopathy	Zithromax			S	Oral	90 Mg, 1x/Day			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2018	15246173	NON-EXPEDITED			US-PFIZER INC-2018313790		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	14732368	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2018US-169468		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown				Sun
	Montelukast			S	Unknown				Not Reported
	Prednisolone			S	Unknown				Taro

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Theophylline	S	Unknown	Sun
Ivig	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	14847740	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018178605		11 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Periorbital Swelling; Rash Erythematous; Respiratory Distress	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15248902	NON-EXPEDITED			US-PFIZER INC-2018313490			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Lamotrigine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15248966	NON-EXPEDITED			US-PFIZER INC-2018315101		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Meperidine Hcl			S		Unk		Unknown
	Azithromycin			S		Unk		Pfizer
	Diltiazem Hcl			S		Unk		Unknown
	Diphenhydramine Hcl			S		Unk		Unknown
	Levofloxacin			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Pfizer
	Prochlorperazine Edisylate			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15250653	EXPEDITED (15-DAY)		LT	IT-SA-2018SA144408		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Toxic Epidermal Necrolysis	Diazepam			S	Oral	20 Drop, Prn		Not Reported	
	Zolpidem Tartrate			S	Oral	10 Mg, Qd		Sanofi	
	Quetiapine Fumarate			S	Oral	200 Mg, Qd		Not Reported	
	Rocefin			S	Parenteral	Unk Unk, Unk		Not Reported	
	Azithromycin Dihydrate			S	Oral	Unk Unk, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15250816	EXPEDITED (15-DAY)		OT	PHEH2018US032196		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acid Fast Bacilli Infection; Breast Abscess; Breast Mass; Mucormycosis; Mycobacterial Infection; Pathogen Resistance	Clindamycin			S	Unknown	Unk		Novartis	
	Clindamycin			S				Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Linezolid			S	Unknown	Unk		Not Reported	
	Levaquin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2018	15251652	NON-EXPEDITED			US-PFIZER INC- 2018313261		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Lisinopril			S		Unk		Not Reported	
	Lopressor			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2018	14994904	NON-EXPEDITED			US-PFIZER INC-2018235966			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Darvon			S		Unk		Not Reported	
	Methadone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	14782714	EXPEDITED (15-DAY)		HO, OT	PT-WEST-WARD PHARMACEUTICALS CORP.-PT-H14001-18-03		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pleural Effusion; Pneumonia; Pyrexia	Amoxicillin/Clavulanic Acid			S	Unknown	Unk Unk, Unknown Freq. ()		Hikma	
	Azithromycin			S	Unknown	Unk Unk, Unknown Freq. ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15259026	EXPEDITED (15-DAY)		HO	PT-HIKMA PHARMACEUTICALS USA INC.-PT-H14001-18-066		63 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pleural Effusion	Ceftriaxone			S	Unknown	()		Hikma	
	Azithromycin			S	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2018	15259083	EXPEDITED (15-DAY)		HO	PT-HIKMA PHARMACEUTICALS USA INC.-PT-H14001-18-066		72 YR	Unknown	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective	Amoxicillin And Clavulanic Acid			S	Unknown			Hikma	
	Azithromycin			S	Unknown	()		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15259430	NON-EXPEDITED			US-PFIZER INC- 2018320451		45 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15259459	NON-EXPEDITED			US-PFIZER INC- 2018319868		58 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15260552	NON-EXPEDITED			US-TEVA-2018-US- 939414			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Disorientation	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Aug-2018	15261991	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- 2018317853			Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Arthralgia; Large Intestinal Stenosis; Oral Herpes;	Azithromycin			S	Unknown	Unk		Pfizer	
	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rash; Tonsillitis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15253845	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-180836		2 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Sun	
	Fluconazole			S	Unknown	6 Mg/Kg, Daily		Sun	
	Ketoconazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15264682	NON-EXPEDITED			US-PFIZER INC- 2018319728		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance	Azithromycin			S		Unk		Pfizer	
	Sulfanilamide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15264884	NON-EXPEDITED			US-PFIZER INC- 2018323604		52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Aug-2018	15265888	NON-EXPEDITED			US-PFIZER INC- 2018321554			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Aug-2018	15267380	EXPEDITED (15-DAY)		DE	FR-ABBVIE-18K-056-2449283-00		56 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Ischaemic; Necrotising Colitis	Humira			S	Subcutaneous	1 Injection/14j		Not Reported	
	Novatrex			S	Oral			Not Reported	
	Naproxene			S	Oral	0-0-1		Not Reported	
	Methotrexate			S	Oral			Not Reported	
	Speciafoldine			C		2 Taken In The Morning Every 7 Days		Not Reported	
	Allopurinol			C				Not Reported	
	Amlodipine			C				Not Reported	
	Valsartan			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	11614195	EXPEDITED (15-DAY)		HO, OT	PHHO2015US014732		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Blinded Azithromycin			S	Respiratory (inhalation)	Code Not Broken		Not Reported	
	Blinded No Treatment Received			S	Respiratory (inhalation)	Code Not Broken		Not Reported	
	Blinded Placebo			S	Respiratory (inhalation)	Code Not Broken		Not Reported	
	Tobi			S	Unknown	Run In Phase		Not Reported	
	Hypersal			C	Respiratory (inhalation)	4 MI, Qd		Not Reported	
	Albuterol			C	Respiratory (inhalation)	2 Df, Bid (2 Puffs)		Not Reported	
	Albuterol			C	Respiratory (inhalation)	0.25 MI, Qd		Not Reported	
	Pulmozyme			C	Respiratory	2.5 MI, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					(inhalation)				
	Ibuprofen	C	Oral	200 Mg, Prn					Not Reported
	Ibuprofen	C							Not Reported
	Miralax	C	Oral	1 Df, Qd (1 To 1/2 Cap)					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15235542	NON-EXPEDITED			US-PFIZER INC-2018313112		35 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Meloxicam			S		Unk		Not Reported	
	Ultram			S		Unk		Not Reported	
	Ambien			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15268557	EXPEDITED (15-DAY)		OT	PHHY2018CZ068201		46 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Pruritus; Pruritus; Pruritus; Swelling; Tongue Pruritus	Azithromycin 1a Pharma			S	Oral	500 Mg, Qd		Novartis	
	Lorista			C	Oral	Unk		Not Reported	
	Letrox			C	Oral	Unk		Not Reported	
	Yasminelle			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15269957	NON-EXPEDITED			US-PFIZER INC-2018323767		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15271278	EXPEDITED (15-DAY)		OT	PHHY2018IT070582		39 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Swelling Face	Azithromycin			S	Oral	Unk			Not Reported
	Amoxicillin+Clavulanic Acid			S	Oral	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15271581	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2018319970			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis Ischaemic	Zithromac			S	Oral	Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15272127	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US- 943496			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactoid Reaction	Azithromycin			S	Oral				Not Reported
	Tacrolimus			C	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2018	15273414	EXPEDITED (15-DAY)		HO	FR- GLAXOSMITHKLINE- FR2018141234		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Myopathy	Sporanox			S		200 Mg, Qd			Glaxosmithkline
	Seretide Diskus			S	Respiratory (inhalation)	2 Puff(S), Qd			Glaxosmithkline
	Azithromycine			S	Oral	250 Mg, Unk			Glaxosmithkline
	Ramipril			C		Unk			Glaxosmithkline

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Lansoprazole		C			Unk			Glaxosmithkline
	Mysoline		C			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15158305	NON-EXPEDITED			US-PFIZER INC-2018287345		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin				S		Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15274800	NON-EXPEDITED			US-TEVA-2018-US-943451		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Azithromycin				S	Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15275613	EXPEDITED (15-DAY)			US-CELLTRION INC.-2018US021030			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Infliximab (Unknown)				S	Endocervical	Unk		Not Reported
	Azithromycin				S	Unknown	Unk		Not Reported
	Mesalamine				S	Unknown			Not Reported
	Remicade				S	Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15276944	EXPEDITED (15-DAY)		HO, OT	ES-GLAXOSMITHKLINE-ES2018142414		67 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation;	Tavanic				S	Oral	1 Al Dia		Glaxosmithkline
Palpitations; Tachycardia	Zinnat				S	Oral	500 Mg, Qd		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zitromax	S	Unknown	Unk	Glaxosmithkline
Ventolin	C	Unknown	1 Eachs 8 Hours	Glaxosmithkline
Atorvastatin	C	Oral	10 Mg. 1 A Day (Night)	Glaxosmithkline
Emcoretic	C	Oral	10 Mg/ 25 Mg	Not Reported
Pulmicort	C	Unknown	1/12 Horas	Not Reported
Openvas	C	Oral	40 Mg. 1 A Day (Night)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15277560	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-943497			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactoid Reaction	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Tacrolimus			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15277933	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20180807532		59 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Myopathy	Sporanox			S	Unknown			Not Reported
	Seretide			S	Respiratory (inhalation)			Not Reported
	Azithromycine			S	Oral			Not Reported
	Mysoline			C	Unknown			Not Reported
	Ramipril			C	Unknown			Not Reported
	Lansoprazole			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15278119	EXPEDITED (15-DAY)		CA, DE, OT	FR-GILEAD-2018-0354689			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Induced; Foetal Exposure During Pregnancy; Foetal Malformation; Limb Deformity	Eviplera	S	Transplacental	1 Df, Qd	Gilead
	Azithromycine	S	Transplacental	1 G, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15278390	EXPEDITED (15-DAY)		OT	PHHY2018IT071714		82 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Oedema Peripheral; Pruritus	Amoxicillin+Clavulanic Acid			S	Oral	2 Df, Unk		Not Reported
	Azithromycin			S	Oral	1 Df, Qd		Novartis
	Simvastatin			C	Oral	1 Df, Unk		Not Reported
	Pantorc			C	Oral	1 Df, Unk		Not Reported
	Gentalyn Beta			C	Cutaneous	1 Df, Unk		Not Reported
	Zyllt			C	Oral	1 Df, Unk		Not Reported
	Cymbalta			C	Oral	1 Df, Unk		Not Reported
	Lexotan			C	Oral	1 Df, Unk		Not Reported
	Norvasc			C	Oral	1 Df, Unk		Not Reported
	Lasix			C	Oral	1 Df, Unk		Not Reported
	Lyrice			C	Oral	1 Df, Unk		Not Reported
	Norapril			C	Oral	1 Df, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2018	15311082	DIRECT		OT			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin Tablets			S	Oral	Quantity:6 Tablet(S);		Sandoz
	Albuterol Mdi			C				Not Reported
	Claritin			C				Not Reported
	Vit C			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	14534229	EXPEDITED (15-DAY)		HO	PHHY2018ES022133		78 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina			S	Oral	500 Mg, Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Dia		Not Reported
	Metamizol			C	Intravenous (not otherwise specified)	2gr/8h		Not Reported
	Metilprednisolona			C	Oral	20 Mg, Dia		Not Reported
	Omeprazol			C	Unknown	1 Cp		Not Reported
	Metformina			C	Oral	Unk		Not Reported
	Insulina Glargina			C	Subcutaneous	10 Ui De		Not Reported
	Paracetamol			C	Intravenous (not otherwise specified)	1 G, Tid (1-1-1)		Not Reported
	Enoxaparina			C	Subcutaneous	40 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	14915364	EXPEDITED (15-DAY)		HO, OT	ES-009507513-1805ESP005546		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anaemia; Mycobacterium Chelonae Infection; Neuropathy Peripheral; Pancreatitis Acute; Product Use In Unapproved Indication; Pulmonary Embolism	Sivextro			S	Oral	Unk		Merck
	Tobramycin			S		Unk		Not Reported
	Moxifloxacin			S	Oral	Unk		Not Reported
	Tigecycline			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Acenocoumarol			C		Unk		Not Reported
	Amoxicillin (+) Clavulanate			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Potassium Amikacin		C		Unk			Not Reported	
	Rifabutin		C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15196922	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018296515		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Neuropathy Peripheral; Pancreatitis Acute; Pulmonary Embolism	Tigecycline			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Moxifloxacin			S	Oral	Unk		Not Reported	
	Tobramycin			S				Not Reported	
	Sivextro			S	Oral	Unk		Not Reported	
	Acenocoumarol			C		Unk		Not Reported	
	Acenocoumarol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15226222	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2018132717		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Pancytopenia	Novatrex			S	Oral	Unk		Glaxosmithkline	
	Voltarene (Diclofenac Sodium)			S	Oral	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15279632	NON-EXPEDITED			US-PFIZER INC-2018324762			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Musculoskeletal Stiffness; Pain	Zithromax			S		Unk		Pfizer	
	Rocephin			S	Intramuscular	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15279852	EXPEDITED (15-DAY)		HO, OT	NL-PFIZER INC-2018324131		65 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Appetite Disorder; Back Pain; Bone Pain; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Dehydration; Dizziness; Fatigue; Headache; Hypersensitivity; Malaise; Myalgia; Nausea; Pneumonia; Sense Of Oppression; Vomiting; Weight Decreased	Azithromycin			S		Unk		Pfizer
	Adenuric			S		Unk		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, 1x/Day		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, 1x/Day		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, 1x/Day		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, 1x/Day		Not Reported
	Nebusal			S	Respiratory (inhalation)	2 Df, 1x/Day		Not Reported
	Spironolacton			C	Oral	1 Df, 1x/Day		Not Reported
	Beclometasone Dipropionate W/Formoterol Fumar			C	Oral	2 Df, 3x/Day		Not Reported
	Budesonide			C	Oral	Unk		Not Reported
	Pantoprazol			C	Oral	1 Df, Twice A Day		Not Reported
	Itraconazol			C	Oral	1 Df, 2x/Day		Not Reported
	Macrogol			C	Oral	Unk		Not Reported
	Benzbromaron			C	Oral	1 Df, 1x/Day		Not Reported
	Benzbromaron			C	Oral	0.5 Df, 1x/Day		Not Reported
	Levothyroxine			C	Oral	3 Df, 1x/Day		Not Reported
	Levothyroxine			C		1 Df, 1x/Day		Not Reported
	Paracetamol			C	Oral	1 Df, 4x/Day		Not Reported
	Paracetamol			C	Oral	1 Df, 3x/Day		Not Reported
	Hidroxicobalamina			C	Subcutaneous	Unk		Not Reported
Kaliumchloride			C	Oral	1 Df, 3x/Day		Not Reported	
Oxicodona			C	Oral	2 Df, 4x/Day		Not Reported	
Colchicine			C	Oral	1 Df, 2x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeine	C	Oral	1 Df, 3x/Day	Not Reported
Azitromycine	C	Oral	1 Df, Three Times Per Week	Not Reported
Azitromycine	C	Oral	1 Df, Three Times A Week	Not Reported
Sodium Chloride	C	Subcutaneous	1 Df, Monthly	Not Reported
Paracetamol Codeine	C	Rectal	Unk	Not Reported
Acetylcysteine	C	Oral	1 Df, Daily	Not Reported
Calciumcarbonaat	C	Oral	2 Df, 1x/Day	Not Reported
Ipratropium W/Salbutamol	C	Oral	Unk	Not Reported
Algeldrate W/Magnesium Hydroxide	C	Oral	15 MI, 2x/Day	Not Reported
Fentanyl	C	Topical	Unk	Not Reported
Oxycodon	C	Oral	Unk	Not Reported
Labetalol	C	Oral	1 Df, 1x/Day	Not Reported
Sumatriptan	C	Oral	Unk	Not Reported
Desloratadine	C	Oral	1 Df, 2x/Day	Not Reported
Metoclopramide	C	Oral	1 Df, As Needed	Not Reported
Metoclopramide	C		1 Df, As Needed	Not Reported
Colistine	C	Oral	1 Df, Twice A Day	Not Reported
Ezetimibe W/Simvastatin	C	Oral	1 Df, 1x/Day	Not Reported
Pregabalin	C	Oral	3 Df, Twice A Day	Not Reported
Salbutamol	C	Respiratory (inhalation)	Unk	Not Reported
Nystatine	C	Oral	5 MI, Four Times A Day	Not Reported
Colecalciferol	C	Oral	2 Df, Unk	Not Reported
Moxifloxacin	C	Oral	1 Df, 1x/Day	Not Reported
Carbasalaatcalcium	C	Oral	1 Df, 1x/Day	Not Reported
Metformine	C	Oral	1 Df, 2x/Day	Not Reported
Prednisolon /00016201/	C		1 Df, 1x/Day	Not Reported
Tiotropium	C	Oral	2 Df, 1x/Day	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Nortriptyline	C	Oral	Unk		Not Reported			
	Bumetanide	C	Oral	1 Df, 2x/Day		Not Reported			
	Fluticasone Furoate	C	Nasal	2 Df, 1x/Day		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15281687	NON-EXPEDITED			US-PFIZER INC-2018329650			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2018	15281875	EXPEDITED (15-DAY)		DE, OT	ID-PFIZER INC-2018329648			Unknown	IDN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15204712	EXPEDITED (15-DAY)		HO	PHHY2018IT052890		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sopor	Aripiprazole			S	Oral	210 Mg, Total		Not Reported	
	Escitalopram			S	Oral	140 Mg, Total		Not Reported	
	Alprazolam			S	Oral	15 MI, Total		Novartis	
	Zitromax			S	Oral	1500 Mg, Total		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	1200 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15283298	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-041261		59 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myopathy	Azithromycin			S	Oral	Every 2 Days		Aurobindo	
	Sporanox			S	Unknown	200 Milligram, Once A Day		Not Reported	
	Seretide Discus			S	Respiratory (inhalation)	2 Puffs A Day		Not Reported	
	Mysoline			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	
	Lansoprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15283436	NON-EXPEDITED			US-PFIZER INC-2018326452		14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2018	15285670	EXPEDITED (15-DAY)		DE, OT	PHHY2018GR068185		65 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Death; Hepatic Cirrhosis	Piperacillin, Tazobactam			S	Unknown	Unk		Novartis	
	Trimethoprim Sulfamethoxazole			S	Unknown	Unk		Not Reported	
	Doxycycline Monohydrate			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Vancomycin Hydrochloride			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	14491068	NON-EXPEDITED		LT	US-PFIZER INC-2018052526		10 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	14540272	EXPEDITED (15-DAY)		OT	US-JNJFOC-20161208062		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Anxiety; Arthralgia;	Imbruvica			S	Oral			Not Reported	
Back Pain; Bleeding Time	Imbruvica			S	Oral			Not Reported	
Prolonged; Blood Blister;	Imbruvica			S	Oral			Not Reported	
Bone Pain; Chest Pain;	Z-Pak			S				Not Reported	
Dry Skin; Dyspnoea;	Z-Pak			S				Not Reported	
Eustachian Tube	Z-Pak			S				Not Reported	
Dysfunction; Eyelid	Lorazepam			C				Not Reported	
Infection; Haemorrhage;	Acyclovir			C				Not Reported	
Impaired Healing; Medical	Bactrim			C				Not Reported	
Device Site Irritation;									
Muscle Spasms; Muscle									
Tightness;									
Musculoskeletal Pain;									
Myalgia; Nasopharyngitis;									
Nausea; Onychomycosis;									
Osteochondroma; Papule;									
Platelet Count Abnormal;									
Pustule; Rash Macular;									
Sinusitis; Skin Abrasion;									
Stomatitis; Stress;									
Temporomandibular Joint									
Syndrome; Tendonitis;									
White Blood Cell Count									
Decreased; Wound									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15130588	EXPEDITED (15-DAY)		HO, OT	FI-PFIZER INC-2018272960		60 YR	Female	FIN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia; Cataract	Zithromax			S		Unk		Pfizer	
Nuclear; Exfoliation	Atrodual			C		Unk		Not Reported	
Glaucoma; Hypoacusis;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Incorrect Product Administration Duration; Ocular Hypertension; Tympanic Membrane Perforation; Visual Impairment	Pulmicort	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15132396	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018014766			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Levofloxacin			S	Oral	1 Dosage Form, Qd		Macleods
	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported
	Olmetec20 Mg			C	Oral	Unk, Film Coated Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15287955	NON-EXPEDITED			US-PFIZER INC- 2018330936		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Reglan			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15288275	NON-EXPEDITED			US-PFIZER INC- 2018330858		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2018	15291643	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT- 942191		182 DAY	Male	ITA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Erythema	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2018	15292003	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-042175		27 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Malaise; Pain In Extremity; Urethritis Mycoplasmal; Urinary Tract Infection	Azithromycin			S	Unknown	1 G, Unk		Aurobindo	
	Azithromycin			S	Unknown	250 Mg, Qd (4 Days)		Aurobindo	
	Azithromycin			S	Unknown	500 Ot, Unk		Aurobindo	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Pristinamycin			S	Unknown	1 G, Qd		Not Reported	
	Pristinamycin			S	Unknown	Unk		Not Reported	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2018	15292031	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR-APL-2018-042416		73 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Ear Discomfort	Azithromycin			S	Oral	750 Milligram, Every Week		Aurobindo	
	Anoro			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	14925357	EXPEDITED (15-DAY)		HO, OT	ES-BAYER-2018-097598		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Mycobacterium Chelonae Infection; Neuropathy Peripheral; Pancreatitis Acute;	Tedizolid Phosphate			S	Oral	Unk		Bayer	
	Moxifloxacin Oral			S		Unk		Bayer	
	Tobramycin			S				Not Reported	
	Tigecycline			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use In Unapproved Indication; Pulmonary Embolism	Azithromycin	S	Unk	Not Reported
	Acenocoumarol	C	Unk	Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Acenocoumarol	C		Not Reported
	Amoxicillin W/Clavulanate	C		Not Reported
	Potassium			
	Amikacin	C		Not Reported
	Rifabutin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15275025	NON-EXPEDITED			US-PFIZER INC- 2018325463		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15293558	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-041809			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Dyspnoea; Hyperhidrosis	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
	Tacrolimus			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15293797	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-041808			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactoid Reaction; Swollen Tongue	Azithromycin			S	Oral	Unk		Aurobindo	
	Tacrolimus			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15294981	NON-EXPEDITED			US-PFIZER INC- 2018334946		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15294984	NON-EXPEDITED			US-PFIZER INC- 2018334004		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Glipizide			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15295022	NON-EXPEDITED			US-PFIZER INC- 2018334587		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15295436	EXPEDITED (15-DAY)		DS	PHHY2018FR072295		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Neuropathy Peripheral; Paraesthesia	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Zyvoxid			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15295575	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT074238		17 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy;	Nimesulide			S	Unknown	Unk		Not Reported	
Conjunctival Hyperaemia;	Clarithromycin			S	Unknown			Novartis	
Enanthema; Eye	Azithromycin			S	Unknown			Not Reported	
Discharge; Genital	Bilastine			S	Unknown			Not Reported	
Ulceration; Lip Erythema;	Brivudine			S	Unknown			Not Reported	
Lip Oedema; Lung									
Infiltration; Nasal Mucosal									
Disorder; Oral Mucosa									
Erosion; Pyrexia; Rash									
Maculovesicular; Rash									
Papular; Stevens-Johnson									
Syndrome									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2018	15318893	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Influenza;	Azithromycin 250 Mg			S				Not Reported	
Swelling									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	14817081	EXPEDITED (15-DAY)		DE, OT	PHHY2018FR073183			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug	Ceftriaxone			S	Intravenous (not	2 G, Qd		Novartis	
Level Increased; Hepatic					otherwise specified)				
Failure; Hepatitis; Off	Ceftriaxone			S	Intravenous (not	100 Mg, Qd		Novartis	
Label Use					otherwise specified)				
	Bisoprolol Fumarate			S	Oral	5 Mg, Qd		Not Reported	
	Trimebutine Arrow			S	Oral	200 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bisoce	S	Oral	5 Mg, Qd	Not Reported
Vfend	S	Intravenous (not otherwise specified)	800 Mg, Qd	Not Reported
Vfend	S	Unknown	400 Mg, Qd	Not Reported
Iclusig	S	Oral	45 Mg, Qd	Not Reported
Zyloric	S	Oral	100 Mg, Bid	Not Reported
Zyloric	S	Oral	100 Mg, Qd	Not Reported
Zyloric	S	Oral	100 Mg, Qd	Not Reported
Zyloric	S	Oral	200 Mg, Qd	Not Reported
Lasilix	S	Oral	40 Mg, Qd	Not Reported
Lasilix	S	Oral	20 Mg, Qd	Not Reported
Hydrocortisone	S	Intravenous (not otherwise specified)	100 Mg, Qd	Not Reported
Polaramine	S	Intravenous (not otherwise specified)	5 Mg, Qd	Not Reported
Zithromax	S	Unknown	500 Mg, Unk (Single)	Not Reported
Zithromax	S	Oral	250 Mg, Qd	Not Reported
Hydrea	S	Oral	500 Mg, Bid	Not Reported
Cortancyl	C	Unknown		Not Reported
Cortancyl	C	Unknown	40 Mg, Qd	Not Reported
Topalgic (Tramadol Hydrochloride)	C	Unknown	50 Mg, Prn	Not Reported
Movicol	C	Unknown		Not Reported
Movicol	C	Unknown	2 Ug/Litre, Qd	Not Reported
Renagel	C	Unknown	800 Mg, (1 Day)	Not Reported
Spasfon [Phloroglucinol]	C	Unknown		Not Reported
Atarax	C	Unknown	12.5 Mg, Qd	Not Reported
Fasturtec	C	Intravenous (not otherwise specified)	7.5 Mg, Once	Not Reported
Stilnox	C	Unknown		Not Reported
Stilnox	C	Unknown	10 Mg, Prn	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Polyethylene Glycol 3350	C	Unknown		Not Reported
	Phloroglucinol	C	Unknown	80 Mg, Prn	Not Reported
	Sodium Hydrogen Carbonate	C	Unknown		Not Reported
	Potassium Chloride	C	Unknown		Not Reported
	Sodium Bicarbonate	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15299085	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-04588			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Metrorrhagia	Blisovi 24 Fe 1 Mg/0.02 Mg And 0.75 Mg Azithromycin			S	Unknown	Unk		Lupin	
				S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15299444	EXPEDITED (15-DAY)		HO, OT	FR-TEVA-2018-FR- 944832		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Myopathy	Azithromycine Anhydre			S	Oral	Every 2 Days		Not Reported	
	Sporanox			S		200 Milligram Daily;		Not Reported	
	Seretide Diskus			S	Respiratory (inhalation)	2 Puffs A Day		Not Reported	
	Mysoline			C				Not Reported	
	Ramipril			C				Not Reported	
	Lansoprazole			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15300877	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT068263		17 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Conjunctival Hyperaemia;	Nimesulide			S	Unknown	Unk		Not Reported	
	Nimesulide			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enanthema; Eye	Azithromycin	S	Unknown	Unk	Novartis
Discharge; Genital	Azithromycin	S			Novartis
Ulceration; Lip Erythema;	Clarithromycin	S	Unknown	Unk	Not Reported
Lip Oedema; Lung	Clarithromycin	S			Not Reported
Infiltration; Nasal Mucosal	Bilastine	S	Unknown	Unk	Not Reported
Disorder; Oral Mucosa	Bilastine	S			Not Reported
Erosion; Pyrexia; Rash	Bilastine	S			Not Reported
Maculovesicular; Rash	Bilastine	S			Not Reported
Papular; Stevens-Johnson	Bilastine	S			Not Reported
Syndrome	Bilastine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15300954	EXPEDITED (15-DAY)		DS	GB-TEVA-2018-GB-947408		73 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Ear Discomfort	Azithromycin Dihydrate			S	Oral				Not Reported
	Anoro			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15301731	EXPEDITED (15-DAY)		OT	PHHY2018GB073268		19 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Oral	1 G, Qd			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15302910	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-16X-056-1269449-00		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Creon			S	Oral	7 Df, Qd			Mylan
	Ventilastin Novolizer			S	Respiratory (inhalation)	Unk			Mylan
	Montelukast			S	Oral	Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aerius (Desloratadine)	S	Oral	1 Df, Qd	Mylan
Pariet	S	Oral	1 Df, Qd (1dosage Formsqd)	Mylan
Orelox	S	Oral	2 Df, Bid (4 Df Dosage Form Every Days)	Mylan
Zithromax	S	Oral	1 Df, Qd (1dosage Formsqd)	Mylan
Tobi 300mg/5ml	S	Respiratory (inhalation)	Form Strength: 300mg/5ml	Mylan
Speciafoldine	S		Unk	Mylan
Mopral /00661201/	S		Unk	Mylan
Augmentin /00756801/	S		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2018	15304739	NON-EXPEDITED			US-PFIZER INC- 2018335122			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2018	6441683	EXPEDITED (15-DAY)		OT	CHNY2007GB03209		21 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Arthropathy; Blood Creatinine Increased; Blood Urea Increased; Drug Interaction; Dyspepsia; Hypophagia; Inadequate Analgesia; Influenza Like Illness; Vomiting; Weight Decreased	Tobramycin			S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd		Novartis
	Azithromycin			S	Unknown			Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported
	Colomycin (Colistin)			S	Intravenous (not otherwise specified)	2 Df, Tid		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306077	NON-EXPEDITED			US-PFIZER INC-2018337898		37 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15306716	EXPEDITED (15-DAY)		HO, LT	PHHY2018US075155		365 DAY	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Overdose; Toxicity To Various Agents	Azithromycin			S	Unknown			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2018	15308047	NON-EXPEDITED			US-PFIZER INC-2018334040			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Reaction To Excipient	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15311521	EXPEDITED (15-DAY)		DS	GB-PFIZER INC-2018335616		73 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Deafness; Ear Discomfort	Azithromycin			S	Oral	750 Mg, 1x/Week		Pfizer	
	Anoro			C		Inhaler		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2018	15312909	EXPEDITED (15-DAY)		HO, LT, OT	ZA-MYLANLABS-2018M1063199		24 YR	Female	ZAF
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Ketoacidosis; Maternal Exposure During Pregnancy	Azithromycin	S	Unknown	Not Reported
	Metronidazole	S	Unknown	Not Reported
	Betamethasone	S	Unknown	Not Reported
	Ceftriaxone	C	Unknown	Mylan
	Ringer Lactate /01126301/	C	Other	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	13120523	NON-EXPEDITED			US-PFIZER INC- 2017014092			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Augmentin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	13952587	EXPEDITED (15-DAY)		OT	CA-ROCHE-1988520		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatitis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Mycophenolate Mofetil			S	Oral			Not Reported	
	Cancidas			S	Intravenous (not otherwise specified)			Not Reported	
	Ciprofloxacin Hydrochloride			S	Oral			Not Reported	
	Montelukast			S	Oral			Not Reported	
	Nifedipine			S	Oral			Not Reported	
	Pantoprazole			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Tacrolimus			S	Oral			Not Reported	
	Trimethoprim Sulfa			S	Oral			Not Reported	
	Voriconazole			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15314333	NON-EXPEDITED			US-PFIZER INC-2018342229		55 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316056	NON-EXPEDITED		OT	US-APOTEX-2018AP019764			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316257	NON-EXPEDITED		OT	US-APOTEX-2018AP019763			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316258	NON-EXPEDITED		OT	US-APOTEX-2018AP019767			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk Unk, Unknown		Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316662	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018337935		59 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Interaction; Myopathy; Product Use	Azithromycine			S	Oral	250 Mg, Every Two Days		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue	Sporanox	S	Respiratory (inhalation)	200 Mg, 1x/Day	Not Reported
	Seretide Discus	S		2 Df, 1x/Day	Not Reported
	Mysoline	C		Unk	Not Reported
	Ramipril	C		Unk	Not Reported
	Lansoprazole	C		Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316746	EXPEDITED (15-DAY)		OT	GB-009507513-2011SP019063		17 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chlamydial Infection; Drug Interaction; Pregnancy With Implant Contraceptive; Skin Infection; Tonsillitis	Implanon			S	Subcutaneous			Merck	
	Azithromycin			S	Oral	1 G, Taken Immediately		Not Reported	
	Penicillin (Unspecified)			S	Oral	250 Mg, Qid		Not Reported	
	Floxacillin			S	Oral			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15316898	NON-EXPEDITED		OT	US-APOTEX-2018AP019765			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15317006	NON-EXPEDITED		OT	US-APOTEX-2018AP019766			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk Unk, Unknown		Apotex	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Aug-2018	15317775	NON-EXPEDITED		OT	US-APOTEX-2018AP019769			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15317788	NON-EXPEDITED		OT	US-APOTEX-2018AP019770			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15317792	NON-EXPEDITED		OT	US-APOTEX-2018AP019768			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2018	15317793	NON-EXPEDITED		OT	US-APOTEX-2018AP019762			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	12957728	EXPEDITED (15-DAY)		OT	FR-ABBVIE-16P-056-1786066-00		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Creon			S	Oral	7 Df, Qd		Not Reported	
	Creon			S				Not Reported	
	Ventilastin Novolizer			S	Respiratory (inhalation)	Unk		Not Reported	
	Aerius (Ebastine)			S	Oral	1 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pariet	S	Oral	1 Df, Qd (1dosage Formsqd)	Not Reported
Orelox	S	Oral	2 Df, Bid (4 Df Dosage Form Every Days)	Not Reported
Zithromax	S	Oral	1 Df, Qd (1dosage Formsqd)	Not Reported
Tobi	S	Respiratory (inhalation)	Form Strength: 300mg/5ml	Not Reported
Speciafoldine	S	Unknown	Unk	Not Reported
Mopral	S	Unknown	Unk	Not Reported
Augmentin	S	Unknown	Unk	Not Reported
Singulair	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15129245	NON-EXPEDITED			US-PFIZER INC-2018278042		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Claritin			S		Unk		Not Reported
	Claritin			S		Unk		Not Reported
	Humira			C	Subcutaneous	Unk		Not Reported
	Cimzia			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15235541	NON-EXPEDITED			US-PFIZER INC-2018309704		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Clindamycin Hcl			S	Oral	Unk		Pfizer
	Azithromycin			S	Oral	Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15287069	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-943316		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Moxifloxacin Hydrochloride			S	Oral	1 Dosage Forms Daily;		Teva	
	Erythromycin			S	Cutaneous	3 Dosage Forms Daily;		Not Reported	
	Augmentin			S	Oral	3 Dosage Forms Daily;		Not Reported	
	Zitromax 500 Mg Compresse			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Rivestite Con Film								
	Diamicron 30 Mg Compresse A Rilascio Modificato			C	Oral			Not Reported	
	Cotareg 80 Mg/12,5 Mg			C	Oral			Not Reported	
	Compresse Rivestite Con Film								
	Metformin Hydrochloride			C	Oral			Not Reported	
	Lyricea			C	Oral			Not Reported	
	Targin 10 Mg/5mg Compresse A Rilascio Prolungato			C	Oral			Not Reported	
	Tareg			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15319764	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-022855		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Doxycycline			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15319793	EXPEDITED (15-DAY)		HO	FR-ROCHE-2174923		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Fall; Small Cell Lung Cancer; Wrist	Mabthera			S	Unknown	Cyclic Doses		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fracture	Mabthera	S	Unknown	Cyclic Doses	Not Reported
	Mabthera	S	Unknown	Cyclic Doses	Not Reported
	Mabthera	S	Unknown	Cyclic Doses Last Dose On /Jan/2010	Not Reported
	Novatrex	S	Oral	2.5 Mg, Unk	Not Reported
	Novatrex	S	Oral	2.5 Mg, Unk	Not Reported
	Orencia	S	Intravenous drip	Last Dose On 23/Mar/2011	Not Reported
	Enbrel	S	Subcutaneous	Last Dose In Dec/2007	Not Reported
	Humira	S	Subcutaneous	Last Dose In Apr/2008	Not Reported
	Mopral	C	Unknown		Not Reported
	Atacand	C	Unknown		Not Reported
	Levothyrox	C	Unknown		Not Reported
	Cortancyl	C	Unknown	Unk	Not Reported
	Tocilizumab	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15320675	EXPEDITED (15-DAY)		OT	PHHY2017GB204608			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Arthralgia; Large Intestinal Stenosis; Oral Herpes; Rash; Tonsillitis	Azithromycin			S	Unknown	Unk		Novartis
	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15322236	EXPEDITED (15-DAY)		HO	PHHY2018ES083026		64 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchospasm; Hypotension	Azitromicina			S	Intravenous (not otherwise specified)	500 Mg, Total		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15323274	EXPEDITED (15-DAY)		OT	PHHY2018CA078597		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mental Status Changes	Imipenem+Cilastatin Sodium			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Novartis	
	Minocycline			S	Unknown			Not Reported	
	Tigecycline			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15323343	EXPEDITED (15-DAY)		OT	US-BAUSCH-BL-2018-022753		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Clindamycin			S	Unknown			Not Reported	
	Clindamycin			S				Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Ceftriaxone			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15323468	EXPEDITED (15-DAY)		DS	PHHY2018GB082290		73 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Ear Discomfort	Azithromycin			S	Oral	750 Mg, Qw		Novartis	
	Anoro			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15323676	EXPEDITED (15-DAY)		HO, OT	ZA-BAXTER-2018BAX022160		24 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated;	Metris	S	Unknown	Claris
Foetal Heart Rate	Azithromycin	S	Unknown	Not Reported
Deceleration Abnormality;	Ringer'S Lactate	C	Intravenous drip	Not Reported
Maternal Exposure During	Ringer'S Lactate	C	Intravenous drip	Not Reported
Pregnancy; Premature	Ceftriaxone	C	Unknown	Not Reported
Labour; Vomiting	Ceftriaxone	C	Unknown	Not Reported
	Betamethasone	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2018	15337779	DIRECT	Y	LT			72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt	Azithromycin			S	Oral		3 DAY	Not Reported
Prolonged;	Cefdinir			C				Not Reported
Hypocalcaemia;								
Hypokalaemia; Loss Of								
Consciousness; Mental								
Status Changes								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15129279	NON-EXPEDITED			US-PFIZER INC- 2018278670		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15319935	EXPEDITED (15-DAY)		HO, OT	ZA-STRIDES ARCOLAB LIMITED- 2018SP007052			Unknown	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Exposure	Metronidazole			S	Unknown	Unknown		Strides
During Pregnancy;	Azithromycin			S	Unknown	Unknown		Not Reported
Ketoacidosis; Metabolic	Betamethasone			S	Unknown	Unknown		Not Reported
Acidosis; Nausea; Sinus								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tachycardia; Tachypnoea; Vomiting	Ceftriaxone	S	Unknown	Unk	Not Reported
	Ringer Lactate /01126301/	S	Intravenous (not otherwise specified)	Unknown	Not Reported
	Dextrose	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15324450	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR- 938739		33 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure Via Breast Milk; Hypersensitivity; Lip Swelling; Mouth Swelling; Swelling Face; Tongue Discomfort	Azithromycine Teva 250 Mg			S		2 Dosage Forms Daily;		Not Reported
	Cetirizine			C	Unknown	1 Tablet Every Evening		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15324619	NON-EXPEDITED			US-PFIZER INC- 2018342096			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Tetracycline Hcl			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15324704	EXPEDITED (15-DAY)		HO, OT	ZA-FLAMINGO-002074		24 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Foetal Heart Rate	Metronidazole			S				Not Reported
Deceleration Abnormality;	Azithromycin			S				Not Reported
Maternal Exposure During	Calcium Chloride			C				Not Reported
	Anhydrous/Potassium							

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pregnancy; Premature Labour; Vomiting Chloride/Sodium Lactate

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15326017	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018343063		67 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Palpitations; Tachycardia	Zitromax			S		Unk		Pfizer
	Zinnat [Cefuroxime Axetil]			S	Oral	500 Mg, 1x/Day		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Atorvastatin			C	Oral	10 Mg, 1x/Day (Night)		Not Reported
	Emcoretic			C	Oral	10 Mg/ 25 Mg		Not Reported
	Pulmicort			C		200 Ug, Alternate Day (1/12 Hours)		Not Reported
	Ventolin [Salbutamol]			C		Unk Unk, 3x/Day (One Every 8 Hours)		Not Reported
	Openvas			C	Oral	40 Mg, 1x/Day (Night)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2018	15327128	NON-EXPEDITED			US-PFIZER INC-2018344881			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	14692963	EXPEDITED (15-DAY)		DS, OT	PHHY2018PT053873		34 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exfoliative Rash; Pain In Extremity; Rash Macular	Azithromycin Sandoz			S	Oral	500 Mg, Qd (24/ 24 Hour)		Novartis
	Paracetamol			C	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15322810	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC-2018340703		29 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Obliterative Bronchiolitis; Toxic Epidermal Necrolysis	Azithromycin			S		0.25 G, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15329987	EXPEDITED (15-DAY)		DS, OT	PHHY2018CA077473		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Azithromycin Sandoz			S	Unknown	Unk		Novartis	
	Ciprofloxacin Sandoz			S	Oral	500 Mg, Qd		Not Reported	
	Ciprofloxacin Sandoz			S				Not Reported	
	Teva Quetiapine			S	Oral	25 Mg, Bid		Not Reported	
	Apo Quetiapine E			S	Oral	100 Mg, Qd		Not Reported	
	Zyprexa			C	Unknown	Unk		Not Reported	
	Risperidone			C	Unknown	Unk		Not Reported	
	Amoxicillin			C	Unknown	Unk		Not Reported	
	Epival			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15329998	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT039932		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pleural Effusion; Pneumonia; Pyrexia	Azithromycin			S	Unknown			Novartis	
	Amoxicillin, Clavulanate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15330045	EXPEDITED (15-DAY)		HO	PHHY2018PT079924		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Amoxicillin And Clavulanate Azithromycin			S S	Unknown Unknown			Novartis Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15330229	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018347187		182 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Azithromycin			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15330902	NON-EXPEDITED			US-PFIZER INC- 2018346409		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl Zithromax			S S		Unk Unk		Pfizer Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15330936	NON-EXPEDITED			US-PFIZER INC- 2018346632			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin Effexor Xr			S S		Unk Unk		Pfizer Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15332089	EXPEDITED (15-DAY)		HO	PHHY2018PT079913		63 YR	Unknown	PRT

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Ceftriaxone			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15332115	EXPEDITED (15-DAY)		HO	PHHY2018PT080010		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Azithromycin			S	Unknown			Novartis	
	Amoxicillin And Clavulanate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15332124	EXPEDITED (15-DAY)		HO	PHHY2018PT079922		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Azithromycin			S	Unknown			Novartis	
	Amoxicillin / Clavulansauere			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2018	15332136	EXPEDITED (15-DAY)		DE, OT	PHHY2018FR080366		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Hepatocellular Injury	Voriconazole			S	Unknown	On Day 8: 400 Mg Morning 200 Mg Night		Novartis	
	Voriconazole			S	Unknown	800 Mg, Qd, From Day 4 To Day 7		Novartis	
	Voriconazole			S	Unknown	200 Mg, Qd, On Day 9: Administered Only In The Morning		Novartis	
	Voriconazole			S	Unknown	400 Mg, Qd, On Day 3		Novartis	
	Azithromycin			S	Unknown	250 Mg, Qd, From Day 3		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	To Day 9	
Ponatinib	S	Unknown	500 Mg, Qd, On Day 2	Not Reported
			45 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	13362559	NON-EXPEDITED			US-PFIZER INC-2017123260		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Celecoxib			S		Unk		Pfizer
	Neurontin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	14243217	NON-EXPEDITED			US-PFIZER INC-2017511119		44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Erythema; Fungal Infection	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	14598409	EXPEDITED (15-DAY)		OT	FR-SYNTHON BV-NL01PV18_46737		60 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Levocetirizine Dihydrochloride			S		5 Mg, Daily		Not Reported
	Montelukast/Montelukast			S		10 Mg, Unk		Not Reported
	Sodium Azithromycin			S		250 Milligram, Every Other Day For 3 Months		Not Reported
	Salbutamol			S		6 Puffs/Day		Not Reported
	Salmeterol			C		Unk		Not Reported
	Fluticasone			C	Nasal	55 ?G/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15143093	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018276213			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Enterocolitis Haemorrhagic; Haemorrhage; Pseudomembranous Colitis	Zithromac 250mg			S		500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15313135	EXPEDITED (15-DAY)		OT	PHHY2007GB013964		52 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury	Tobramycin			S	Intravenous (not otherwise specified)	120 Mg, Tid		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Tobi			S	Unknown	Unk		Not Reported	
	Colomycin (Colistin)			S	Intravenous (not otherwise specified)	120 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15334038	EXPEDITED (15-DAY)		OT	US-APOTEX-2018AP019947		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Mycophenolate			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15334086	EXPEDITED (15-DAY)		HO	PHHY2018PT080003		72 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Amoxicillin And Clavulanate			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15334099	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT039857		63 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pleural Effusion; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Novartis	
	Azithromycin			S				Novartis	
	Ceftriaxone			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15334116	EXPEDITED (15-DAY)		OT	PHHY2018DE081552		11 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Nephritis	Azithromycin			S	Unknown	Unk		Novartis	
	Elvanse			C	Unknown	Unk		Not Reported	
	Mictonetten			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15334285	NON-EXPEDITED			US-PFIZER INC- 2018346422			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334301	NON-EXPEDITED			US-PFIZER INC-2018346511			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334307	NON-EXPEDITED			US-PFIZER INC-2018348952		48 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334402	NON-EXPEDITED			US-PFIZER INC-2018348259			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334446	NON-EXPEDITED			US-PFIZER INC-2018348467		52 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Aug-2018	15334846	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-949962		69 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acne; Pemphigoid; Pruritus; Pustule	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Amoxicillina E Acido Clavulanico	S	Oral					Not Reported	
	Hexal Ag	S						Not Reported	
	Momenxsin 200 Mg/30 Mg								
	Comprime Rivestite Con Film								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15335072	NON-EXPEDITED			US-TEVA-2018-US-948963		12 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15335730	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-948118			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rectal Haemorrhage	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15336091	EXPEDITED (15-DAY)		HO	PL-BAUSCH-BL-2018-023765		10 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Gentamicin			S	Topical				Bausch And Lomb
	Hydrocortisone			S	Topical				Not Reported
	Azithromycin			S	Oral				Not Reported
	Betamethasone			S	Topical				Not Reported
	Clotrimazole			S	Topical				Not Reported
	Sodium Chloride			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15336186	EXPEDITED (15-DAY)		HO, OT	ZA-B. BRAUN MEDICAL INC.-2054494		24 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Heart Rate Deceleration Abnormality; Maternal Exposure During Pregnancy; Nausea; Premature Labour; Tachypnoea; Vomiting	Metronidazole Injection Usp (5 Mg/Ml) In Pab® Plastic Container (Nda 0 Azithromycin Ringer'S Lactate Solution [Calcium Chloride, Potassium Chloride, Sodi	S S C	B Braun Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2018	15355601	DIRECT		LT			34 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Azithromycin			S	Oral	Quantity:6 Tablet(S);		Pliva	
	Levorthorexine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2018	15339153	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-824		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Renal Pain; Urinary Tract Infection; Urine Odour Abnormal	Maximum Strength Mucinex D Tablets			S	Unknown	1200 Mg, Bid		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	14705938	NON-EXPEDITED			US-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2018- BI-01		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Cough; Dry Eye; Dyspnoea; Fatigue; Myalgia; Oropharyngeal Pain	Ofev			S	Oral			Boehringer Ingelheim	
	Azithromycin			S	Unknown			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
	Benzonatate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zetia	C	Oral	Qd; Form Strength: 10mg	Not Reported
Aspirin	C	Oral	Qd; Form Strength: 81mg	Not Reported
Dexilant	C	Oral	Qd; Form Strength: 60mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15231059	NON-EXPEDITED		OT	US-APOTEX-2018AP018371		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Pleural Effusion	Dasatinib			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown			Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2018	15342555	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-183098		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myopathy	Azithromycin			S	Oral	250 Mg, Tous Les 2 Jours		Sun	
	Seretide Diskus			S	Respiratory (inhalation)	2 Bouffees Par Jour		Not Reported	
	Sporanox			S	Unknown	200 Mg, Daily		Not Reported	
	Lansoprazole			C	Unknown	Unk		Not Reported	
	Mysoline			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	14078500	NON-EXPEDITED			US-PFIZER INC-2017438954			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeine	S	Unk	Not Reported
Macrobid [Nitrofurantoin]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	14586888	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-010152		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Montelukast Film-Coated Tablet			S	Unknown	10 Milligram, Daily		Aurobindo	
	Levocetirizine			S	Unknown	5 Milligram, Once A Day		Not Reported	
	Salbutamol			S	Unknown	6 Puffs/Day		Not Reported	
	Azithromycin Film-Coated Tablets			S	Unknown	250 Milligram,Every Other Day For 3 Months		Aurobindo	
	Salmeterol			S	Unknown	6 Puffs/Day; 100 G/Day		Not Reported	
	Salmeterol			S	Unknown	0.1 Milligram		Not Reported	
	Fluticasone			S	Nasal	Dose: 55g/Day		Not Reported	
	Fluticasone			S	Unknown	1000 Ug,Qd		Not Reported	
	Fluticasone			S	Nasal	0.06 Milligram		Not Reported	
	Fluticasone			S	Nasal	1 Milligram		Not Reported	
	Salbutamol Sulfate			S	Unknown	6 Dosage Form, Once A Day (6 Puffs/Day)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15310008	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-AXELLIA-001882		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Drug Interaction; Drug Level Above Therapeutic; Hepatocellular Injury	Voriconazole			S		On Day 3,On Day 8: 400 Mg Morning 200 Mg Night;From Day 4 To Day 7		Not Reported	
	Ponatinib			S				Not Reported	
	Azithromycin			S		From Day 3 To Day 9		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Iclusig		S			45 Mg, Qd At Noon			Not Reported
	Azithromycin		S	Unknown		On Day 2			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15346067	EXPEDITED (15-DAY)		HO	HR-TEVA-2018-HR-951178		60 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Rash	Sumamed			S		Oral	500 Milligram Daily;		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15346441	NON-EXPEDITED			US-PFIZER INC-2018354385		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S			Unk		Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15347807	NON-EXPEDITED			US-TEVA-2018-US-949669		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Muscle Spasms	Azithromycin			S		Unknown			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15347910	EXPEDITED (15-DAY)		HO	IND-PT-009507513-1808PRT013002		49 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspartate Amino transferase Increased; Eosinophil Count Increased; Gamma-Glutamyltransferase Increased; Rash Maculo-Papular; Rash Pruritic	Exxiv 30 Mg Film-Coated Tablet			S		Oral	1 Df, Qd		Merck
	Zithromax			S		Oral			Not Reported
	Inderal			C		Oral	20 Mg, Qd		Not Reported
	Cipraxel			C		Oral	10 Mg, Qd		Not Reported
	Alprazolam			C		Oral	2 Mg, Qd		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15348143	EXPEDITED (15-DAY)		DE, OT	GB-JNJFOC-20180842660		68 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Off Label Use; Product Use In Unapproved Indication	Bedaquiline			S	Oral	400 Mg Daily For 2 Weeks Followed By 200 Mg Three Times A Week		Not Reported
	Azithromycin			S	Oral			Not Reported
	Trimethoprim			C	Unknown			Not Reported
	Morphine Sulphate			C	Unknown	10 Mg/ 5 MI		Not Reported
	Sertraline			C	Unknown	Morning		Not Reported
	Salbutamol			C	Unknown	Morning		Not Reported
	Ciprofloxacin			C	Unknown	Morning		Not Reported
	Clofazimine			C	Unknown	Morning		Not Reported
	Tiotropium			C	Unknown	Morning		Not Reported
	Rifampicin			C	Unknown	Morning		Not Reported
	Quinine Sulfate			C	Unknown	At Night		Not Reported
	Clarithromycin			C	Unknown	At Night		Not Reported
	Seretide			C	Unknown			Not Reported
	Co-Amilofruse			C	Unknown			Not Reported
	Oxygen			C	Unknown	On Long Term Oxygen Therapy		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2018	15367959	DIRECT	Y	DE			24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Azithromycin			S	Oral	Other Frequency:3 Times A Week;		Not Reported
	Albuterol			S	Respiratory			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

(inhalation)

Aquadeks	C	Not Reported
Breo Ellipta 200-25mch	C	Not Reported
Inhalation		
Escitalapram	C	Not Reported
Fluconazole	C	Not Reported
Heparin 100 Units/MI 5ml	C	Not Reported
Subcutaneous		
Lansoprazole	C	Not Reported
Loratadine	C	Not Reported
Megestrol	C	Not Reported
Mirtazapine	C	Not Reported
Montelukast	C	Not Reported
Proair Hfa 90 Mcg Inhaler	C	Not Reported
Pulmozyme	C	Not Reported
Tobramycin Inhalation	C	Not Reported
Ursodiol	C	Not Reported
Zenpep	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	13712669	EXPEDITED (15-DAY)		DE, HO, OT	RS-BAUSCH-BL-2017-016143		56 YR	Female	SRB

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Drug Ineffective; Megacolon; Metabolic Acidosis; Multiple Organ Dysfunction Syndrome	Amikacin Sulfate			S	Unknown	Ampoule		Not Reported
	Levofloxacin			S	Unknown	Ampoule		Not Reported
	Vancomycin			S	Unknown	Ampoule		Not Reported
	Vancomycin			S	Unknown			Not Reported
	Metronidazole			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S	Unknown	Ampoule		Not Reported
	Azithromycin Dihydrate			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	14922989	EXPEDITED (15-DAY)		OT	PHHY2018FR001533		60 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Montelukast Sodium	S	Unknown	10 Mg, Qd	Novartis
	Azithromycin	S	Unknown	250 Mg, Qod, For 3 Months	Not Reported
	Azithromycin	S	Unknown	250 Mg, Bid	Not Reported
	Azithromycin	S	Unknown	250 Milligram, Every Other Day For 3 Months	Not Reported
	Levocetirizine	S	Unknown	5 Mg, Qd	Not Reported
	Fluticasone Propionate	S	Unknown	1000 Mg, Unk	Not Reported
	Fluticasone Propionate	S	Nasal	55 G, Qd	Not Reported
	Salbutamol Sulfate	S	Unknown	6 Puffs/Day	Not Reported
	Salmeterol	S	Unknown	6 Df, Qd (6 Puffs)	Not Reported
	Salmeterol	S	Unknown	100 Mg, Qd (6 Puffs/Day; 100 ?G/Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15239191	EXPEDITED (15-DAY)		HO	PT-TEVA-2018-PT-933617		27 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Erythematous	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported
	Strepsils (Amylmetacresol\ Dichlorobenzyl Alcohol)			S	Oral	1 Dosage Forms Daily;		Not Reported
	Brufen			S	Oral	1 Dosage Forms Daily;		Not Reported
	Omeprazole			C	Oral	1 Dosage Forms Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2018	15343613	NON-EXPEDITED			US-PFIZER INC-2018352364		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Erythromycin			S		Unk			Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15352080	NON-EXPEDITED			PHEH2018US037033			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15352779	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2018351647		56 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Colitis Ischaemic; Necrotising Colitis	Novatrex			S	Oral	5 Mg, Weekly		Pfizer	
	Naproxene [Naproxen]			S	Oral	550 Mg, 1x/Day		Not Reported	
	Methotrexate			S	Oral	5 Mg, Weekly		Not Reported	
	Humira			S	Subcutaneous	1 Df, Unk		Not Reported	
	Speciafoldine			C		10 Mg, Weekly		Not Reported	
	Allopurinol			C		100 Mg, Daily		Not Reported	
	Valsartan			C		1 Df, Daily		Not Reported	
	Amlodipine			C		1 Df, Daily		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15353157	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2018243263		76 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Electrocardiogram Qt Prolonged; Loss Of Consciousness	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer	
	Lochol			C	Oral	20 Mg, 1x/Day		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2018	15371330	DIRECT	Y	HO, LT			78 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15049091	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2018-031839		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Mycobacterium Chelonae Infection; Neuropathy Peripheral; Pancreatitis Acute; Product Use In Unapproved Indication; Pulmonary Embolism	Azithromycin			S	Unknown	Unk		Aurobindo	
	Moxifloxacin			S	Oral	Unk		Aurobindo	
	Sivextro			S	Oral	Unk		Not Reported	
	Tigecycline			S	Unknown	Unk		Not Reported	
	Tigecycline			S				Not Reported	
	Tobramycin			S	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Amoxicillin And Clavulanate			C	Unknown	Unk		Not Reported	
Potassium									
Amikacin				C	Endocervical	Unk		Not Reported	
Rifabutin				C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15348702	EXPEDITED (15-DAY)		OT	FR-JNJFOC- 20180843093		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prostate Cancer	Remicade	S	Intravenous (not otherwise specified)	Not Reported
	Novatrex	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15354171	EXPEDITED (15-DAY)		OT	PHHY2018IT088754		69 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Pemphigoid; Pruritus; Pustule	Azithromycin			S	Oral	Unk		Novartis	
	Amoxicillina E Acido Clavulanico Hexal Ag			S	Oral	Unk		Not Reported	
	Ibuprofen With Pseudoephedrine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2018	15355106	NON-EXPEDITED			US-PFIZER INC-2018358720			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	12206492	NON-EXPEDITED			US-PFIZER INC-2016147043			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	12445400	NON-EXPEDITED			NL-LUPIN PHARMACEUTICALS INC.-2016-02129		14 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tachycardia	Azithromycin			S	Unknown	Unk Unk,Unk,Unknown		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fexofenadine	S	Unknown	Unk Unk,Unk,Unknown	Not Reported
Fluticasone	C	Nasal	Unk Unk,Bid,	Not Reported
Fluticasone/Salmeterol	C	Respiratory (inhalation)	100/50 Microg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	14943197	EXPEDITED (15-DAY)		HO, OT	HR-LUPIN PHARMACEUTICALS INC.-2018-03903		29 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous	Azithromycin Tablets, 500 Mg			S	Oral	500 Mg, Qd (3 Tablets Total)		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	14981186	EXPEDITED (15-DAY)		HO, OT	ES-CHIESI USA INC.-ES-2018CHI000144		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Tobramycin			S	Unknown	Unk		Chiesi	
Anaemia; Mycobacterium Chelonae Infection;	Moxifloxacin /01453202/			S	Oral			Not Reported	
Neuropathy Peripheral;	Tigecycline			S	Unknown	Unk		Not Reported	
Pancreatitis Acute;	Azithromycin			S	Unknown	Unk		Not Reported	
Product Use In Unapproved Indication;	Sivextro			S	Oral	Unk		Not Reported	
Pulmonary Embolism	Acenocoumarol			C		Unk		Not Reported	
	Amoxicillin And Clavulanate Potassium			C		Unk		Not Reported	
	Amikacin			C		Unk		Not Reported	
	Rifabutin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15088822	NON-EXPEDITED			US-PFIZER INC-2018264500		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359837	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-04387			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359838	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-05121			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Product Use In Unapproved Indication	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, As Directed		Lupin	
	Cymbalta			C	Oral	30 Mg, Qd		Not Reported	
	Montelukast			C	Oral	10 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359840	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-05714			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Abnormal; Pyrexia	Azithromycin Tablets			S	Unknown	Unk		Lupin	
	Magnesium			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359841	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-04500			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Azithromycin Tablets			S	Unknown	Unk		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15359842	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-04495			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin Tablets			S	Unknown	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15362526	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2011181999		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Non-Cardiac Chest Pain; Small Cell Lung Cancer; Wrist Fracture	Novatrex			S	Oral	2.5 Mg, Unk		Pfizer	
	Novatrex			S	Oral	2.5 Mg, Unk		Pfizer	
	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Orencia			S	Intravenous drip	Unk		Not Reported	
	Mabthera			S		Cyclic Doses		Not Reported	
	Mabthera			S		Cyclic Doses		Not Reported	
	Mabthera			S		Cyclic Doses		Not Reported	
	Mabthera			S		Cyclic Doses		Not Reported	
	Levothyrox			C				Not Reported	
	Atacand			C				Not Reported	
	Mopral			C				Not Reported	
	Cortancyl			C		Unk		Not Reported	
	Tocilizumab			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15362566	EXPEDITED (15-DAY)		OT	LV- GLAXOSMITHKLINE- LV2018GSK160689		17 YR	Female	LVA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During Pregnancy; Live Birth; Polyhydramnios;	Paracetamol	S							Glaxosmithkline
Premature Rupture Of Membranes; Treatment Noncompliance	Azithromycinum (Azithromycin)	S			500 Mg, Qd				Not Reported
	Ferrum	S							Not Reported
	Cefuroxime	S			750 Mg, Bid				Glaxosmithkline
	Penicillin G Benzathine	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Sep-2018	15362604	EXPEDITED (15-DAY)		CA, HO, OT	LV-GLAXOSMITHKLINE-LV2018GSK162548			Female	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Atresia; Foetal Exposure During Pregnancy	Paracetamol			S				Glaxosmithkline
	Azithromycinum (Azithromycin)			S				Not Reported
	Ferrum			S				Not Reported
	Cefuroxime			S				Glaxosmithkline
	Penicillin G Benzathine			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2018	15363917	NON-EXPEDITED			PHEH2018US036662			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Malaise	Azithromycin			S	Unknown	250 Mg, Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	14615923	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2017-07613		31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Exposure During Pregnancy	Azithromycin Tablets Usp, 250 Mg			S	Oral	2 Df, Qd		Lupin
	Azithromycin Tablets Usp, 250 Mg			S	Oral	1 Df, Qd		Lupin
	Diclegis			C		Not Provided		Not Reported
	Diclegis			C				Not Reported
	Tylenol Sinus			C		Not Provided		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	14988650	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018229184		88 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pain; Rhabdomyolysis	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromac 250mg			S				Pfizer	
	Aimix			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15204761	EXPEDITED (15-DAY)		HO, OT	PHHY2018ES053887		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Mycobacterium Chelonae Infection; Neuropathy Peripheral; Pancreatitis Acute; Product Use In Unapproved Indication; Pulmonary Embolism	Tobramycin			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Moxifloxacin			S	Oral	Unk		Not Reported	
	Tigecycline			S	Unknown	Unk		Not Reported	
	Tigecycline			S				Not Reported	
	Sivextro			S	Oral	Unk		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Amoxicillin And Clavula.			C	Unknown	Unk		Not Reported	
	Potassium Rifabutin			C	Unknown	Unk		Not Reported	
	Amikacin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2018	15241312	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2018-039314		18 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cardiac Arrest; Chest Pain; Dyspnoea;	Azithromycin			S	Unknown	Unk		Aurobindo	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Empyema; Lemierre
Syndrome; Lung Disorder;
Pleurisy; Pneumothorax;
Pyrexia; Respiratory
Failure

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15270190	NON-EXPEDITED			US-PFIZER INC- 2018322636		58 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15364671	NON-EXPEDITED			IN-LUPIN LIMITED- 2018-04437		21 YR	Male	IND
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
No Adverse Event; Product Physical Issue	Z-1 Film C. Tabls 500 Mg (Azithromycin)			S	Oral	1 Df, Qd		Lupin	
	Z-1 Film C. Tabls 500 Mg (Azithromycin)			S				Lupin	
	Z-1 Film C. Tabls 500 Mg (Azithromycin)			S				Lupin	
	Z-1 Film C. Tabls 500 Mg (Azithromycin)			S				Lupin	
	Pyrigesic			C	Oral	Unk, Tid		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15367563	NON-EXPEDITED			US-PFIZER INC- 2018362540		80 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Swelling	Azithromycin			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Sep-2018	15391989	DIRECT	Y	LT			60 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	12845590	NON-EXPEDITED			US-PFIZER INC-2016477339			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	14695515	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018125444		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Hypogammaglobulinaemia ; Product Use Issue; Sinusitis	Azithromycin			S		250 Mg, Alternate Day (Every Other Day For Three Months)		Pfizer	
	Montelukast			C		10 Mg, Daily		Not Reported	
	Levocetirizine			C		5 Mg, Daily		Not Reported	
	Salbutamol			C		Six Puffs A Day		Not Reported	
	Salmeterol			C		0.1 Mg, Daily		Not Reported	
	Fluticasone			C		1 Mg, Daily		Not Reported	
	Fluticasone			C	Nasal	0.055 Mg, Daily		Not Reported	
	<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>
11-Sep-2018	15362292	NON-EXPEDITED			PHEH2018US037057			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin Sandoz			S	Unknown			Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369044	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2018-024664			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection; Respiratory Distress	Prednisolone			S	Unknown			Bausch And Lomb	
	Azithromycin			S	Unknown			Not Reported	
	Montelukast			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369181	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020114		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Increased; Stress	Azithromycin			S	Oral	250 Mg, Q.3w		Apotex	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	300 Mg, Once Every 2 Week		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Salbutamol Sulfate			C	Respiratory (inhalation)	Unk, Inhalation		Not Reported	
	Spiriva			C	Respiratory (inhalation)	1 Df, Qd Inhalation		Not Reported	
	Symbicort			C	Respiratory (inhalation)	3 Df, Bid, Inhalation		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369365	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020115		25 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Headache	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefixime	S	Unknown	Unk	Not Reported
Remicade	S	Intravenous (not otherwise specified)	5 Mg/Kg, Once Every 8 Weeks	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369366	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020140		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chapped Lips; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder; Stomatitis; Urticaria	Azithromycin			S	Unknown	250 Mg, Unk		Apotex
	Xolair			S	Subcutaneous	300 Mg, Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Benadryl /00000402/			C	Oral	1 Df, Unk		Not Reported
	Cetirizine Hydrochloride			C	Oral	1 Df, Qd		Not Reported
	Prednisone			C	Oral	1 Df, Unk		Not Reported
	Singulair			C	Oral	10 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15369438	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-184000		69 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Pemphigoid; Pruritus; Pustule	Azithromycin			S	Oral	()		Sun
	Amoxicillina E Acido Clavulanico Hexal Ag			S	Oral	()		Not Reported
	Momenxsin 200 Mg/30 Mg Comprese Rivestite Con Film			S	Unknown	()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15370377	EXPEDITED (15-DAY)		HO, OT	JP-MYLANLABS-2018M1066420		53 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aspergillus Infection;	Hydrocortisone	S	Unknown	Not Reported
Fungal Infection;	Hydrocortisone	S		Not Reported
Mucormycosis; Peritonitis	Azithromycin	S	Unknown	Not Reported
	Azithromycin	S		Not Reported
	Meropenem	S	Unknown	Mylan
	Meropenem	S		Mylan
	Meropenem	S		Mylan
	Immunoglobulin /00025201/	C	Unknown	Mylan
	Immunoglobulin /00025201/	C		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2018	15370923	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP020137		68 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Cardiac Failure; Emphysema	Azithromycin			S	Unknown	Unk		Apotex
	Fluticasone			S	Unknown	2 Df, Bid		Apotex
	Rabeprazole			S	Unknown	Unk		Apotex
	Salbutamol			S	Unknown	Unk		Apotex
	Olodaterol Hydrochloride W/Tiotropi/08889701/			C	Other	2 Df, Qd , Route: Inhalation		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	8097248	EXPEDITED (15-DAY)		HO, OT	FR-AMGEN-FRASP2011040979		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fall; Non-Cardiac Chest Pain; Small Cell Lung Cancer; Wrist Fracture	Enbrel			S	Subcutaneous	Unk		Amgen
	Novatrex			S	Oral	2.5 Mg, Unk		Not Reported
	Novatrex			S	Oral	2.5 Mg, Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Orencia			S	Intravenous drip	Unk		Not Reported
	Mabthera			S	Unknown	Cyclic Doses		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mabthera	S	Unknown	Cyclic Doses	Not Reported
Mabthera	S	Unknown	Cyclic Doses	Not Reported
Mabthera	S	Unknown	Cyclic Doses	Not Reported
Levothyrox	C		Unk	Not Reported
Atacand	C		Unk	Not Reported
Mopral /00661201/	C		Unk	Not Reported
Cortancyl	C		Unk	Not Reported
Tocilizumab	C		Unk	Not Reported
Novatrex	S	Oral	2.5 Mg, Unk	Not Reported
Novatrex	S	Oral	2.5 Mg, Unk	Not Reported
Mopral	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	14707593	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-169107		60 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Montelukast			S	Unknown	10 Mg, Daily		Not Reported
	Levocetirizine			S	Unknown	5 Mg, Daily		Sun
	Azithromycin			S	Unknown	250 Milligram,Every Other Day For 3 Months		Sun
	Salbutamol Sulfate			S	Unknown	Daily		Not Reported
	Salmeterol			S	Unknown	6 Puffs/Day; 100 ?G/Day		Not Reported
	Fluticasone			C	Nasal	Dose: 55g/Day ()		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15100922	NON-EXPEDITED			US-PFIZER INC- 2018266370			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity; Muscle	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Spasms; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15337540	NON-EXPEDITED			US-PFIZER INC-2018350896		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15374521	NON-EXPEDITED			US-APOTEX-2018AP020050		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia	Azithromycin			S	Unknown			Apotex	
	Azithromycin			S				Apotex	
	Rosuvastatin			S	Unknown			Apotex	
	Rosuvastatin			S				Apotex	
	Immunoglobulin /00025201/			C	Intravenous (not otherwise specified)			Not Reported	
	Immunoglobulin /00025201/			C				Not Reported	
	Rituximab			C	Unknown			Not Reported	
	Rituximab			C				Not Reported	
	Fluticasone			C	Unknown			Not Reported	
	Fluticasone			C				Not Reported	
	Montelukast			C	Unknown			Not Reported	
	Montelukast			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15376437	EXPEDITED (15-DAY)		DS	PHHY2018PT096493		46 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Generalised Exanthematous Pustulosis	Azithromycin	S	Oral	500 Mg, Qd	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2018	15395995	DIRECT		DS, HO			64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Cough; Dyspnoea; Pruritus; Rash; Urticaria	Azithromycin			S	Oral	Quantity:2 Df Dosage Form;		Not Reported
	Diltiazem			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Proair/Hfa			C				Not Reported
	Albuterol Nebnephron			C				Not Reported
	Symbicort			C				Not Reported
	Singulair			C				Not Reported
	Metformin			C				Not Reported
	Cetirizine			C				Not Reported
	Ranitidine			C				Not Reported
	Diclofenac			C				Not Reported
	Cyclobenzaprine			C				Not Reported
	Tramadol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	12297846	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2016220465		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Psoriasiform	Solu-Medrol			S	Intravenous drip	20 Mg, Unk		Pfizer
	Novatrex			S	Oral	15 Mg, Weekly		Pfizer
	Orencia			S	Intravenous drip	750 Mg, 3x/Day (Thrice Weekly)		Not Reported
	Lyrica			C		50		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	13364529	EXPEDITED (15-DAY)		HO	FR-BEH-2017079054		21 YR	Male	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Myoclonus; Paraesthesia	Hizentra			S	Subcutaneous	Unk		Csl Behring
	Pantoprazole			S	Oral	Unk		Not Reported
	Hydrocortisone			S	Oral	Unk		Not Reported
	Seresta			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Neoral			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk		Not Reported
	Folinoral			S	Oral	Unk		Not Reported
	Zelitrex			S	Oral	Unk		Not Reported
	Oracillin /00001802/			S	Oral	Unk		Not Reported
	Vfend			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Ventolin /00139501/			S	Respiratory (inhalation)	Unk		Not Reported
	Pulmicort			S	Respiratory (inhalation)	Unk		Not Reported
	Terbutaline Sulphate			S	Respiratory (inhalation)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	14281826	NON-EXPEDITED		HO	US-PFIZER INC- 2017529077		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Intolerance; Nausea; Pain; Screaming	Azithromycin			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15306844	EXPEDITED (15-DAY)			ZA-PFIZER INC- 2018336584			Male	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Maternal Exposure During Pregnancy	Azithromycin	S	Transplacental	Unk	Pfizer
	Metronidazole	S	Transplacental	Unk	Not Reported
	Ringer-Lactate Solution	C	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15306977	EXPEDITED (15-DAY)			ZA-PFIZER INC-2018332255		24 YR	Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Vomiting	Azithromycin			S		Unk		Pfizer
	Metronidazole			S		Unk		Not Reported
	Ringer-Lactate Solution			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2018	15377194	NON-EXPEDITED			US-PFIZER INC-2018366377		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Advil			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Aleve			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	14712544	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-017497		63 YR	Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Pleural Effusion; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S				Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15221484	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-		19 YR	Female	GBR

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2018300880

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous	Azithromycin			S	Oral	1 G, Single (Stat Dose)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15385756	EXPEDITED (15-DAY)		HO	JP-TEVA-2018-JP-954206		53 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Fungal Infection; Mucormycosis; Peritonitis	Hydrocortisone			S	Unknown	Subsequently Tapered To 100 Mg/Day And Then 50 Mg/Day		Actavis	
	Azithromycin			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Immunoglobulin Nos			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15387460	EXPEDITED (15-DAY)		HO, OT	SK-MYLANLABS-2018M1067143			Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Live Birth; Maternal Exposure During Pregnancy; Retroplacental Haematoma	Azithromycin			S	Unknown	In 5 Gestation Week Of Pregnancy		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Sep-2018	15387462	EXPEDITED (15-DAY)		CA, HO	SK-MYLANLABS-2018M1067139			Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Congenital Cystic Lung; Foetal Exposure During	Azithromycin			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregnancy; Live Birth

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	14459456	EXPEDITED (15-DAY)		HO, OT	DE-ASTELLAS-2018US005664		1 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Off Label Use; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Amphotericin B, Liposome			S	Unknown			Astellas	
	Amphotericin B, Liposome			S	Unknown			Astellas	
	Amphotericin B, Liposome			S	Unknown			Astellas	
	Amphotericin B, Liposome			S	Unknown			Astellas	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg, Once Daily For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg, Once Daily For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg, In 2 Single Doses For 21 Days		Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg, In 2 Single Doses For 21 Days		Not Reported	
	Prednisone			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Prednisone			S	Unknown	Unk, Unknown Freq.		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)			Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Voriconazole	S	Intravenous (not otherwise specified)		Not Reported
Sodium Chloride	S	Nasal	0.9 %, Unknown Freq.	Not Reported
Sodium Chloride	S	Nasal	0.9 %, Unknown Freq.	Not Reported
Dexamethason /00016001/	S	Unknown	10 Mg/M2, For 21 Days Then Tapering	Not Reported
Dexamethason /00016001/	S	Unknown	10 Mg/M2, For 21 Days Then Tapering	Not Reported
Pegaspargase	S	Unknown	Unk, Unknown Freq.	Not Reported
Pegaspargase	S	Unknown	Unk, Unknown Freq.	Not Reported
Daunorubicin	C	Unknown	Unk, Unknown Freq.	Not Reported
Vincristine	C	Unknown	Unk, Unknown Freq.	Not Reported
Methotrexate	C	Unknown	Unk, Unknown Freq.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15296983	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018095189		76 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; White Blood Cell Count Increased	Solu-Medrol 500mg			S	Intravenous drip	500 Mg, Single		Pfizer
	Zithromac			S	Intravenous drip	500 Mg, Single		Pfizer
	Ceftriaxone Sodium			S	Intravenous drip	2 G, 1x/Day		Pfizer
	Heparin Sodium			S	Intravenous drip	Unk		Not Reported
	Nitroglycerin			S	Intravenous drip	Unk		Not Reported
	Hanp			S	Intravenous drip	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15389166	EXPEDITED (15-DAY)		HO, OT	NL-AUROBINDO-AUR-APL-2018-043937		70 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption; Neuroborreliosis; Rash	Methotrexate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythematous	Prednisolone	S	Unknown	Unk	Aurobindo
	Azithromycin	S			Aurobindo
	Azithromycin	S			Aurobindo
	Azithromycin	S			Aurobindo
	Azithromycin	S			Aurobindo
	Azithromycin	S			Aurobindo
	Prednisone	S	Intrathecal	Unk	Not Reported
	Vincristine	S	Unknown	Unk	Not Reported
	Cytarabine	S	Unknown	Unk, High Dose	Not Reported
	Rituximab	S	Unknown	Unk	Not Reported
	Doxorubicine /00330901/	S	Unknown	Unk	Not Reported
	Cyclophosphamide	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15391097	EXPEDITED (15-DAY)		OT	US-VELOXIS PHARMACEUTICALS, INC.-2018VELUS1155		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Envarsus Xr			S	Unknown	Unk		Unknown
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Sulfamethoxazole, Trimethoprim			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15391099	EXPEDITED (15-DAY)		OT	US-VELOXIS PHARMACEUTICALS, INC.-2018VELUS1156		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Envarsus Xr			S	Unknown	Unk		Unknown
	Ondansetron			S	Intravenous (not otherwise specified)	4 Mg, Single		Not Reported
	Prochlorperazine			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azithromycin	S	Unknown	Unk				Not Reported	
	Sulfamethoxazole, Trimethoprim	C	Unknown					Not Reported	
	Levalbuterol	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15392003	NON-EXPEDITED			US-PFIZER INC-2018373687		14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15392117	NON-EXPEDITED			US-PFIZER INC-2018370711			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atenolol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Chlorthalidone			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Losartan			S				Not Reported	
	Mobic			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15392359	EXPEDITED (15-DAY)		DS, HO, OT	FR-PFIZER INC-2013217833		71 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Dizziness; Dysarthria; Eye Pain; Feeling Drunk; Gait	Novatrex			S	Oral	15 Mg, Weekly		Pfizer	
	Novatrex			S	Oral	17.5 Mg, Weekly		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disturbance; Headache; Hemiparesis; Malaise; Migraine With Aura; Muscular Weakness; Musculoskeletal Stiffness; Somnolence; Transient Ischaemic Attack; Vertigo; Visual Impairment; Vomiting	Folic Acid Perindopril Xatral - Slow Release Asasantin - Slow Release Aspegic [Acetylsalicylate Lysine] Doliprane Chondrosulf Pariet	C C C C C C C C		(Maximum) 10 Mg, Daily 2 Mg, 1x/Day 10 Mg, 1x/Day 2 Df, Daily (200 Mg/25 Mg, 2df, Daily) Unk 1 G, 3x/Day 3 Df, 1x/Day Unk Unk, Daily (20mg To 40mg Daily)	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15392546	EXPEDITED (15-DAY)		OT	ES-APOTEX- 2018AP020640		26 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amniotic Cavity Infection; Exposure During Pregnancy; Live Birth; Pathogen Resistance	Azithromycin Ampicillin Betamethasone Oxytocin			S S S S	Oral Unknown Unknown Unknown	1 G, Unk 2 G Ampicillin Then 1 G/6 H For 48 H 500 Mg, Every 8 Hourly Unk		Apotex Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2018	15393040	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2018368250		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Prostate Cancer	Novatrex Remicade Valsartan Furosemide Atorvastatine [Atorvastatin]			S S C C C	Oral Intravenous (not otherwise specified)	Unk 1 Df, Unk		Pfizer Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Kardegic	C	Not Reported
Diffu-K	C	Not Reported
Ventoline [Salbutamol]	C	Not Reported
Onbrez	C	Not Reported
Pantoprazole	C	Not Reported
Zopiclone	C	Not Reported
Symbicort	C	Not Reported
Sotalol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	6433362	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2007078944		20 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Tubulointerstitial Nephritis	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Azithromycin			S				Pfizer
	Tobramycin			S	Intravenous (not otherwise specified)	160 Mg, 3x/Day		Unknown
	Tobramycin			S				Unknown
	Ceftazidime			S	Intravenous (not otherwise specified)	3 G, 3x/Day		Not Reported
	Ceftazidime			S				Not Reported
	Colomycin /00013203/			S	Intravenous (not otherwise specified)	Unk, 3x/Day		Not Reported
	Colomycin /00013203/			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	14021478	NON-EXPEDITED			US-DRREDDYS-USA/USA/17/0092015		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Amoxicillin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	14254627	NON-EXPEDITED			US-PFIZER INC-2017520672		72 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
	Sutent			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	14409981	NON-EXPEDITED			US-PFIZER INC-2018019029			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Amitiza			S		Unk		Not Reported	
	Percocet			S		Unk (Oxycodone Hydrochloride-10, Paracetamol-325)		Not Reported	
	Darvocet-N			S		Unk (100)		Not Reported	
	Kapidex			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15201029	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-AUROBINDO-AUR-APL-2018-037342		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Drug Level Above Therapeutic; Hepatic Failure; Hepatocellular Injury; Hepatotoxicity; Off Label Use	Azithromycin			S	Unknown	250 Milligram, Once A Day (250 Milligram From Day 3 To Day 9)		Aurobindo	
	Azithromycin			S	Unknown	500 Milligram, Once A Day (On Day 2)		Aurobindo	
	Azithromycin			S	Unknown	From Day 3 To Day 9		Aurobindo	
	Voriconazole			S	Unknown	400 Milligram, Once A Day (400 Mg, Bid (Morning And Night))		Aurobindo	
	Voriconazole			S	Unknown	200 Milligram, Once A Day (On Day 9: Administered		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Voriconazole	S	Unknown	Only In The Morning)	Aurobindo
Voriconazole	S	Unknown	From Day 4 To Day 7 (Morning And Night)	Aurobindo
Voriconazole	S		On Day 8: 400 Mg Morning (Qam) / 200 Mg Night (Qhs) ()	Aurobindo
Voriconazole	S		400mg In The Morning And 200mg At Night	Aurobindo
Voriconazole	S	Unknown	On Day 3, 400 Mg, Bid (Morning And Night)	Aurobindo
Voriconazole	S	Unknown	On Day 9: Administered Only In The Morning (Qam)200 Mg, Q.H.S.	Aurobindo
Voriconazole	S	Unknown	On Day 3	Aurobindo
Voriconazole	S	Unknown	On Day 9: Administered Only In The Morning (Qam)	Aurobindo
Voriconazole	S	Unknown	From Day 4 To Day 7 (Morning And Night)	Aurobindo
Voriconazole	S	Unknown	On Day 8: 400 Mg Morning (Qam) / 200 Mg Night (Qhs) ()	Aurobindo
Ponatinib	S	Unknown	(45 Mg/Day At Noon) 45 Milligram, Once A Day	Not Reported
Ponatinib	S			Not Reported
Ponatinib	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15232318	EXPEDITED (15-DAY)		HO	PHHY2018FR062516		21 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Myoclonus; Paraesthesia	Neoral			S	Oral	Unk		Novartis
	Azithromycin			S	Oral	Unk		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Terbutaline Sulfate	S	Respiratory (inhalation)	Unk	Not Reported
Pantoprazole	S	Oral	Unk	Not Reported
Hydrocortisone	S	Oral	Unk	Not Reported
Hizentra	S	Subcutaneous	Unk	Not Reported
Bactrim	S	Oral	Unk	Not Reported
Oracilline	S	Oral	Unk	Not Reported
Zelitrex	S	Oral	Unk	Not Reported
Ventolin	S	Respiratory (inhalation)	Unk	Not Reported
Vfend	S	Oral	Unk	Not Reported
Folinoral	S	Oral	Unk	Not Reported
Seresta	S	Oral	Unk	Not Reported
Pulmicort	S	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15367706	EXPEDITED (15-DAY)		OT	PHHY2018BR089020			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Blood Pressure Increased; Dysuria; Facial Nerve Disorder; Malaise; Nausea; Neck Pain; Renal Pain; Spinal Pain; Tension Headache; Vomiting	Levofloxacin			S	Unknown	Unk		Novartis
	Azithromycin Sandoz			S	Unknown	Unk		Not Reported
	Ciprofloxacin Hydrochloride			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15396746	EXPEDITED (15-DAY)		OT	PHHY2018JP092960		53 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection;	Piperacillin+Tazobactam			S	Unknown	13.5 G, Qd		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fungal Infection; Gastrointestinal Fistula; Gastrointestinal Fungal Infection; Gastrointestinal Wall Thinning; Inflammation; Large Intestinal Ulcer; Large Intestine Perforation; Mucormycosis; Peritonitis; Pyrexia	Azithromycin Meropenem Meropenem Hydrocortisone Hydrocortisone Hydrocortisone	S S S S S S	Unknown Unknown Unknown Unknown Unknown Unknown	500 Mg, Qd 2 G, Qd 200 Mg, Qd 100 Mg, Qd 50 Mg, Qd	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15397037	NON-EXPEDITED			US-PFIZER INC- 2018375548			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15397197	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2843179		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Aciclovir			S	Transplacental	Unk		Unknown
	Azithromycin			S	Transplacental	Freq: 2 Day; Interval: 1.		Pfizer
	Bactrim			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Mg, Freq: 2 Day; Interval: 1.		Not Reported
	Isentress			S	Transplacental	400 Mg, Freq: 2 Day; Interval: 1.		Not Reported
	Prezista			S	Transplacental	600 Mg, Freq: 2 Day; Interval: 1.		Not Reported
	Abacavir			C	Transplacental	300 Mg, Freq: 2 Day; Interval: 1.		Not Reported
	Lamivudine			S	Transplacental	150 Mg, Freq: 2 Day; Interval: 1.		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ritonavir	S	Transplacental	100 Mg, Freq: 2 Day; Interval: 1.	Not Reported
Tenofovir	S	Transdermal	300 Mg, Freq: 1 Day; Interval: 1.	Not Reported
Zidovudine	S	Transplacental	300 Mg, Freq: 2 Day; Interval: 1.	Not Reported
Folic Acid	C		Unk	Not Reported
Iron	C		Unk	Not Reported
Magnesium Gluconate	C		Unk	Not Reported
Prenatal Vitamins /02014401/	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2018	15398303	EXPEDITED (15-DAY)		OT	ES-MYLANLABS- 2018M1068162		10 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azithromycin			S	Oral	250 Mg Dia		Not Reported
	Salbutamol			C	Respiratory (inhalation)	2-2-2		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	14738041	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC- 2018139044		44 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Multiple Organ Dysfunction Syndrome; Sepsis; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Zithromax			S	Oral	250 Mg, 2x/Day (Afternoon And In The Evening)		Pfizer
	Tamiflu			C	Oral	75 Mg, 2x/Day		Not Reported
	Acetaminophen			C	Oral	500 Mg, Single		Not Reported
	Cheratussin Ac			C	Oral	10 MI, Every 4 Hrs		Not Reported
	Calcium			C	Oral	1 Df, 2x/Day		Not Reported
	Vitamin D2			C	Oral	(50,000 Unit) 1 Df, Weekly		Not Reported
	Vitamin E			C	Oral	(1000 Unit) 1 Df, Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	14966136	EXPEDITED (15-DAY)		HO, OT	PHHY2011CA123123		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Alopecia; Asthenia;	Xolair			S	Subcutaneous	375 Mg, Biw (Every 2 Weeks)		Not Reported
Asthma; Balance Disorder;								
Bladder Disorder; Blood	Xolair			S	Subcutaneous	Unk		Not Reported
Glucose Abnormal; Blood	Xolair			S	Subcutaneous	375 Mg, Biw (Every 2 Weeks)		Not Reported
Pressure Systolic								
Increased; Body	Xolair			S	Subcutaneous	Unk		Not Reported
Temperature Decreased;	Xolair			S	Subcutaneous	Unk		Not Reported
Brain Hypoxia; Breath	Xolair			S	Subcutaneous	Unk		Not Reported
Odour; Breath Sounds	Xolair			S	Subcutaneous	375 Mg, Biw (Every 2 Weeks)		Not Reported
Abnormal; Bronchitis;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Carbon Dioxide Increased;								
Chest Discomfort; Chest	Xolair			S	Subcutaneous	Unk		Not Reported
Pain; Cough; Crepitations;	Xolair			S	Subcutaneous	Unk		Not Reported
Diarrhoea; Dizziness;	Xolair			S	Subcutaneous	Unk		Not Reported
Dizziness; Drug	Xolair			S	Subcutaneous	Unk		Not Reported
Ineffective; Dyspepsia;	Xolair			S	Subcutaneous	Unk		Not Reported
Dyspnoea; Dyspnoea	Xolair			S	Subcutaneous	Unk		Not Reported
Exertional; Fall; Fatigue;	Xolair			S	Subcutaneous	Unk		Not Reported
Feeling Abnormal; Forced	Xolair			S	Subcutaneous	Unk		Not Reported
Expiratory Volume	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Frustration	Xolair			S	Subcutaneous	Unk		Not Reported
Tolerance Decreased;	Xolair			S	Subcutaneous	Unk		Not Reported
Gait Disturbance;	Xolair			S	Subcutaneous	Unk		Not Reported
Gastrooesophageal Reflux	Xolair			S	Subcutaneous	Unk		Not Reported
Disease; General Physical	Xolair			S	Subcutaneous	Unk		Not Reported
Health Deterioration;	Xolair			S	Subcutaneous	Unk		Not Reported
Haemarthrosis; Headache;	Xolair			S	Subcutaneous	Unk		Not Reported
Headache; Heart Rate	Xolair			S	Subcutaneous	Unk		Not Reported
Increased; Humidity	Xolair			S	Subcutaneous	Unk		Not Reported
Intolerance;	Xolair			S	Subcutaneous	Unk		Not Reported
Hypersensitivity;	Xolair			S	Subcutaneous	Unk		Not Reported
Hypoventilation; Infection;	Xolair			S	Subcutaneous	Unk		Not Reported
Injury; Insomnia; Joint	Xolair			S	Subcutaneous	Unk		Not Reported
Swelling; Malaise; Memory								
Impairment; Muscle								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Muscle Spasms;	Xolair	S	Subcutaneous	Unk	Not Reported
Musculoskeletal	Xolair	S	Subcutaneous	Unk	Not Reported
Discomfort;	Xolair	S	Subcutaneous	Unk	Not Reported
Nasopharyngitis;	Xolair	S	Subcutaneous	Unk	Not Reported
Odynophagia; Oral	Xolair	S	Subcutaneous	Unk	Not Reported
Candidiasis;	Xolair	S	Subcutaneous	Unk	Not Reported
Oropharyngeal Pain; Pain	Xolair	S	Subcutaneous	Unk	Not Reported
In Extremity; Palpitations;	Xolair	S	Subcutaneous	Unk	Not Reported
Paraesthesia; Peak	Xolair	S	Subcutaneous	Unk	Not Reported
Expiratory Flow Rate	Xolair	S	Subcutaneous	Unk	Not Reported
Abnormal; Peak Expiratory	Xolair	S	Subcutaneous	Unk	Not Reported
Flow Rate Decreased;	Xolair	S	Subcutaneous	Unk	Not Reported
Peripheral Swelling;	Xolair	S	Subcutaneous	Unk	Not Reported
Pneumonia; Pollakiuria;	Xolair	S	Subcutaneous	Unk	Not Reported
Poor Quality Sleep;	Xolair	S	Subcutaneous	Unk	Not Reported
Productive Cough;	Xolair	S	Subcutaneous	Unk	Not Reported
Pulmonary Function Test	Xolair	S	Subcutaneous	Unk	Not Reported
Decreased; Pyrexia;	Xolair	S	Subcutaneous	Unk	Not Reported
Respiratory Rate	Xolair	S	Subcutaneous	Unk	Not Reported
Increased; Respiratory	Xolair	S	Subcutaneous	Unk	Not Reported
Tract Congestion;	Xolair	S	Subcutaneous	Unk	Not Reported
Rhinorrhoea; Seasonal	Xolair	S	Subcutaneous	Unk	Not Reported
Allergy; Sputum	Xolair	S	Subcutaneous	Unk	Not Reported
Discoloured; Stress;	Xolair	S	Subcutaneous	Unk	Not Reported
Tendonitis; Tremor; Viral	Xolair	S	Subcutaneous	Unk	Not Reported
Infection; Vomiting; Weight	Xolair	S	Subcutaneous	Unk	Not Reported
Decreased; Wheezing	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	375 Mg, Biw	Not Reported
	Ventolin	S	Unknown	Unk	Not Reported
	Ventolin	S	Unknown	Unk, Qd	Not Reported
	Ventolin	S	Unknown	Unk	Not Reported
	Ventolin	S	Unknown	40 Puffs, Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ventolin	S	Unknown	Unk, Qd	Not Reported
Ventolin	S	Respiratory (inhalation)	2 To 8 Puffs Daily	Not Reported
Ventolin	S	Unknown	Unk, Qd	Not Reported
Ventolin	S	Unknown	60 Df (60 Puffs)	Not Reported
Ventolin	S	Unknown	2 Df, Qid	Not Reported
Zithromax	S	Unknown	250 Mg, Tiw (3 Times A Week, Monday, Wednesday And Friday)	Not Reported
Zithromax	S			Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg, Qd	Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg For 7 Days Days With Weaning Orders (10 Mg Every 3 Days)	Not Reported
Prednisone	S	Unknown	50 Mg, For 4 Days (Tapered Dose)	Not Reported
Prednisone	S	Unknown	50 Mg, For 5 Days	Not Reported
Prednisone	S	Unknown	50 Mg, For Five More Days And Then A Tapered Dose	Not Reported
Prednisone	S	Unknown	50 Mg, Qd	Not Reported
Prednisone	S	Unknown	50 Mg, Qd	Not Reported
Prednisone	S	Unknown	50 Mg, Qd (For 5 Days)	Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	15 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg, (Will Be Tapering For 17 More Days)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	50 Mg, Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	40 Mg, Unk	Not Reported
Advair	C	Respiratory (inhalation)	200 Ot, Bid	Not Reported
Advair	C	Respiratory (inhalation)	1 Df (500), Bid	Not Reported
Diltiazem	C	Unknown	Unk Unk, Qd	Not Reported
Alvesco	C	Unknown	2 Df, Qid	Not Reported
Spiriva	C	Unknown	2 Df, Qd	Not Reported
Zenhale	C	Unknown		Not Reported
Combivent	C	Unknown	20 Ug, Unk	Not Reported
Gaviscon	C	Oral	1 Df, Qid	Not Reported
Gaviscon	C	Oral	1 Df, Bid	Not Reported
Tums	C	Unknown	1 Df, Unk	Not Reported
Dexilant	C	Unknown	1 Df, Qd	Not Reported
Atrovent	C	Unknown	2 Df, Qid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15327963	EXPEDITED (15-DAY)		HO, OT	ZA-BAUSCH-BL-2018-023671		24 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Ketoacidosis	Metronidazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Betamethasone			S	Unknown			Not Reported	
	Ceftriaxone Sodium			S	Unknown			Not Reported	
	Ringers Lactate			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15399968	EXPEDITED (15-DAY)		OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-184659		53 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Fungal Infection; Large Intestine Perforation; Mucormycosis	Meropenem			S	Unknown	2 G, Daily		Not Reported	
	Teicoplanin			S	Unknown	600 Mg, Daily		Not Reported	
	Teicoplanin			S	Unknown	300 Mg, Daily		Not Reported	
	Metronidazole			S	Unknown			Mutual	
	Piperacillin/Tazobactam			S	Unknown	13.5 G, Daily		Not Reported	
	Azithromycin			S	Unknown	500 Mg, Daily		Sun	
	Linezolid			S	Unknown	1200 Mg, Daily		Not Reported	
	Hydrocortisone			S	Unknown	200 Mg, Daily		Not Reported	
	Hydrocortisone			S	Unknown	100 Mg, Daily		Not Reported	
	Hydrocortisone			S		50 Mg, Daily		Not Reported	
	Immunoglobulin Nos			C	Unknown	5 G, Daily		Not Reported	
	Caspofungin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15400825	EXPEDITED (15-DAY)		DS	PT-AUROBINDO-AUR- APL-2018-046222		46 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401537	NON-EXPEDITED			US-PFIZER INC- 2018374885			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine Sulfate			S		Unk			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401727	NON-EXPEDITED			US-PFIZER INC-2018379499		70 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401942	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2844340		56 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Aciclovir			S		Transplacental	Unk		Unknown
	Azithromycin			S		Transplacental	Freq: 2 Day; Interval: 1		Pfizer
	Bactrim			S		Transplacental	Unk		Not Reported
	Intelence			S		Transplacental	200 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Isentress			S		Transplacental	400 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Prezista			S		Transplacental	600 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Abacavir			S		Transplacental	300 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Lamivudine			S		Transplacental	150 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Ritonavir			S		Transplacental	100 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Tenofovir			S		Transdermal	300 Mg, Freq: 1 Day; Interval: 1		Not Reported
	Zidovudine			S		Transplacental	300 Mg, Freq: 2 Day; Interval: 1		Not Reported
	Folic Acid			C			Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Iron		C		Unk				Not Reported
	Magnesium Gluconate		C		Unk				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15401962	NON-EXPEDITED			PHEH2018US038014			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin 250 Mg			S	Unknown	200 Mg, Qd		Novartis	
Abdominal Pain Upper;	Lisinopril			C	Unknown	Unk		Not Reported	
Diarrhoea	Tylenol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15402198	EXPEDITED (15-DAY)		OT	MX-PFIZER INC-2018376691			Unknown	MEX
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Oedema; Glossitis;	Azitrocin			S		500 Mg, Unk		Pfizer	
Poisoning; Rash	Flanax Naproxen			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15402399	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018371639			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterocolitis	Zithromac			S		Unk		Pfizer	
Haemorrhagic									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15402853	NON-EXPEDITED			US-MYLANLABS-2018M1068399			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Clarithromycin			S	Oral	Unk		Not Reported	
	Clindamycin			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Augmentin		S	Oral		Unk			Mylan
	Z-Pak		S	Oral		Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2018	15403500	NON-EXPEDITED			US-PFIZER INC-2018378476			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15018784	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-031300		64 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cell Death; Cholestasis; Liver Disorder	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15294307	EXPEDITED (15-DAY)		OT	GB-BAUSCH-BL-2018-021586		27 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Condition Aggravated; Malaise; Pain In Extremity; Urethritis Mycoplasmal; Urinary Tract Infection	Doxycycline			S	Unknown			Not Reported	
	Pristinamycin			S	Unknown	1 G, Qd		Not Reported	
	Pristinamycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	250 Mg, Qd (4 Days)		Not Reported	
	Azithromycin			S	Unknown	500 Ot, Unk		Not Reported	
	Moxifloxacin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15314197	NON-EXPEDITED			US-PFIZER INC-2018340653			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Heart Rate Increased	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15407349	EXPEDITED (15-DAY)		DE, OT	NL- GLAXOSMITHKLINE- NL2018GSK171140		79 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Congestive; Drug Ineffective	Cefuroxime Sodium Azithromycin Ciprofloxacin			S S S				Glaxosmithkline Glaxosmithkline Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15407641	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018377976		69 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Colitis; Gastrooesophageal Reflux Disease; Malignant Melanoma; Pemphigoid; Pruritus; Pustule	Azithromycin Amoxicillina E Acido Clavulanico Momenxsin 200 Mg/30 Mg Compresse Rivestite Con Film			S S S	Oral Oral	Unk Unk Unk		Pfizer Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15408843	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC- 2018379707		81 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Acute Kidney Injury; Adjustment Disorder; Anaemia; Angina Pectoris; Atrophy; Back Pain; Bundle Branch Block Left; Death; Drug Hypersensitivity; Drug Intolerance; Hepatic Steatosis;	Codeine Zithromax Aclasta Aclasta Aclasta			S S S S S		Unk Unk Unk Unk 5 Mg, Every 1 Year		Not Reported Pfizer Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypercalcaemia; Hypertension; Monoclonal Gammopathy;	Aclasta	S	Intravenous (not otherwise specified)	5 Mg, Unk	Not Reported
Musculoskeletal Pain;	Aclasta	S	Intravenous drip	Unk	Not Reported
Osteoarthritis; Palmar	Aclasta	S	Intravenous drip	Unk	Not Reported
Erythema; Plasma Cell Myeloma; Sacroiliitis; Spinal Disorder; Toxicity To Various Agents	Aclasta	S	Intravenous (not otherwise specified)	5 Mg, Every 1 Year	Not Reported
	Actonel	S		Unk	Not Reported
	Amoxil	S		Unk	Not Reported
	Dilaudid	C		1 Mg, Unk	Not Reported
	Esomeprazole Sodium	C		40 Mg, 1x/Day	Not Reported
	Nitroglycerin	C	Oral	1 Df, Unk	Not Reported
	Propranolol Hydrochloride	C		80 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15408983	EXPEDITED (15-DAY)		HO	FR-SA-2018SA157371		21 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysuria; Myoclonus; Paraesthesia	Pantoprazole			S	Oral	Non Communiquee		Not Reported
	Alprazolam			S	Oral	Unk		Not Reported
	Oracilline			S	Oral	Unk		Not Reported
	Budesonide			S	Respiratory (inhalation)	Unk		Not Reported
	Hydrocortisone		Y	S	Oral	Unk		Sanofi
	Azithromycin			S	Oral	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Oral	Unk		Not Reported
	Oxazepam			S	Oral	Unk		Not Reported
	Terbutaline Sulfate			S	Respiratory (inhalation)	Unk		Sanofi
	Calcium Folate			S	Oral	Unk		Not Reported
	Salbutamol Sulfate			S	Respiratory (inhalation)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Voriconazole	S	Oral	Unk		Not Reported
	Zelitrex	S	Oral	Unk		Not Reported
	Hizentra	S	Subcutaneous	Unk		Not Reported
	Neoral	S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15409070	NON-EXPEDITED			US-PFIZER INC-2018381928			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2018	15409579	NON-EXPEDITED			PHEH2018US039193			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	250 Mg, Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	14284250	EXPEDITED (15-DAY)		DE, HO, OT	GB-AUROBINDO-AUR-APL-2017-45246			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Azithromycin			S	Unknown	Unk		Aurobindo
Abdominal Pain Upper;	Pirfenidone			S	Oral	801 Milligram, Once A Day		Not Reported
Alopecia; Anxiety;	Pirfenidone			S	Oral	801 Milligram, Once A Day		Not Reported
Asthenia; Breast Pain;	Pirfenidone			S	Oral	Full Dose		Not Reported
Cataract; Cellulitis; Chest Pain; Condition	Pirfenidone			S	Oral	2403 Milligram, Once A Day		Not Reported
Aggravated; Cough;	Pirfenidone			S	Oral	2403 Milligram, Once A Day		Not Reported
Death; Depressed Mood; Depression; Drug	Pirfenidone			S	Oral	2403 Milligram, Once A Day		Not Reported
Ineffective; Dyspnoea;								
Dyspnoea; Erythema;								
Fatigue; Fatigue; Flushing;								

Frequent Bowel
Movements;
Gastrointestinal Disorder;
Gastrointestinal Pain;
Gastroesophageal Reflux
Disease;
Gastroesophageal Reflux
Disease; General Physical
Health Deterioration;
Haemoptysis; Headache;
Heart Rate Increased;
Hiatus Hernia;
Hypotension; Increased
Upper Airway Secretion;
Inguinal Hernia; Insomnia;
Jaw Cyst; Lethargy; Lower
Respiratory Tract
Infection; Lower
Respiratory Tract
Infection; Malaise;
Musculoskeletal Stiffness;
Nasopharyngitis;
Osteomyelitis;
Osteomyelitis; Oxygen
Saturation Decreased;
Panic Attack; Pneumonia;
Pneumonia; Productive
Cough; Pruritus;
Pulmonary Function Test
Decreased; Pulmonary
Oedema; Pulmonary Pain;
Rash; Seasonal Allergy;
Seborrhoea; Skin Irritation;
Skin Ulcer; Sunburn;
Swelling; Tearfulness;
Therapeutic Product Effect
Decreased; Tinnitus;
Tooth Injury; Total Lung
Capacity Decreased;
Tremor; Ulcer; Upper-
Airway Cough Syndrome;
Vertigo; Viral Infection;

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Weight Decreased; Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	14419932	EXPEDITED (15-DAY)		HO	US-DSJP-DSU-2017-139217			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dehydration; Diarrhoea; Dizziness; Gastroesophageal Reflux Disease; Melaena; Sprue-Like Enteropathy	Benicar Azithromycin			S S	Oral	20 Mg, Qd Unk		Daiichi Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	14571796	NON-EXPEDITED			US-PFIZER INC-2018078888			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin Ciprofloxacin			S S		Unk Unk		Pfizer Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15114446	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-922279		21 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Pantoprazole Alprazolam Azithromycine Anhydre Neoral Hydrocortisone Hizentra Bactrim Oracilline			S S S S S S S S	Oral Oral Oral Oral Oral Subcutaneous Oral Oral	Non Communiquee Non Communiquee Non Communiquee Non Communiquee Non Communiquee Non Communiquee Non Communiquee Non Communiquee		Teva Actavis Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Seresta	S	Oral	Non Communiquee	Not Reported
Vfend	S	Oral	Non Communiquee	Not Reported
Ventoline	S	Respiratory (inhalation)	Non Communiquee	Not Reported
Terbutaline (Sulfate De)	C	Respiratory (inhalation)	Non Communiquee	Not Reported
Pulmicort	C	Respiratory (inhalation)	Non Communiquee	Not Reported
Folinoral	C	Oral	Non Communiquee	Not Reported
Zelitrex	C	Oral	Non Communiquee	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15411249	NON-EXPEDITED			US-PFIZER INC-2018379073		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Disease Recurrence	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15411273	NON-EXPEDITED			US-PFIZER INC-2018378729			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15411553	NON-EXPEDITED			CO-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-835			Male	COL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Mucinex Tabletas De Liberacion Prolongada 600mg			S	Unknown	Unk		Not Reported	
	Mucinex Tabletas De Liberacion Prolongada 600mg			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Mucinex Tablet De Liberacion		S						Not Reported
	Prolongada 600mg								
	Zitromax		S	Unknown	Unk				Not Reported
	Zitromax		S						Not Reported
	Zitromax		S						Not Reported
	Betaduo		S	Unknown	Unk				Not Reported
	Betaduo		S						Not Reported
	Betaduo		S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15411746	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-869		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Maximum Strength Mucinex Tablets			S	Unknown	1200 Mg, Single			Not Reported
	Maximum Strength Mucinex Tablets			S	Unknown	1200 Mg, Bid			Not Reported
	Maximum Strength Mucinex Tablets			S					Not Reported
	Z-Pak			S	Unknown	Unk			Not Reported
	Z-Pak			S					Not Reported
	Z-Pak			S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15413347	NON-EXPEDITED			US-PFIZER INC- 2018381833			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Bacitracin			S		Unk			Pfizer
	Dilantin			S		Unk			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2018	15433514	DIRECT		OT			6 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Emotional Disorder; Hostility	Azithromycin 250mg			S	Oral	Quantity:5 Tablet		Teva	
	Melatonin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	14203669	NON-EXPEDITED			US-PFIZER INC-2017495043		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Fluctuation; Rhinorrhoea	Xeljanz			S	Oral	5 Mg, 2x/Day (Take 1 Tablet)		Pfizer	
	Zithromax			S		1 G, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	15314176	NON-EXPEDITED			US-PFIZER INC-2018340393			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
	Clavulanate Potassium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	15384945	NON-EXPEDITED			US-PFIZER INC-2018370580			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Vancomycin Hcl			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Lipitor			S		Unk		Pfizer	
	Gentamicin Sulfate			S		Unk		Unknown	
	Toviaz			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Effexor	S	Unk	Pfizer
Nitrofurantoin	S	Unk	Not Reported
Dicloxacillin	S	Unk	Not Reported
Dexamethasone	S	Unk	Not Reported
Digoxin	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Losartan	S	Unk	Not Reported
Macrochantin	S	Unk	Not Reported
Taxol	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Benadryl	S	Unk	Not Reported
Monistat 3	S	Unk	Not Reported
Norco	S	Unk	Not Reported
Mucinex	S	Unk	Not Reported
Vesicare	S	Unk	Not Reported
Hydrocodone	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Metamucil [Psyllium Hydrophilic Mucilloid]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2018	15419413	NON-EXPEDITED			US-PFIZER INC-2018382973		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		Unk		Pfizer
	Rocephin			S		Single Dose		Not Reported
	Enbrel			C	Subcutaneous	50 Mg, Weekly		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	14613660	EXPEDITED (15-DAY)		HO	PT-PFIZER INC-2018058855		68 YR	Female	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Erythema; Hypersensitivity; Papule; Pruritus	Zithromax			S	Oral	500 Mg, Once A Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2018	15392036	NON-EXPEDITED			US-PFIZER INC- 2018372154			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	13368231	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2017121650		21 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Azithromycine			S	Oral	Unk		Pfizer	
	Alprazolam			S	Oral	Unk		Pfizer	
	Pantoprazole			S	Oral	Unk		Pfizer	
	Vfend			S	Oral	Unk		Pfizer	
	Hydrocortisone			S	Oral	Unk		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
	Oracilline			S	Oral	Unk		Not Reported	
	Hizentra			S	Subcutaneous	Unk		Not Reported	
	Neoral			S	Oral	Unk		Not Reported	
	Folinoral			S	Oral	Unk		Not Reported	
	Zelitrex			S	Oral	Unk		Not Reported	
	Seresta			S	Oral	Unk		Not Reported	
	Ventoline			S	Respiratory (inhalation)	Unk		Not Reported	
	Pulmicort			S	Respiratory	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Terbutaline Sulfate	S	(inhalation) Respiratory (inhalation)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	14473711	NON-EXPEDITED			US-PFIZER INC-2018034594			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dehydration; Hernia; Muscle Spasms; Muscle Tightness; Muscle Tightness	Azithromycin			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15119054	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-922505		64 YR	Male	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cell Death; Cholestasis; Liver Disorder	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15429177	NON-EXPEDITED			US-PFIZER INC-2018387005		56 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Dyspnoea; Heart Rate Abnormal	Azithromycin			S	Oral	500 Mg Two Tablets On The First Day And 250 Mg For Four Consecutive Days By Mouth		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Sep-2018	15429280	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1069665		25 YR	Female	ITA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anal Inflammation; Intertrigo; Proctalgia		Azithromycin		S	Oral	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2018	15429888	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX- 2018AP021162		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia; Liver Disorder	Azithromycin			S	Oral	500 Mg, Qd (1 Cp Dia)		Apotex	
	Cymbalta			C	Oral	1 Cp Dia		Not Reported	
	Pravastatina /00880401/			C	Unknown	0-0-1		Not Reported	
	Amoxicilina Clavulanico Kern Pharma			C	Oral	1-1-1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	14289025	EXPEDITED (15-DAY)		DE, HO, OT	GB-TEVA-2017-GB- 834792			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Asthenia; Cataract; Cataract; Chest Pain; Chest Pain; Condition Aggravated; Cough; Death; Depressed Mood; Dyspnoea; Erythema; Fatigue; Fatigue; Frequent Bowel Movements; Gastrointestinal Disorder; Gastrooesophageal Reflux Disease; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Haemoptysis; Headache; Heart Rate Increased;	Azithromycin			S	Unknown			Not Reported	
	Pirfenidone			S	Oral	801 Milligram Daily;		Not Reported	
	Pirfenidone			S	Oral	801 Milligram Daily;		Not Reported	

Hiatus Hernia;
Hypotension; Increased
Upper Airway Secretion;
Insomnia; Jaw Cyst;
Lethargy; Lower
Respiratory Tract
Infection; Lower
Respiratory Tract
Infection; Malaise;
Musculoskeletal Stiffness;
Nasopharyngitis;
Osteomyelitis;
Osteomyelitis; Oxygen
Saturation Decreased;
Pneumonia; Productive
Cough; Pruritus; Pruritus;
Pulmonary Function Test
Decreased; Pulmonary
Oedema; Rash; Seasonal
Allergy; Seborrhoea; Skin
Irritation; Sunburn;
Tearfulness; Therapeutic
Product Effect Decreased;
Tinnitus; Tooth Injury;
Total Lung Capacity
Decreased; Tremor;
Upper-Airway Cough
Syndrome; Vertigo; Viral
Infection; Weight
Decreased; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	14605137	EXPEDITED (15-DAY)		HO, OT	PHHY2017DE196094		1 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection; Cerebral Aspergillosis; Hypokalaemia; Nosocomial Infection; Off	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg, In 2 Single Doses For 21 Days		Novartis
	Azithromycin			S	Unknown	10 Mg/Kg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Label Use; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Dexamethasone	S	Unknown	10 Mg/M2, (For 21 Days Then Tapering)	Not Reported
	Prednisone	S	Unknown		Not Reported
	Voriconazole	S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd	Not Reported
	Voriconazole	S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily	Not Reported
	Amphotericin B, Liposome	S	Unknown	4 Mg/Kg, Qd	Not Reported
	Amphotericin B, Liposome	S	Intravenous drip	8 Mg/Kg, Qd	Not Reported
	Amphotericin B, Liposome	S	Intravenous drip	5 Mg/Kg, Qd	Not Reported
	Peg-Asparaginase	S	Unknown		Not Reported
	Sodium Chloride	S	Nasal	Unk	Not Reported
	Methotrexate	C	Intrathecal	Unk	Not Reported
	Daunorubicin	C	Unknown		Not Reported
	Vincristine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	14720990	EXPEDITED (15-DAY)		DS	PHHY2018PT059146		85 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anosmia	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Mometasona Furoato			S	Nasal	2 (Ug/L), Qd		Not Reported
	Losartan			C	Oral	50 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15170709	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT- 929420		57 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported
	Levofloxacin			S	Oral	1 Dosage Forms Daily;		Teva
	Olmotec 20 Mg Compresse			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rivestite Con Film

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15435636	EXPEDITED (15-DAY)		DE, OT	PHHY2018NL109512		79 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Congestive; Drug Ineffective	Azithromycin			S	Unknown			Novartis	
	Ciprofloxacin			S	Unknown			Not Reported	
	Cefuroxime Sodium			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15435748	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2018387428		53 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemorrhage	Zithromac			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15436805	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US- 957408		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Product Use Complaint	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2018	15455792	DIRECT	Y				79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S				Not Reported	
	Methadone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	12354031	NON-EXPEDITED		OT	US-AMGEN- USASP2016052749		82 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Arthralgia; Blindness; Depression; Diarrhoea; Fatigue; Frustration Tolerance Decreased; Injection Site Pain; Joint Swelling; Malaise; Nasopharyngitis; Neuropathy Peripheral; Pain; Peripheral Swelling; Product Dose Omission; Psoriasis; Rash; Somnolence	Enbrel			S	Subcutaneous	50 Mg, Weekly		Amgen	
	Enbrel			S	Subcutaneous	50 Mg, Qwk		Amgen	
	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
	Enbrel			S	Unknown	Unk		Amgen	
	Enbrel			S	Unknown	Unk		Amgen	
	Z-Pak			S	Unknown	Unk		Not Reported	
	Armour Thyroid			C		Unk		Not Reported	
	Istalol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	13829050	NON-EXPEDITED			US-PFIZER INC-2017334258		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15058379	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-176532		21 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Pantoprazole			S	Oral	Non Communiquee ()		Sun	
	Azithromycin			S	Oral	Non Communiquee ()		Sun	
	Ventoline			S	Respiratory (inhalation)	Non Communiquee ()		Not Reported	
	Terbutaline (Sulfate De)			C	Respiratory (inhalation)	Non Communiquee ()		Not Reported	
	Neoral			S	Oral	Non Communiquee ()		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vfend	S	Oral	Non Communiquee ()	Not Reported
Folinoral	C	Oral	Non Communiquee ()	Not Reported
Hydrocortisone	S	Oral	Non Communiquee ()	Not Reported
Hizentra	S	Subcutaneous	Non Communiquee ()	Not Reported
Seresta	C	Oral	Non Communiquee ()	Not Reported
Pulmicort	C	Respiratory (inhalation)	Non Communiquee ()	Not Reported
Bactrim	S	Oral	Non Communiquee ()	Not Reported
Alprazolam	S	Oral	Non Communiquee ()	Not Reported
Oracilline	S	Oral	Non Communiquee ()	Not Reported
Zelitrex	S	Oral	Non Communiquee ()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15439018	NON-EXPEDITED			US-PFIZER INC-2018392637		83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15439040	NON-EXPEDITED			US-PFIZER INC-2018391291		75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Gastrointestinal Disorder	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15440006	NON-EXPEDITED			US-TEVA-2018-US-958049		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Nausea; Pain;	Azithromycin			S	Oral	Took 2 The First Day, Now		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Product Lot Number Issue; Pyrexia; Weight Decreased				Takes 1 Tablet Per Day For Days 2-5							
Azithromycin				S					Not Reported		
Lyrica				S	Oral	300 Milligram Daily;				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2018	15441039	NON-EXPEDITED			US-PFIZER INC- 2018391789			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2018	12463966	EXPEDITED (15-DAY)		DE, HO, LT	JP-ABBVIE-16P-087- 1649264-00		82 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Blood Pressure Decreased;	Viekirax			S	Oral			Not Reported
Diarrhoea; Electrolyte Imbalance; Fall; Fall;	Viekirax			S	Oral			Not Reported
Femoral Neck Fracture; Full Blood Count Decreased; Gait Disturbance; General Physical Health	Luprac			S	Unknown			Not Reported
Deterioration; Hepatic Encephalopathy;	Spiroonolactone			S	Unknown			Not Reported
Hyperkalaemia; Hypoglycaemia;	Zithromac			S	Unknown			Not Reported
Hyponatraemia; Nutritional Condition Abnormal;	Amlodipine Besilate			C	Oral			Not Reported
Pneumonia; Septic Shock;	Valsartan			C	Oral			Not Reported
Urinary Tract Infection	Bifidobacterium			C	Oral			Not Reported
	Bifidobacterium			C	Oral			Not Reported
	Senna Leaf/Senna Pod			C	Oral			Not Reported
	Senna Leaf/Senna Pod			C	Oral			Not Reported
	Brotizolam			C	Oral			Not Reported
	Brotizolam			C	Oral			Not Reported
	Esomeprazole Magnesium			C				Not Reported
	Livact			C	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	14481834	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2018042410		1 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks		Pfizer	
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Pfizer	
	Voriconazole			S		8 Mg/Kg, 0.5 Units 1x/Day		Pfizer	
	Amphotericin B, Liposome			S		4 Mg/Kg, Daily		Not Reported	
	Amphotericin B, Liposome			S		8 Mg/Kg, Daily As A 3-Hour Infusion		Not Reported	
	Amphotericin B, Liposome			S		5 Mg/Kg, Daily As A 2-Hour Infusion		Not Reported	
	Dexamethasone			S		10 Mg/M2 For 21 Days Then Tapering		Not Reported	
	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Not Reported	
	Oncaspar			S	Unknown	Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Sodium Chloride			S	Nasal	0.9% Nose Spray		Not Reported	
	Vincristine			C	Unknown	Unk		Not Reported	
	Daunorubicin			C		Unk		Not Reported	
	Methotrexate			C	Intrathecal	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15203211	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2018300614		88 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dermatitis Exfoliative	Dalacin C Fosfato	S	3 Df, 1x/Day	Pfizer
Generalised; Rash	Zitromax	S	1 Df, 1x/Day	Pfizer
Pustular	Lasix /00032601/	C	Unk	Not Reported
	Minias	C	Unk	Not Reported
	Cardioaspirin	C	Unk	Not Reported
	Sandimmun	C	Unk	Not Reported
	Triatec /00116401/	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15257732	EXPEDITED (15-DAY)		HO, OT	PHHY2015BR074552		49 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Asthmatic Crisis;	Xolair			S	Subcutaneous	300 Mg (2 Ampoules),		Not Reported
Asthmatic Crisis; Back						Qmo		
Pain; Blood	Xolair			S	Subcutaneous	1 Ampoule, Every 15 Days		Not Reported
Immunoglobulin E						(Two Doses Per Month)		
Increased; Cestode	Xolair			S	Unknown	Unk		Not Reported
Infection; Chest Pain;	Xolair			S	Unknown	Unk		Not Reported
Coordination Abnormal;	Xolair			S	Unknown	Unk		Not Reported
Depressed Mood; Drug	Xolair			S	Unknown	150 Mg, Every 15 Days		Not Reported
Hypersensitivity; Drug	Azithromycin			S	Unknown	Unk		Novartis
Ineffective; Dyspnoea;	Azithromycin			S	Unknown	Unk		Novartis
Fatigue; Limb Discomfort;	Tamiram			S	Unknown			Not Reported
Migraine; Muscle Spasms;	Depakote			C	Oral	2 Df, Qd (On Treatment		Not Reported
Paraesthesia; Pharyngitis;						For Two Years)		
Pharyngitis; Pneumonia;	Depakote			C	Oral	1 Df (20 Mg), Q12h		Not Reported
Pneumonia; Pyrexia;	Depakote			C	Oral	1 Df, Q12h		Not Reported
Seizure; Serum Ferritin	Depakote			C	Oral	1 Df, Qd (On Treatment		Not Reported
Decreased; Tachycardia;	Esomeprazole			C	Oral	For Three Years)		
Tremor; Weight	Neutrofer			C	Oral	1 Df, Qd (On Treatment		Not Reported
Decreased; Wheezing	Nebilet			C	Oral	For Two Years)		
						0.25 Df, Qd (Atsrted: 3		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			Years Ago)	
Nebilet	C			Not Reported
Clenil	C	Unknown	200 Mg, Tid	Not Reported
Atrovent	C	Respiratory (inhalation)	20 Mg, Tid (Started 6 Months Ago)	Not Reported
Pantoprazole	C	Oral	1 Df, Qd (6 Months Ago)	Not Reported
Pantoprazole	C			Not Reported
Nystatin	C	Oral	Tid	Not Reported
Aas	C	Oral	1 Df, Qd (Started 3 Years Ago)	Not Reported
Aas	C	Oral	2 Df (100 Mg), Qd	Not Reported
Rosuvastatin	C	Oral	1 Df, Qd	Not Reported
Omeprazole	C	Oral	1 Df, Qd	Not Reported
Symbicort	C	Respiratory (inhalation)	Unk Unk, Q12h	Not Reported
Egide	C	Oral	1 Df, Qd	Not Reported
Egide	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15297388	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2018146892			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Dry Mouth; Dyspnoea; Malaise; Pneumonia; Sleep Apnoea Syndrome	Advair Diskus			S	Respiratory (inhalation)	1 Puff(S), Bid (250/50)		Glaxosmithkline
	Advair Diskus			S		Unk (500/50)		Glaxosmithkline
	Incruse Ellipta			S	Respiratory (inhalation)	1 Puff(S), 1d		Glaxosmithkline
	Z-Pak			S		Unk		Glaxosmithkline
	Prednisone			S		Unk		Not Reported
	Proair Respiclick			S		Unk		Not Reported
	Oxygen			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15378051	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2018365621		3 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myasthenic Syndrome	Zithromax			S		Unk		Pfizer	
	Nanogam			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15418366	EXPEDITED (15-DAY)		DE, OT	ET-PFIZER INC-2018384247		7 YR	Male	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Vomiting	Zithromax			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15450523	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-047862		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pulmonary Nocardiosis	Prednisone			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Atovaquone			C	Unknown	1500 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451393	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP021407		69 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Bronchospasm; Palatal Oedema	Azithromycin			S	Oral	500 Mg, Qd		Apotex	
	Acethyl Cysteine			S	Oral	200 Mg, Tid		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451460	EXPEDITED (15-DAY)		DE	AU-PFIZER INC-2018393046		50 YR	Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Meropenem			S				Pfizer	
	Granulocyte Colony Stimulating Factor			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2018	15451797	NON-EXPEDITED			US-PFIZER INC-2018393130			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	14759188	EXPEDITED (15-DAY)		DE, OT	GB-PFIZER INC-2018147708			Female	ZMB
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Product Administration Error	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15369506	NON-EXPEDITED			US-PFIZER INC-2018363762			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diphenhydramine Hcl	S	Unk	Unknown
Epinephrine	S	Unk	Unknown
Ketorolac Tromethamine	S	Unk	Pfizer
Theophylline	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15383366	EXPEDITED (15-DAY)		HO	PHHY2018PL092428		10 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Hydrocortisone			S	Topical	Unk		Not Reported
	Gentamicin			S	Topical	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Betamethasone			S	Topical			Not Reported
	Clotrimazole			S	Topical	Unk		Not Reported
	Sodium Chloride			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2018	15456819	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018177748		85 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug Level Above Therapeutic; Drug Interaction	Warfarin Sodium			S	Unknown	Unk		Glaxosmithkline
	Cefuroxime			S	Unknown	Unk		Glaxosmithkline
	Azithromycin			S	Unknown	Unk		Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	7021798	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2009222715		35 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Death	Zithromac 250mg			S	Oral	1000 Mg, 1x/Day		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mylis			S		Vaginal		Frequency: Every Week;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Oct-2018	14169438	NON-EXPEDITED			US-PFIZER INC-2017475924			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Oct-2018	14577881	EXPEDITED (15-DAY)		OT	US-JAZZ-2018-US-002686		36 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abnormal Sleep-Related Event; Bronchitis; Hyperhidrosis; Nausea; Pain In Extremity; Pre-Existing Condition Improved; Product Preparation Error; Sleep Talking; Therapeutic Response Unexpected; Tremor; Urticaria	Xyrem			S	Oral	2.25 G, Bid		Jazz		
	Xyrem			S			Jazz			
	Zithromax			S			Not Reported			
	Motrin Ib			C			Not Reported			
	Propranolol			C			Not Reported			
	Adderall			C			Not Reported			
	Amitriptyline Hcl			C			Not Reported			
	Fluoxetine Hcl			C			Not Reported			
	Prozac			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
03-Oct-2018	14739002	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US14859			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Therapy Non-Responder	Montelukast			S	Unknown	Unk		Cipla		
	Azithromycin			S	Unknown	Unk		Not Reported		
	Theophylline			S	Unknown	Unk		Not Reported		
	Prednisolone			S	Unknown	Unk		Not Reported		
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15348262	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2018GSK159415			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cystic Fibrosis; Ill-Defined Disorder	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z(Monthly)		Glaxosmithkline	
	Prednisone			S		Unk		Not Reported	
	Zithromax			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15441467	NON-EXPEDITED			US-PFIZER INC-2018391849			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Meperidine Hcl			S		Unk		Unknown	
	Hydrocodone			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15458527	EXPEDITED (15-DAY)		OT	AU-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-185918		57 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Resistance; Nocardiosis	Azithromycin			S	Unknown			Sun	
	Ceftriaxone			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
	Mycophenolate			S	Unknown			Not Reported	
	Prednisolone			S	Unknown			Taro	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tacrolimus			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15458799	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018174925		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Cough; Drug Ineffective; Dysgeusia; Nausea; Off Label Use; Parosmia; Product Use In Unapproved Indication; Sneezing; Throat Irritation; Weight Decreased	Advair Diskus Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Bid		Glaxosmithkline	
	Z-Pak Tablet			S		Unk Unk, U		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15459105	NON-EXPEDITED			PHEH2018US040831			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature Increased; Ear Infection; Flatulence; Gastrointestinal Disorder; Malaise; Retching; Sinusitis; Weight Decreased	Zofran			S	Intravenous drip			Novartis	
	Azithromycin			S	Intravenous drip	500 Mg, Qd		Not Reported	
	Dextrose			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15460277	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1071913		31 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Faeces Soft; Haematochezia; Mucous Stools	Azithromycin			S	Oral	500 Mg, Total		Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2018	15478774	DIRECT		DS			54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Unilateral; Product Substitution	Azithromycin			S	Oral	Quantity:1 Tot - Total;		Teva	
	Cymbalta			C				Not Reported	
	Abilify			C				Not Reported	
	Wellbutrin			C				Not Reported	
	Ritalin La 40			C				Not Reported	
	Nuvigil			C				Not Reported	
	Activan			C				Not Reported	
	Myrbetric Er			C				Not Reported	
	Progesterone			C				Not Reported	
	Norco (Prn For Painful Periods)			C				Not Reported	
	Motilium (From Canada)			C				Not Reported	
	Amitiza 8			C				Not Reported	
	Zantac			C				Not Reported	
	Miralax			C				Not Reported	
	Benadryl			C				Not Reported	
	Allegra			C				Not Reported	
	Bonetrex			C				Not Reported	
	Omega 3-6-9			C				Not Reported	
	Coq 10			C				Not Reported	
	Gnc Multivitamin			C				Not Reported	
	Gnc Triflex (Joints)			C				Not Reported	
	Probiotic			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	7602120	NON-EXPEDITED			US-PFIZER INC- 2010117452		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Product Dispensing Error; Product Use In Unapproved Indication; Vomiting	Zithromax			S		4 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	13939615	NON-EXPEDITED			US-PFIZER INC-2017381019		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	14565373	EXPEDITED (15-DAY)		DS	PT-AUROBINDO-AUR-APL-2018-009589		85 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Mometasona Sandoz			S	Nasal	2 Dosage Form, Once A Day		Not Reported	
	Losartan			C	Oral	50 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15418214	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018382445		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Antidiuretic Hormone Secretion	Zithromax			S	Oral	500 Mg, Single (500 Mg For 1 Dose)		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day (250 Mg Once-Daily)		Pfizer	
	Unasyn [Ampicillin Sodium;Sulbactam Sodium]			C	Intravenous (not otherwise specified)	1.5 G, 4x/Day (1.5 G Q.I.D)		Not Reported	
	Ceftazidime			C	Intravenous (not otherwise specified)	1 G, 3x/Day (1 G Q8h)		Not Reported	
	Diazepam			C	Oral	5 Mg, 2x/Day		Not Reported	
	Acetazolamide			C	Oral	250 Mg, 4x/Day (250 Mg Q.I.D)		Not Reported	
	Bisacodyl			C	Rectal	10 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Dextrose 5%	C	Intravenous (not otherwise specified)	In Nacl 0.45% Solution At A Rate Of 75 Mi/H				Not Reported	
	Salbutamol Sulfate	C	Respiratory (inhalation)	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15465488	NON-EXPEDITED			US-MAYNE PHARMA-2018MYN000715			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Rash	Fabior			S	Topical	Unk, Qd		Mayne	
	Azithromycin			S	Oral	Unk, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2018	15465566	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2018M1072969			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Renal Failure	Azithromycin			S	Unknown	Unk		Not Reported	
	Itraconazole			S		Unk		Not Reported	
	Tildiem			S	Unknown	Unk		Mylan	
	Crestor			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	7454734	NON-EXPEDITED			US-PFIZER INC-2007024850		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Mucosal Blistering; Stomatitis; Tongue Blistering	Zithromax			S	Oral	Unk		Pfizer	
	Zithromax			S				Pfizer	
	Motrin			C				Not Reported	
	Tylenol			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	10354928	NON-EXPEDITED			US-PFIZER INC-2014209820		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	250 Mg, Two Times A Day For First Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, Once A Day Til Therapy For Chronic Sinusitis		Pfizer	
	Omnicef			S		300 Mg, 2x/Day		Not Reported	
	Prenatal Vitamins			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15462935	NON-EXPEDITED			US-PFIZER INC-2018400513		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin Hcl			S		Unk		Unknown	
	Clindamycin Hcl			S		Unk		Pfizer	
	Clindamycin Palmitate Hcl			S		Unk		Pfizer	
	Clindamycin Phosphate			S		Unk		Pfizer	
	Lyrica			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15467494	EXPEDITED (15-DAY)		DE, OT	NL-AUROBINDO-AUR-APL-2018-048675		79 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Congestive; Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ciprofloxacin			S	Unknown	Unk		Aurobindo	
	Cefuroxime Sodium			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2018	15467958	EXPEDITED (15-DAY)		OT	AU-APOTEX-2018AP021646		57 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Abscess; Brain Abscess; Drug Ineffective; Drug Resistance; Pulmonary Nocardiosis	Tacrolimus			S	Unknown	Unk		Not Reported	
	Mycophenolate			S	Unknown	Unk		Apotex	
	Meropenem			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Apotex	
	Azithromycin			S				Apotex	
	Prednisolone			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S				Not Reported	
	Ciprofloxacin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2018	15499472	DIRECT		OT			64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Irregular; Hepatic Pain	Azithromycin 500mg Tablet			S	Oral	Quantity:1 Tablet(S);		Unknown	
	Atenolol			C				Not Reported	
	Multivitamins			C				Not Reported	
	Coq10			C				Not Reported	
	Low Dose Aspirin (81mg)			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	7003708	EXPEDITED (15-DAY)		OT	ZA-PFIZER INC-2009214164		40 YR	Female	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Hot; Loss Of Consciousness; Nausea	Zithromax			S	Oral	2 G, Single		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	14922545	NON-EXPEDITED			US-PFIZER INC-2018208939			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15207345	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018302889		22 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Urticaria	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15456739	NON-EXPEDITED			US-PFIZER INC-2018397840			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15472740	NON-EXPEDITED			US-PFIZER INC-2018398450			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15472926	NON-EXPEDITED			US-PFIZER INC-2018401748			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15472953	NON-EXPEDITED			US-PFIZER INC-2018399986		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15473024	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-PURDUE PHARMA-CAN-2018-0009045		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Purdue	
	Morphine Sulfate			S	Intravenous (not otherwise specified)	1 Every 10 Minutes		Purdue	
	Amiodarone			S	Unknown	Unk		Not Reported	
	Aprepitant			C	Oral	125 Mg, Unk		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported	
	Dexamethasone			C	Oral	20 Mg, Daily		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	10 Mg, Q1h		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Mg, Q4h		Not Reported	
	Diltiazem Cd			S	Oral	180 Mg, Unk		Not Reported	
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Mg, Q4h		Not Reported	
	Doxorubicin			S	Intravenous (not otherwise specified)	106 Mg, Every 14 Days		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Mg, Daily		Not Reported	
	Filgrastim			C	Subcutaneous	300 Mcg, Daily		Not Reported	
	Furosemide			S	Oral	40 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gabapentin	C	Oral	100 Mg, Tid	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q4h	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Q6h	Not Reported
Metoclopramide	C	Oral	10 Mg, Qid	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Mg, Q6h	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Mg, Q6h	Not Reported
Ondansetron	C	Oral	8 Mg, Bid	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Every 14 Days	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Q1h	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Daily	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Every 14 Days	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Every 14 Days	Not Reported
Trastuzumab	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2018	15474738	EXPEDITED (15-DAY)	HO		ES-MYLANLABS-2018M1074014		85 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bronchospasm; Rash	Azithromycin			S	Oral	500 Mg, Qd			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15348899	EXPEDITED (15-DAY)	CA, DE		PHHY2018FR086061			Unknown	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Foetal Malformation; Limb Deformity	Azithromycin			S	Transplacental	1 G, Qd		Novartis	
	Eviplera			S	Transplacental	1 Mg/L, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15357860	EXPEDITED (15-DAY)		OT	PHHY2018BR084195			Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis Gonococcal; Condition Aggravated; Drug Ineffective; Joint Swelling; Product Prescribing Error; Product Use In Unapproved Indication	Azithromycin Sandoz			S	Oral	1 Df, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15434696	EXPEDITED (15-DAY)		HO	US-EMD SERONO-9045126		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Related Reaction	Avelumab			S	Intravenous (not otherwise specified)			Not Reported	
	Vx 15/2503			S		Intravenous (not otherwise specified)		Not Reported	
	Azithromycin			S		1 Df, Qd; Unknown, Duration 5 Days		Not Reported	
	Metformin W/Sitagliptin			C				Not Reported	
	Bifidobacterium Lactobacillus			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Glucosamine And Chondrotin With Msm			C				Not Reported	
	Ferrous Fumarate/Ferrous Fumarate			C				Not Reported	
	Tylenol Pm			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aleve	C	Not Reported
Multivitamin	C	Not Reported
Potassium Chloride	C	Not Reported
Multivitamin With Minerals	C	Not Reported
Aspirin/Acetylsalicylic Acid	C	Not Reported
Tamsulosin	C	Not Reported
Fish Oil	C	Not Reported
Magnesium Gluconate	C	Not Reported
Fenofibrate	C	Not Reported
Gabapentin/Gabapentin	C	Not Reported
Ipratropium	C	Not Reported
Metoprolol Succinate	C	Not Reported
Omeprazole	C	Not Reported
Metoclopramide Hydrochloride	C	Not Reported
Hydrochlorothiazide	C	Not Reported
Losartan	C	Not Reported
Compazine	C	Not Reported
Ondansetron	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15470292	EXPEDITED (15-DAY)		DE, OT	NL-PFIZER INC-2018400468		79 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Failure	Azithromycin			S				Pfizer
Congestive; Drug	Cefuroxime Sodium			S				Not Reported
Ineffective	Ciprofloxacin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15476126	EXPEDITED (15-DAY)		DE, HO	PHHO2018NL010905		60 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Dyspnoea	Lampren			S	Oral	100 Mg, Qd		Novartis
	Ethambutol			S	Oral	1000 Mg, Qd		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Posaconazol			C	Unknown	300 Mg, Qd		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15476551	EXPEDITED (15-DAY)		OT	CA-ACS-001229		85 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Above Therapeutic; Drug Interaction	Cefuroxime			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Warfarin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15476737	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2018AP022038		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oesophageal Ulcer; Oesophagitis; Rash; Stevens-Johnson Syndrome	Azithromycin			S	Unknown			Apotex	
	Ciprofloxacin			S	Oral	500 Mg, Bid		Apotex	
	Fluticasone W/Salmeterol			C	Unknown			Not Reported	
	Salbutamol			C	Unknown			Not Reported	
	Tiotropium			C	Unknown			Not Reported	
	Ipratropium			C	Unknown			Not Reported	
	Quetiapine			C	Unknown			Not Reported	
	Risedronate			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15477098	NON-EXPEDITED			US-PFIZER INC-2018404277		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash; Throat Tightness	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15478209	EXPEDITED (15-DAY)		HO, OT	CH-MYLANLABS-2018M1072614		65 YR	Female	CHE

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Drug-Induced Liver Injury	Azithromycin			S	Unknown			Not Reported	
	Atovaquone/Proguanil			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15478510	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2018406600		29 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Phlebitis	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15478661	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018402803		93 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Single		Pfizer	
	Pregabalin			C		50 Mg, Unk		Not Reported	
	Carvedilol			C	6.25 Mg, Unk		Not Reported		
	Elopram [Citalopram Hydrobromide]			C	Oropharingeal	5 Gtt, Unk		Not Reported	
	Apixaban			C	Oral	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15479479	EXPEDITED (15-DAY)		LT	CN-PFIZER INC- 2018406528		50 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Chest Discomfort; Chills; Heart Rate Decreased; Pallor	Zithromax			S	Intravenous drip	500 Mg, 1x/Day		Pfizer	
	Sodium Chloride			C	Intravenous drip	100 MI, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15479875	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1072340		12 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dizziness; Headache; Hot Flush; Insomnia; Nervousness; Oropharyngeal Pain; Palpitations; Paraesthesia; Pharyngitis Mycoplasmal; Pyrexia	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15480050	EXPEDITED (15-DAY)		OT	PHHY2018CZ118366			Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Oliguria	Azithromycin Sandoz			S	Unknown	Unk(3 Tablets, Week Pause, Then 3 Tablets Again)		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2018	15480056	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018GSK161328		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthma; Blood Count Abnormal; Chills; Choking; Cough; Diarrhoea; Dysphagia; Dyspnoea; Dyspnoea Exertional; Ill-Defined Disorder; Obstruction; Oral Candidiasis; Pyrexia; Rhinitis Allergic; Sinusitis; Therapeutic Product Effect Incomplete; Weight	Salbutamol Sulphate			S		3 Puff(S), Prn		Glaxosmithkline	
	Pulmicort			S	Respiratory (inhalation)	200 Unk, Tid		Not Reported	
	Zenhale			S	Respiratory (inhalation)	200 Unk, Bid		Not Reported	
	Azithromycin			S		500 Mg, Unk		Not Reported	
	Prednison			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Fluctuation; Wheezing

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15231211	EXPEDITED (15-DAY)		OT	PHHY2018GB002172		27 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Malaise; Pain In Extremity; Urethritis Mycoplasmal; Urinary Tract Infection	Moxifloxacin			S	Unknown	1 Df, (Ug/Litre)		Not Reported
	Doxycycline			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	1 G, Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd (4 Days)		Not Reported
	Azithromycin			S	Unknown	500 Ot, Unk		Not Reported
	Pristinamycin			S	Unknown	1 G, Qd		Not Reported
	Pristinamycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15369666	NON-EXPEDITED			US-TEVA-2018-US-952425			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Food Aversion; Infection; Pain; Product Taste Abnormal; Wrong Technique In Product Usage Process	Azithromycin			S	Unknown			Not Reported
	Glycopyrrolate			C	Unknown			Not Reported
	Zonisamide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15370143	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020139		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Oral	500 Mg, Qd		Apotex
	Amoxicillin Trihydrate/Clavulanate Potassium			S	Unknown			Apotex
	Aspirin /00002701/			C	Oral	81 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	B12 /00056201/	C	Unknown			Not Reported
	Folic Acid	C	Oral	1 Mg, Qd		Not Reported
	Hydrochlorothiazide W/Triamterene	C	Oral	25 Mg, Qd		Not Reported
	Infliximab	C	Intravenous (not otherwise specified)	315 Mg, Unk		Not Reported
	Methotrexate	C	Oral	20 Mg, Q.Wk.		Not Reported
	Pantoloc /01263201/	C	Oral	40 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15480686	EXPEDITED (15-DAY)		OT	PHHY2018CA050098		85 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug Level Above Therapeutic; Drug Interaction; Peripheral Swelling	Azithromycin			S	Unknown	Unk		Novartis
	Cefuroxime			S	Unknown	Unk		Not Reported
	Warfarin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15481413	EXPEDITED (15-DAY)		OT	ES-APOTEX- 2018AP022278		62 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hyperkalaemia; Metabolic Acidosis	Azithromycin			S	Oral	Every 12 Hours		Apotex
	Piperacilina + Tazobactam			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cotrimoxazol			S	Intravenous (not otherwise specified)	Every 6 Hours		Not Reported
	Ciclosporin			S	Oral	Every 12 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15481749	EXPEDITED (15-DAY)		OT	CA-009507513- 1412CAN002259		19 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Maternal Exposure During Pregnancy	Isentress	S	Oral	400 Mg, 2x/Day	Merck
	Abacavir	S		300 Mg, 2x/Day	Not Reported
	Acyclovir	S		Unk	Not Reported
	Azithromycin	S		2 Df, Qd	Not Reported
	Bactrim	S		400 Mg, Bid	Not Reported
	Intelence	S	Oral	200 Mg, Bid	Not Reported
	Lamivudine	S		150 Mg, 2x/Day	Not Reported
	Prezista	S		600 Mg, 2x/Day	Not Reported
	Ritonavir	S		100 Mg, 2x/Day	Not Reported
	Tenofovir	S		300 Mg, 1x/Day	Not Reported
	Zidovudine	S		300 Mg, 2x/Day	Not Reported
	Folic Acid	C	Oral	Unk	Not Reported
	Iron (Unspecified)	C		Unk	Not Reported
	Magnesium Gluconate	C		Unk	Not Reported
	Vitamins (Unspecified)	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15484721	DIRECT					21 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Gastrointestinal Sounds Abnormal	Azithromycin Tablets Usp			S	Oral	Quantity:1 Tablet(S);		Lupin
	Kids Cheawble Tylenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2018	15485472	EXPEDITED (15-DAY)		HO	PHHY2018FR120334		76 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Pancytopenia	Ramipril			S	Oral	2.5 Mg, Qd		Not Reported
	Alprazolam			S	Oral	0.25 Mg, Qd		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mirtazapine	S	Oral	15 Mg, Qd	Not Reported
Acide Folique	S	Oral	2 Cp De 5 Mg En Une Prise	Not Reported
Adiazine	S	Oral	1000 Mg, Qd	Not Reported
Bisoce	S	Oral	Unk Unk, Qd	Not Reported
Oxycontin Lp	S	Oral	2 Df, Qd	Not Reported
Malocide (Pyrimethamine)	S	Oral	50 Mg, Qd	Not Reported
Risperdal	S	Oral	0.25 Mg, Qd	Not Reported
Oxynorm	S	Oral	5 Mg, Qd	Not Reported
Sertraline	S	Oral	25 Mg, Qd	Not Reported
Lyrica	S	Oral	150 Mg, Qd	Not Reported
Novatrex	S	Oral	4 Cp De 2,5 Mg En Une Prise/Semaine	Not Reported
Kardegic	S	Oral	75 Mg, Qd	Not Reported
Cortancyl	S	Oral	9 Mg, Qd	Not Reported
Pantoprazole	S	Unknown	20 Mg, Qd	Not Reported
Phosphoneuros	S	Oral	100 Mg, Qd	Not Reported
Orencia	S	Intravenous (not otherwise specified)	Une Perfusion	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	12607807	EXPEDITED (15-DAY)		HO	FR-JNJFOC- 20160717333		76 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Pancytopenia	Risperdal			S	Oral	From Long Time		Not Reported
	Folic Acid			S	Oral	2 Tablets Of 5 Mg In One Intake		Not Reported
	Azithromycin			S	Oral	4 Tablets Of 2.5 Mg In One Intake; Long Term		Not Reported
	Orencia			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Adiazine	S	Oral	Not Reported
Mirtazapine	S	Oral	Not Reported
Ramipril	S	Oral	Not Reported
Cortancyl	S	Oral	Not Reported
Oxycontin Lp	S	Oral	Not Reported
Lyrica	S	Oral	Not Reported
Pyrimethamine	S	Oral	Not Reported
Pantoprazole	S	Unknown	Not Reported
Phosphoneuros	S	Oral	Not Reported
Oxynorm	S	Oral	Not Reported
Alprazolam	S	Oral	Not Reported
Bisoce	S	Oral	Not Reported
Kardegic	S	Oral	Not Reported
Sertraline	S	Oral	Not Reported
Novatrex	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	14227856	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017501712		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	14536015	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-855975		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Fatigue; Flank Pain; Gait Disturbance; Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Prednisone			S	Oral	20 Milligram Daily; 20 Mg, Daily		Actavis
	Prednisone			S	Oral	60 Milligram Daily; 60 Mg, Once Daily (Qd), 30 Mg,		Actavis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

				2x/Day (At Breakfast Time)	
Prograf	S	Oral		10 Milligram Daily; 5 Mg, 2x/Day (1 In The Morning And 1 Before Dinner)	Not Reported
Prograf	S	Oral		2x/Day (Bid) (4.5 Mg Before Breakfast And 4 Mg Before Dinner))	Not Reported
Zitromax	S	Oral		250 Mg, Ev 2 Days (Qod)(1df, On L-X-V At Lunch Time)	Not Reported
Septrin	S	Oral		1 Dosage Forms Daily; Once Daily (Qd) 400 Mg/80 Mg	Not Reported
Septrin	S				Not Reported
Cellcept	S	Oral		2000 Milligram Daily; 1000 Mg, 2x/Day (Bid), 500 Mg, 4x/Day (2 At Breakfast And 2 At Dinner)	Not Reported
Cellcept	S	Oral		2 At Breakfast And 2 At Dinner	Not Reported
Valganciclovir	S	Oral		900 Mg, 1x/Day (At Lunch Time)	Not Reported
Valganciclovir	S	Oral		At Lunch Time	Not Reported
Abelcet	C	Respiratory (inhalation)		50 Mg, Weekly (On Mondays In The Afternoon)	Not Reported
Omeprazole	C	Oral		20 Milligram Daily; 20 Mg, 1x/Day (At Breakfast)	Not Reported
Paracetamol	C	Oral		At 500 Mg (2 At Breakfast, 2 At Lunch, 2 At Dinner), As Needed	Not Reported
Dexketoprofen	C	Oral		At 25 Mg (1 At Breakfast, 1 At Lunch, 1 At Dinner), As Needed	Not Reported
Calcium + Vitamin D	C	Oral		Unk, 2x/Day 500/400	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lorazepam C Oral 1 Milligram Daily; 1 Mg, 1x/Day (At Bedtime) Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15456308	EXPEDITED (15-DAY)		HO, OT	PHHY2018SI114440			Male	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Azithromycin			S	Unknown	Unk		Novartis
Arthralgia; Asthenia; Blood Pressure Decreased;	Moxifloxacin			S	Unknown	Unk		Not Reported
Body Temperature Decreased; Body Temperature Increased;								
Cough; Decreased Appetite; Dermatitis Exfoliative Generalised;								
Dyspnoea; Fatigue; Fibrosis; Flatulence;								
Haemoglobin Decreased;								
Haemophagocytic Lymphohistiocytosis;								
Hypermetabolism;								
Hypersensitivity;								
Lymphadenopathy;								
Lymphoma; Mobility Decreased;								
Myelodysplastic Syndrome; Natural Killer Cell Count Decreased;								
Nausea; Night Sweats;								
Oedema Peripheral;								
Palpitations; Psoriatic Arthropathy; Pyrexia;								
Rales; Serum Ferritin Increased; Skin Exfoliation; Swelling;								
Vomiting; Weight Decreased								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15486879	NON-EXPEDITED			US-TEVA-2018-US-961674		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Feeling Jittery; Headache; Nervousness; Tinnitus	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15487339	EXPEDITED (15-DAY)		OT	GR-ALKEM LABORATORIES LIMITED-GR-ALKEM- 2018-06390		26 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Cefuroxime Axetil			S	Oral	500 Mg, Bid		Alkem	
	Cefuroxime Axetil			S				Alkem	
	Clavam			S	Oral	Unk		Not Reported	
	Itraconazole			S	Oral	Unk		Alkem	
	Clotrimazole			S	Vaginal	Unk		Not Reported	
	Fenticonazole Nitrate			S	Vaginal	600 Mg, Unk		Not Reported	
	Fenticonazole			S				Not Reported	
	Ciprofloxacin			S	Oral	Unk		Not Reported	
	Cefprozil			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Clindamycin Cream			S	Topical	Unk		Not Reported	
	Ketoconazole			S	Vaginal	Unk		Not Reported	
	Natalizumab			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15487762	NON-EXPEDITED		HO, OT	US-APOTEX- 2018AP022506		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged	Azithromycin	S	Oral	500 Mg, Qd	Apotex
	Azithromycin	S	Unknown	250 Mg, Daily	Apotex
	Amikacin	S	Intravenous (not otherwise specified)	15 Mg/Kg, Every Monday, Wednesday, And Friday	Not Reported
	Amikacin	S	Other	250 Mg In 100 MI Normal Saline Every Monday, Wednesday, And Friday Via Wound Vacuum	Not Reported
	Imipenem Cilastatin /00820501/	S	Intravenous (not otherwise specified)	500 Mg, Tid	Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)	100 Mg, Q.12h	Not Reported
	Clofazimine	S	Oral	100 Mg, Daily	Not Reported
	Clofazimine	S	Unknown	50 Mg, Daily	Not Reported
	Clofazimine	S	Unknown	100 Mg, T.I.W	Not Reported
	Imipenem	S	Intravenous (not otherwise specified)	500 Mg, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15489434	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018406787		28 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amaurosis Fugax; Chest Discomfort	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer
	Kai Wei Ke			C	Intravenous drip	5 G, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15489578	NON-EXPEDITED			US-PFIZER INC-2018412042		81 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15489936	EXPEDITED (15-DAY)		LT	IT-MYLANLABS-2018M1075721		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Toxic Epidermal Necrolysis	Diazepam			S	Oral	20 Gtt, Unk		Not Reported	
	Quetiapine			S	Oral	200 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Zolpidem			S	Oral	10 Mg, Qd		Not Reported	
	Rocefin			S	Parenteral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2018	15490301	NON-EXPEDITED			US-PFIZER INC-2018408832			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		600 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15175649	EXPEDITED (15-DAY)		HO	PHHY2018FR048251		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Methotrexate			S	Intramuscular	Unk		Novartis	
	Novatrex			S	Oral	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15480742	EXPEDITED (15-DAY)		HO	PHEH2018US042389			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cough; Expired Product Administered; Inflammation; Malaise;	Azithromycin 250 Mg			S	Unknown	250 Mg, Bid		Novartis	
	Zecra			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting	Clonazepam	C	Unknown	Unk		Not Reported
	Tylenol	C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15483741	NON-EXPEDITED			US-PFIZER INC-2018404104			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Palpitations	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15491189	EXPEDITED (15-DAY)		HO, OT	UA-TEVA-2018-UA-962664			Male	UKR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bronchiolitis; Drug Ineffective	Sumamed			S	Unknown			Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15491925	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-050348		59 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cholestasis; Hepatocellular Injury	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
	Zithromax			S	Intravenous (not otherwise specified)	500 Milligram		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Oct-2018	15492436	EXPEDITED (15-DAY)		OT	CA-LUPIN PHARMACEUTICALS INC.-2018-07144		85 YR	Male	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anticoagulation Drug Level Above Therapeutic;	Azithromycin			S	Endocervical	Unk		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction	Cefuroxime	S	Unknown	Unk	Not Reported
	Warfarin	S	Unknown	Unk	Not Reported
	Warfarin	S	Unknown	Unk (Dose Decreased)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15495071	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP022355		30 DAY	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azithromycin			S	Oral	40 Mg, Qd		Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2018	15496061	EXPEDITED (15-DAY)		OT	PHHY2018US118650			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Oxacillin			S	Transplacental	1,000 Mg/L ,Unk (Maternal Dose)		Novartis
	Oxacillin			S	Transplacental	1,000 Mg/L ,Unk (Maternal Dose)		Novartis
	Ampicillin			S	Transplacental	Unk (Maternal Dose)		Not Reported
	Azithromycin			S	Transplacental	Unk(Maternal Dose)		Not Reported
	Betamethasone			S	Transplacental	Unk (Maternal Dose)		Not Reported
	Indigo Carmine			S	Transplacental	5 MI (Maternal Dose)		Not Reported
	Acyclovir			S	Transplacental	Unk (Maternal Dose)		Not Reported
	Nacl			S	Transplacental	400 MI Of 0.9 % Concentration (Maternal Dose)		Not Reported
	Nacl			S	Transplacental	800 MI Of 0.9% Concentration (Maternal Dose)		Not Reported
	Penicillin			S	Transplacental	Unk (Maternal Dose)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	14256450	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017517951		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Mycobacterium Abscessus Infection	Azithromycin			S		Unk		Pfizer	
	Ethambutol			S		Unk		Not Reported	
	Rifampin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15401615	NON-EXPEDITED			US-PFIZER INC-2018379051		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15487012	NON-EXPEDITED			US-TEVA-2018-US-961655		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Feeling Abnormal; Feeling Jittery; Headache; Swelling Face	Azithromycin Zpak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15499247	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2018M1074613		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Infection; Appendicitis Perforated; Cushing'S Syndrome; Electrocardiogram Qt Prolonged; Mycobacterium	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Oral	Later, The Dose Was Reduced Temporarily		Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abscessus Infection	Methylprednisolone	S	Unknown	The Dosage Were Tapering	Mylan
	Cellcept /01275102/	S	Unknown		Mylan
	Imuran /00001501/	S	Unknown		Mylan
	Clofazimine	S	Oral	At Times, The Dose Was Temporarily Reduced To 50 Mg Daily	Mylan
	Clofazimine	S	Oral	50 Mg, Qd	Mylan
	Amikacin	C	Intravenous (not otherwise specified)	Administered Every Monday, Wednesday And Friday	Mylan
	Amikacin	C	Other	Istillation Of Amikacin 250 Mg In 100 MI Normal Saline Every Monday, Wednesday And Friday Via Wou...	Mylan
	Imipenem/Cilastatin	C	Intravenous (not otherwise specified)	500 Mg, Q8h	Mylan
	Tigecycline	C	Intravenous (not otherwise specified)	100 Mg	Mylan
	Voriconazole	C	Unknown	300 Mg Every Morning And 200 Mg Every Evening	Mylan
	Normal Saline	C	Other		Mylan
	Hydroxychloroquine	C	Unknown		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15499322	EXPEDITED (15-DAY)		OT	GR-GLAXOSMITHKLINE-GR2017204398			Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Diclofenac			S	Transplacental	Maternal Dose: 50 Mg, Every 12 Hours		Glaxosmithkline	
	Metronidazole			S	Transplacental	Maternal Dose: 1g, Qd		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Betamethasone	S	Transplacental	Maternal Dose: Two Doses Of 12 Mg With A 24-Hour Interval	Glaxosmithkline
Azithromycin	S	Transplacental	Unk	Glaxosmithkline
Atosiban	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15500036	EXPEDITED (15-DAY)		OT	PHHY2018NL122319		61 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Toxicity; Hepatotoxicity; Steroid Diabetes; Treatment Failure	Ciclosporin			S	Unknown			Novartis
	Methotrexate			S	Unknown			Not Reported
	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Cyclophosphamide			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Hydroxychloroquine			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2018	15500534	NON-EXPEDITED			US-TEVA-2018-US-962447			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Dizziness; Hyperhidrosis; Nausea	Azithromycin			S	Unknown			Not Reported
	Gabapentin			C				Not Reported
	Trileptal			C				Not Reported
	Prednisone			C				Not Reported
	Cyclosporine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	12604597	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2016355691		76 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure;	Novatrex			S	Oral	4 Tablets Of 2.5 Mg,		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Myelodysplastic Syndrome; Pancytopenia				Weekly	
	Lyrica	S	Oral	150 Mg, 1x/Day	Pfizer
	Alprazolam	S	Oral	0.25 Mg, 1x/Day	Pfizer
	Sertraline Hcl	S	Oral	25 Mg, 1x/Day	Pfizer
	Ramipril	S	Oral	2.5 Mg, 1x/Day	Pfizer
	Mirtazapine	S	Oral	15 Mg, 1x/Day	Not Reported
	Pantoprazole	S		20 Mg, 1x/Day	Pfizer
	Orencia	S	Intravenous (not otherwise specified)	500 Mg, Monthly	Not Reported
	Orencia	S		Unk	Not Reported
	Adiazine	S	Oral	1000 Mg, 1x/Day	Not Reported
	Cortancyl	S	Oral	9 Mg, 1x/Day	Not Reported
	Folic Acid	S	Oral	2 Tablets Of 5 Mg, Weekly	Not Reported
	Oxycontin Lp	S	Oral	30 Mg, 1x/Day	Not Reported
	Malocide /00112501/	S	Oral	50 Mg, 1x/Day	Not Reported
	Phosphoneuros	S	Oral	100 Mg, 1x/Day	Not Reported
	Oxynorm	S	Oral	5 Mg, 1x/Day	Not Reported
	Bisoce	S	Oral	1.25 Mg, 1x/Day	Not Reported
	Kardegic	S	Oral	75 Mg, 1x/Day	Not Reported
	Risperdal	S	Oral	0.25 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	14677063	EXPEDITED (15-DAY)		OT	DE-AMGEN-DEUSP2018037202		51 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Repatha			S	Subcutaneous	140 Mg, Unk		Amgen	
	Moxifloxacin			S	Oral	400 Mg, 5 Days		Not Reported	
	Azithromycin			S	Unknown	1x		Not Reported	
	Restex			C	Oral	100 Mg/25 Mg		Not Reported	
	Valsartan			C		160 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15351965	EXPEDITED (15-DAY)		CA, DE	FR-PFIZER INC-2018355600			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Malformation; Limb Deformity; Maternal Exposure During Pregnancy	Azithromycine			S	Transplacental	1 G, 1x/Day		Pfizer	
	Eviplera			S	Transplacental	1 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15505959	NON-EXPEDITED			US-PFIZER INC-2018419519		11 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15505966	NON-EXPEDITED			US-PFIZER INC-2018419405		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15506018	NON-EXPEDITED			US-PFIZER INC-2018420882		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2018	15506648	EXPEDITED (15-DAY)		HO, OT	CH-TEVA-2018-CH-963217		65 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Autoimmune Hepatitis;	Azithromycin	S	Unknown	Not Reported
Hepatitis	Atovaquone/Proguanil	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15473477	EXPEDITED (15-DAY)	HO		JP-PFIZER INC-2018397464		72 YR	Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Eczema;	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer
Peripheral Swelling;	Unasyn-S			S	Intravenous drip	Unk		Pfizer
Product Use Issue; Rash;	Lansoprazole			C	Oral	Unk		Not Reported
Skin Exfoliation; Swelling	Mucodyne			C	Oral	Unk		Not Reported
Face	Spiriva			C	Oral	Unk		Not Reported
	Allopurinol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515178	EXPEDITED (15-DAY)		OT	PL-TEVA-2018-PL-964358			Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Cardiac Murmur;	Sumamed Forte			S	Unknown			Not Reported
Decreased Appetite;								
Dysphagia; Enterocolitis								
Fungal; Fungal								
Oesophagitis; Fungal								
Pharyngitis; Malaise; Oral								
Fungal Infection; Salivary								
Hypersecretion;								
Somnolence								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15515887	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2018-050910		58 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Rectal Haemorrhage	Ventolin /00139501/	C	Respiratory (inhalation)	As Necessary	Not Reported
	Zaditen	C	Ophthalmic	As Necessary	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516130	NON-EXPEDITED			US-PFIZER INC-2018416866		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15516962	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1075916		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Self-Injury; Sopor	Aripiprazole			S	Oral	210 Mg, Total		Not Reported	
	Escitalopram			S	Oral	140 Mg, Total		Not Reported	
	Alprazolam			S	Oral	15 MI, Total		Not Reported	
	Prozin /00011902/			S	Oral	1200 Mg, Total		Mylan	
	Zitromax			S	Oral	1500 Mg, Total		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15517806	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1077805		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Decreased Appetite; Dysgeusia; Haemoptysis	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Amikacin			S	Respiratory (inhalation)	Unk		Mylan	
	Lamprene /00224701/			S	Oral	100 Mg, Qd		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15518021	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK201810644		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported	
	Zithromax			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2018	15518588	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018422084		58 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Ventolin [Salbutamol Sulfate]			C	Respiratory (inhalation)	Unk Unk, As Needed		Not Reported	
	Zaditen			C	Ophthalmic	Unk Unk, As Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15308236	EXPEDITED (15-DAY)		CA, DE	FR-TEVA-2018-FR-945861			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Foetal Exposure During Pregnancy; Foetal Malformation; Limb Deformity	Azithromycine Anhydre			S	Transplacental			Not Reported	
	Eviplera 200 Mg/25 Mg/245 Mg, Comprimé Pelliculé			S	Transplacental	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15385961	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018GSK164953		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Palpitations; Product Use Issue	Breo Ellipta Inhalation Powder	S	Respiratory (inhalation)	1 Puff(S), Qd	Glaxosmithkline
	Azithromycin	S	Oral	250 Mg, Unk	Glaxosmithkline
	Azithromycin	S		5 Mg/Kg, Unk	Glaxosmithkline
	Vyvanse	S	Oral	40 Mg, Unk	Not Reported
	Vyvanse	S	Oral	60 Mg, Unk	Not Reported
	Vyvanse	S	Oral	40 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15497387	NON-EXPEDITED			US-PFIZER INC-2018418599			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Hydrocodone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15523451	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP022689		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Factor V Inhibition; Intra-Abdominal Haematoma	Azithromycin			S	Unknown	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15524686	NON-EXPEDITED			US-PFIZER INC-2018418935		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Allergies	Ramipril			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Cephalexin [Cefalexin]			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15525328	EXPEDITED (15-DAY)		HO	US-APOTEX-2018AP022685		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Factor V Inhibition	Azithromycin			S	Unknown	Unk		Apotex	
	Ertapenem			S	Unknown	Unk		Not Reported	
	Voriconazole			S	Unknown	Unk		Not Reported	
	Cisplatin			C	Unknown	Unk		Not Reported	
	Etoposide			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15526369	EXPEDITED (15-DAY)		OT	ES-009507513-1810ESP006845		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Respiratory Alkalosis	Montelukast Sodium			S	Oral	Unk		Merck	
	Albuterol (+) Ipratropium Bromide			S		Every Eight Hours		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Terbutaline Sulfate			S		Unk		Not Reported	
	Fluticasone Propionate (+) Salmeterol Xinafoate			S		1500/150 Mcg Day		Not Reported	
	Deflazacort			S		As Required		Not Reported	
	Corticosteroids (Unspecified)			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15529984	EXPEDITED (15-DAY)		DE, HO, LT	US-PFIZER INC-2018421420		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Levofloxacin			S		Unk (For 14 Days) (2 Weeks)		Pfizer	
	Methylprednisolone Sodium			S	Intravenous (not	1 Mg/Kg, 2x/Day (2		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Succinate		otherwise specified)	Weeks)	
Azithromycin	S		Unk (5-Day Course)	Pfizer
Vancomycin Hcl	S		Unk (5-Day Course)	Pfizer
Cefepime Hcl	S		Unk (5-Day Course)	Unknown
Pembrolizumab	C		200 Mg, Every 3 Weeks	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15530261	NON-EXPEDITED			US-PFIZER INC-2018424225			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Spironolactone			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2018	15530433	EXPEDITED (15-DAY)		OT	PHHY2018ES127304		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Respiratory Alkalosis	Montelukast Sodium			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Salmeterol/Fluticasone			S	Unknown	1500/150 Mcg Day		Not Reported
	Ipratropium Bromide And Salbutamol Sulfate			S	Unknown	Unk Unk, Q8h		Not Reported
	Terbutaline			S	Unknown	Unk		Not Reported
	Deflazacort			S	Unknown	Unk, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	14351744	EXPEDITED (15-DAY)		DE, LT	AU-PFIZER INC-2017556412		10 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Lincomycin Hcl			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem	S	Respiratory (inhalation)	Unk	Pfizer
Vancomycin Hcl	S		Unk	Pfizer
Azithromycin	S		Unk	Pfizer
Sulfamethoxazole/Trimethoprim	S		Unk	Pfizer
Prostacyclin	S		Unk	Not Reported
Oseltamivir	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15049643	NON-EXPEDITED			US-PFIZER INC-2018251895		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Phosphate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15524421	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018413953		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15531179	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-965844		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Levofloxacin			S	Intravenous (not otherwise specified)			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax S Intravenous (not otherwise specified) Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15531348	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-965829		47 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Blood Bilirubin Increased; Transaminases Increased	Azithromycine Anhydre			S	Oral	1000 Milligram Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15531616	NON-EXPEDITED			US-PFIZER INC-2018406506		64 YR	Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15533395	EXPEDITED (15-DAY)		OT	PHHY2018US128826		68 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pneumonia	Azithromycin			S	Unknown	Unk		Novartis
	Voriconazole			S	Unknown	Unk		Not Reported
	Ertapenem			S	Unknown	Unk		Not Reported
	Cisplatin			S	Unknown	Unk		Not Reported
	Etoposide			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Oct-2018	15533448	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018412099		2 YR	Male	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mental Disorder; Peripheral Coldness; Pruritus; Pyrexia; Vomiting	Zithromax			S	Intravenous drip	0.12 G, 1x/Day		Pfizer	
	Vitamin B6			C	Intravenous drip	0.1 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2018	15533967	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018413898		47 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Bilirubin Increased; Transaminases Increased	Azithromycine			S	Oral	1000 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2018	14379280	EXPEDITED (15-DAY)		LT	AU-STRIDES ARCOLAB LIMITED- 2018SP000198		10 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Ineffective For Unapproved Indication	Vancomycin			S	Unknown	Unk		Strides	
	Oseltamivir			S	Unknown	Unk		Strides	
	Lincomycin			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Prostacyclin			S		Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Oct-2018	15529668	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2018-051309		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective;	Montelukast			S	Unknown	Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Respiratory Alkalosis	Ipratropium Bromide And Salbutamol Sulfate	S	Unknown	Every Eight Hours	Not Reported
	Azitromicin	S	Unknown	Unk	Not Reported
	Terbutaline	S	Unknown	Unk	Not Reported
	Fluticasone W/Salmeterol	S	Unknown	1500/150 Mcg Day	Not Reported
	Deflazacort	S	Unknown	As Required	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	14295570	NON-EXPEDITED			US-PFIZER INC-2017536775		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Cleocin			S		Unk		Pfizer
	Cleocin			S	Vaginal	Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Sulfadiazine Silver			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Norco			S		Unk		Not Reported
	Emycin			S		Unk		Not Reported
	Zithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15158284	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1051234		62 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Macroglossia; Palatal Oedema	Brufen 600 Mg Granulato Effervescente			S	Oral	Unk		Mylan
	Zitromax 500 Mg Compresse			S	Oral	1 Df, Qd		Mylan
	Rivestite Con Film							
	Colchicine			C				Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15450549	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-048079		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nocardiosis	Prednisone			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Tacrolimus			S				Not Reported	
	Atovaquone			C	Unknown	1500 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15535497	NON-EXPEDITED			US-TEVA-2018-US-964154			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Urticaria	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15538183	EXPEDITED (15-DAY)		OT	MA-PFIZER INC-2018423399			Female	MAR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Product Misuse; Loss Of Consciousness; Syncope; Wrong Dose	Zithromax			S		2 Df (500 Mg Tablets, 2 Separate Tablets On The First Day)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15538227	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2018411928		35 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Macule; Papule	Zithromax			S	Oral	1 Df, 1x/Day		Pfizer	
	Amoxicillin			S	Oral	0.5 G, 3x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15538611	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1078645		36 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Bilirubin Increased; Blood Lactate Dehydrogenase Increased; Chills; Dyspnoea; Haemoglobin Decreased; Haemolytic Anaemia; Hepatocellular Injury; Jaundice	Azithromycin			S	Oral	500 Mg, Unk		Not Reported	
	Paracetamol			C	Oral	1 G, Unk		Mylan	
	Omeprazole			C	Oral	20 Mg, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2018	15538800	NON-EXPEDITED			US-TEVA-2018-US-964532			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	Twice On Day 1 And Once From Day 2-5		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	12561750	EXPEDITED (15-DAY)		DE, OT	FR-PFIZER INC-2016343183		4 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Diarrhoea; Drug Interaction; Overdose; Product Prescribing Error; Toxicity To Various Agents; Vomiting	Zithromax			S		Unk		Pfizer	
	Colchicine			S		8 Mg Of Colchicine 2 Times A Day (16 Tablets Of 0.5 Mg Crushed With A Bit Of Water)		Not Reported	
	Paracetamol			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15536861	EXPEDITED (15-DAY)		DE, HO	CA-PFIZER INC-2018428599		19 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Metabolic Acidosis; Overdose; Toxicity To Various Agents	Codeine			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Pfizer	
	Ciprofloxacin			S	Oral	Unk		Unknown	
	Aerius [Desloratadine]			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Caffeine			S	Oral	Unk		Not Reported	
	Caffeine			S	Oral	Unk		Not Reported	
	Tylenol With Codeine No.3			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15538465	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018425338		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Respiratory Alkalosis	Azithromycin			S		Unk		Pfizer	
	Montelukast Sodium			S		Unk		Not Reported	
	Ipratropium Bromide And Albuterol Sulfate			S		Unk Unk, 3x/Day (Every Eight Hours)		Not Reported	
	Terbutaline			S		Unk		Not Reported	
	Salmeterol/Fluticasonpropionaat			S		1500/150 Mcg Day		Not Reported	
	Deflazacort			S		As Required		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15539489	EXPEDITED (15-DAY)		OT	ES-TEVA-2018-ES-967542		58 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Ventolin 100 Microgramos/Inhalación Suspensión Para Inhalación En Enva	C	Respiratory (inhalation)		Not Reported
	Zaditen 0,25 Mg/MI Colirio En Solucion En Envase Unidosis , 20 Envases	C	Ophthalmic		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15539936	EXPEDITED (15-DAY)		HO	UA-TEVA-2018-UA- 966945			Unknown	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Sumamed			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15540245	EXPEDITED (15-DAY)		CA, DE	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-183333			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Foetal Exposure During Pregnancy; Foetal Malformation; Limb Deformity	Azithromycine			S	Transplacental	1 G, Daily			Sun
	Eviplera 200 Mg/25 Mg/245 Mg, Comprime Pellicule			S	Transplacental	1 Df, Daily			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15540794	EXPEDITED (15-DAY)		HO	UA-TEVA-2018-UA- 966947			Unknown	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Sumamed			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2018	15541353	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2018431651		29 YR	Female	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Hypersensitivity; Hypotension; Lip Oedema; Oedema Mouth; Oedema Mucosal; Rash	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Cefazolin Sodium			S	Intravenous drip	2 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	14974027	EXPEDITED (15-DAY)		HO	PL-MYLANLABS- 2018M1036924		2 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Auscultation; Blood Lactate Dehydrogenase Increased; Cough; Drug Ineffective; Dry Mouth; Electrolyte Imbalance; Hyponatraemia; Pneumonitis; Pyrexia; Renal Failure; Streptococcus Test Positive	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15346436	NON-EXPEDITED			US-PFIZER INC- 2018356150			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544313	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20181025267		25 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	Y S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Not Reported
	Diphenhydramine Hydrochloride	Y S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Pms Azithromycin	S	Unknown	Not Reported
	Rifadine	S	Unknown	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15544445	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-965317			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Alendronate			S	Oral			Actavis	
	Alendronate			S				Actavis	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xolair	S	Subcutaneous		Not Reported
	Xolair	S	Subcutaneous		Not Reported
	Alvesco	C		4 Dosage Forms Daily;	Not Reported
	Calcium	C	Oral	2 Dosage Forms Daily;	Not Reported
	Calcium	C			Not Reported
	Singulair	C	Oral	1 Dosage Forms Daily;	Not Reported
	Spiriva	C		1 Dosage Forms Daily;	Not Reported
	Symbicort Turbuhaler	C		4 Dosage Forms Daily;	Not Reported
	Ventolin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15545781	NON-EXPEDITED			PHEH2018US044460			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Vomiting	Rifampin			S	Unknown	Unk		Novartis
	Rifampin			S				Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Ethambutol			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15547335	NON-EXPEDITED			US-TEVA-2018-US-965737			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2018	15547338	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-966574		57 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Wall Infection; Acute Kidney Injury; Appendicitis Perforated; Deafness; Diarrhoea; Electrocardiogram Qt Prolonged; Glucose Tolerance Impaired; Mycobacterium Abscessus Infection; Nausea; Obesity; Osteoporosis; Pituitary-Dependent Cushing'S Syndrome; Seizure; Sleep Apnoea Syndrome	Prednisone	S	Unknown		Actavis
	Methylprednisolone	S	Unknown	The Dosage Were Tapering	Not Reported
	Amikacin	S	Intravenous (not otherwise specified)	Administered Every Monday, Wednesday And Friday	Teva
	Amikacin	S	Other	Istillation Of Amikacin 250 Mg In 100 MI Normal Saline Every Monday, Wednesday And Friday Via Wou...	Teva
	Cellcept	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Imipenem/Cilastatin	S	Intravenous (not otherwise specified)		Not Reported
	Azithromycin	S	Oral	Later, The Dose Was Reduced Temporarily	Not Reported
	Azithromycin	S	Oral		Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)		Not Reported
	Clofazimine	S	Oral	At Times, The Dose Was Temporarily Reduced To 50 Mg Daily	Not Reported
	Clofazimine	S	Oral		Not Reported
	Hydroxychloroquine	C	Unknown		Not Reported
	Voriconazole	C	Unknown	300 Mg Every Morning And 200 Mg Every Evening	Not Reported
	Normal Saline	C	Other		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	6977433	EXPEDITED (15-DAY)		DS, HO, LT, OT	CY-PFIZER INC- 2009198817		16 YR	Male	CYP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Hepatic Failure; Bone Marrow Disorder; Drug Ineffective; Drug- Induced Liver Injury; Drug- Induced Liver Injury; Encephalopathy; Hepatic Encephalopathy; Hepatic Necrosis; Intracranial Pressure Increased; Lymphoid Tissue Hyperplasia; Neurological Symptom; Renal Failure	Zithromax Zithromax Zithromax Zithromax Co-Amoxiclave Formoterol Prednisolone	S S S S S C C	Oral Respiratory (inhalation)	500 Mg, 1x/Day Unk Unk Unk	Pfizer Pfizer Pfizer Pfizer Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15406528	NON-EXPEDITED			US-PFIZER INC- 2018379484		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S	Oral	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15482798	NON-EXPEDITED			US-PFIZER INC- 2018407158		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective	Zithromax Zithromax Zithromax			S S S		Unk		Pfizer Pfizer Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15548692	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-189001		58 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin Ventolin 100			S C	Oral Respiratory	500 Mg, Daily ()As Necessary		Sun Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Microgramos/Inhalacion
Suspension Para Inhalacion En
E...
Zaditen 0,25 Mg/MI Colirio En
Solucion En Envase Unidosis ,
20 Enva...

(inhalation)

C

Ophthalmic

()As Necessary

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15548919	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-967013		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Salbutamol Sulfate			S	Unknown			Not Reported
	Alvesco			S	Unknown	2 Dosage Forms Daily;		Not Reported
	Spiriva			S	Unknown	4 Dosage Forms Daily;		Not Reported
	Zenhale			S	Unknown	4 Dosage Forms Daily;		Not Reported
	Zithromax			S	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15549487	NON-EXPEDITED			US-PFIZER INC-2018431087		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sinusitis	Azithromycin			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Unknown
	Xeljanz Xr			S		11 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15549881	EXPEDITED (15-DAY)		OT	PHHY2018MY135940		39 YR	Male	MYS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Delirium; Disorganised Speech; Hallucination, Auditory;	Amoxicillin+Clavulanate			S	Intravenous (not otherwise specified)			Novartis

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Irritability; Psychotic Disorder		Azithromycin		S	Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15551048	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1077289		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Factor V Inhibition; Splenic Haematoma	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15551323	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018430030		67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Ototoxicity; Product Use Issue	Azithromycin			S	Oral	750 Mg, 1x/Day (On A Monday, Wednesday And Friday)			Pfizer
	Amitriptyline Hydrochloride			C		Unk			Not Reported
	Fostair			C		Unk			Not Reported
	Paracetamol			C		Unk			Not Reported
	Montelukast Sodium			C		Unk			Not Reported
	Co-Codamol			C		Unk			Not Reported
	Esomeprazole Magnesium			C		Unk			Not Reported
	Salbutamol			C		Unk			Not Reported
	Fluoxetine Hydrochloride			C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2018	15552277	NON-EXPEDITED			US-PFIZER INC-2018435810			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	13990346	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017401771		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Diarrhoea; Nausea; Optic Neuritis; Visual Impairment; Weight Decreased	Azithromycin			S		250 Mg, Daily		Pfizer
	Ethambutol			S		15 Mg/Kg, Daily		Not Reported
	Moxifloxacin			S		400 Mg, Daily		Not Reported
	Prednisone			C		5 Mg, Daily		Not Reported
	Tacrolimus			C		5 Mg, 2x/Day		Not Reported
	Atorvastatin			C		10 Mg, 1x/Day (At Night)		Not Reported
	Filgrastim			C	Subcutaneous	300 Ug, Weekly		Not Reported
	Pentamidine			C	Respiratory (inhalation)	300 Mg, Monthly		Not Reported
	Rifampin			C		600 Mg, Daily		Not Reported
	Levemir			C	Subcutaneous	Every Morning		Not Reported
	Insulin Aspart			C	Subcutaneous	With Meals		Not Reported
	Acetylsalicylic Acid			C		162 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	14149186	EXPEDITED (15-DAY)		HO, LT, OT	US-SA-2017SA199498		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acinetobacter Infection; Blood Creatinine Increased; Condition Aggravated; Delirium; Drug Ineffective; Drug Resistance; Emphysematous Cholecystitis; Hepatic Function Abnormal; Hypotension; Renal	Azithromycin			S	Unknown	Unk Unk,Unk,On Day 36		Not Reported
	Azithromycin			S	Unknown	Unk Unk,Unk		Not Reported
	Meropenem			S	Unknown	Unk Unk,Unk		Not Reported
	Rifampicin			S	Unknown	Unk Unk,Unk		Sanofi
	Colistin Sulfate			S	Unknown	Unk Unk,Unk, On Day 36		Not Reported
	Colistin Sulfate			S	Unknown	Unk Unk,Unk		Not Reported
	Vancomycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Impairment; Respiratory Failure; Unresponsive To Stimuli; White Blood Cell Count Increased	Tigecycline	S	Unknown	Unk Unk,Unk	Not Reported
	Fluconazole	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15014568	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-907426		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Methotrexate			S	Intramuscular			Barr	
	Novatrex			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15494215	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2018408416			Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Product Use Issue	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15553048	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-052034		67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Ototoxicity	Azithromycin			S	Oral	750 Milligram, Daily,On A Monday, Wednesday And Friday		Aurobindo	
	Amitriptyline Hydrochloride			C	Unknown	Unk		Not Reported	
	Co-Codamol			C	Unknown	Unk		Not Reported	
	Esomeprazole /01479302/			C	Unknown	Unk		Not Reported	
	Fluoxetine Hydrochloride			C	Unknown	Unk		Not Reported	
	Fostair			C	Unknown	Unk		Not Reported	
	Montelukast Sodium			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Paracetamol		C	Unknown	Unk			Not Reported	
	Salbutamol		C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15554252	NON-EXPEDITED			US-PFIZER INC-2018439935			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Palpitations	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15555266	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-965487			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Dry Mouth; Dyspnoea; Malaise; Pneumonia; Product Use In Unapproved Indication; Sleep Apnoea Syndrome	Proair Respiclick			S	Unknown			Teva	
	Advair Diskus			S	Respiratory (inhalation)	2 Dosage Forms Daily; 250/50		Not Reported	
	Advair Diskus			S	Respiratory (inhalation)	Unknown Dose		Not Reported	
	Advair Diskus			S	Respiratory (inhalation)	500/50		Not Reported	
	Z-Pak			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Oxygen			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15555292	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-969346		67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Ototoxicity	Azithromycin Monohydrate			S	Oral	750 Milligram Daily; On A Monday, Wednesday And Friday		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Amitriptyline Hydrochloride	C	Unknown	Not Reported
	Fostair	C	Unknown	Not Reported
	Paracetamol	C	Unknown	Not Reported
	Montelukast Sodium	C	Unknown	Not Reported
	Co-Codamol	C	Unknown	Not Reported
	Generics Uk Esomeprazole	C	Unknown	Not Reported
	Gastro-Resistant Salbutamol	C	Unknown	Not Reported
	Fluoxetine Hydrochloride	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15555358	EXPEDITED (15-DAY)		OT	US-DRREDDYS-USA/USA/18/0104852		17 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eosinophilic Pneumonia	Minocycline Hydrochloride			S	Unknown			Not Reported	
	Amoxicillin W/Clavulanate Potassium			S	Unknown			Not Reported	
	Ciprofloxacin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15555797	EXPEDITED (15-DAY)		DE, HO, LT	US-APOTEX-2018AP023141		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Cefepime			S	Unknown	Unk, Unknown		Apotex	
	Azithromycin			S	Unknown	Unk, Unknown		Apotex	
	Levofloxacin			S	Unknown	Unk, Unknown		Apotex	
	Vancomycin			S	Unknown	Unk, Unknown		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	1 Mg/Kg, Bid		Not Reported	
	Pembrolizumab			C	Unknown	200 Mg, Every 3 Weeks		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15556898	EXPEDITED (15-DAY)		HO	PHHY2018FR136837		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Cefpodoxime Proxetil			S	Oral	200 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Novartis	
	Mabthera			S	Intravenous drip	1000 Mg, Unk For 9 Months		Not Reported	
	Naproxene			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2018	15557026	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-07P-167-0417838-00		21 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Arthropathy; Blood Creatinine Increased; Blood Urea Increased; Drug Interaction; Dyspepsia; Hypophagia; Influenza Like Illness; Polyarthrits; Vomiting; Weight Decreased	Ibuprofen			S		Not Reported		Not Reported	
	Ibuprofen			S				Not Reported	
	Tobramycin			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported	
	Tobramycin			S		32milligramqid		Not Reported	
	Tobramycin			S				Not Reported	
	Azithromycin			S		Not Reported		Not Reported	
	Colomycin /00013206/			S		2 Megaunits, 3 Times A Day		Mylan	
	Colistin			C		2 Megaunits, 3 Times A Day		Mylan	
	Colistin			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2018	15533167	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029225		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Toxic Epidermal Necrolysis	Ibuprofen	S	Oral	Not Reported
	Azithromycin	S	Oral	Zydus Pharm
	Olanzapine	C		Not Reported
	Venlafaxine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2018	15557556	EXPEDITED (15-DAY)		HO	FR-ROCHE-2205559		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Mabthera			S	Intravenous drip	This Was The Most Recent Dose Of Rituximab		Not Reported
	Naproxen			S	Oral			Not Reported
	Cefpodoxime			S	Oral			Not Reported
	Azithromycin Anhydrous			S	Oral	On 20/Sep/2018, The Patient Received Most Recent Dose Of Azithromycin.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2018	15557781	EXPEDITED (15-DAY)		LT	AU-MACLEODS PHARMACEUTICALS US LTD- MAC2018018076			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Oseltamivir			S	Unknown	Unk		Macleods
	Azithromycin			S	Unknown	Unk		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Epoprostenol			S	Respiratory (inhalation)	Unk, (Inhalation)		Not Reported
	Lincomycin			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported
	Sulfamethoxazole/Trimethoprim			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Oct-2018	15560274	DIRECT	Y	DS			48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Large Intestine Infection; Tendon Rupture	Azithromycin			S	Oral			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2018	15558324	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2018-US-967227		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Acquired	Azithromycin			S	Oral			Not Reported	
Mixed Hyperlipidaemia;	Prinivil			C		40 Milligram Daily;		Not Reported	
Atrial Fibrillation; Cardiac	Norvasc			C		5 Milligram Daily;		Not Reported	
Ablation; Colitis; Colitis	Hydrochlorthiazide			C		12.5 Milligram Daily;		Not Reported	
Ischaemic; Coronary	Zentac			C		150 Milligram Daily;		Not Reported	
Artery Disease; Diarrhoea;	Colace			C		200 Milligram Daily;		Not Reported	
Diverticulum; Drug	Pravachol			C		40 Milligram Daily;		Not Reported	
Hypersensitivity; Essential	Metoprolol			C		50 Milligram Daily;		Not Reported	
Hypertension;	Baby Aspirin			C		162 Milligram Daily;		Not Reported	
Hyperkalaemia;	Cospot			C		Ophthalmic		Not Reported	
Hyponatraemia; Rectal	Calcium			C				Not Reported	
Haemorrhage									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559263	EXPEDITED (15-DAY)		OT	BE-APOTEX-2018AP023035		10 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Pallor	Azithromycin			S	Oral	In Total		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15559796	EXPEDITED (15-DAY)		OT	PHHY2018DE137433			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abnormal Behaviour; Ageusia; Aggression; Autophobia; Cardiovascular Disorder; Dizziness; Hallucination, Visual; Impaired Driving Ability; Indifference; Insomnia; Loss Of Personal Independence In Daily Activities; Muscular Weakness; Palpitations; Sudden Hearing Loss; Vision Blurred	Azithromycin			S	Oral	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560085	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR- APL-2018-052446		40 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acoustic Neuroma; Insomnia; Nausea; Ototoxicity	Azithromycin			S	Oral	500 Milligram, Daily		Aurobindo
	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo
	Clofazimine			S	Oral	100 Milligram, Daily		Not Reported
	Moxifloxacin			S	Oral	400 Milligram, Daily		Not Reported
	Amikacin			S	Intravenous (not otherwise specified)	525 Milligram, Two Times A Day		Not Reported
	Amikacin			S	Respiratory (inhalation)	500 Milligram, Two Times A Day (Nebulised)		Not Reported
	Minocycline			S	Oral	100 Milligram, Two Times A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560168	EXPEDITED (15-DAY)		HO	IN-MYLANLABS-2018M1078429		26 YR	Female	IND
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	2.25 Mg		Not Reported	
	Monocef /00145501/			S	Intravenous (not otherwise specified)			Mylan	
	Artesunate			C	Intravenous (not otherwise specified)			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15560755	NON-EXPEDITED			US-PFIZER INC-2018440790			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15561016	NON-EXPEDITED			US-PFIZER INC-2018438075		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Lyrica			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15561526	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018436802			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Ageusia; Aggression; Autophobia; Cardiovascular Disorder; Dizziness; Hallucination, Visual; Impaired Driving Ability; Indifference; Insomnia; Loss Of Personal Independence In Daily Activities; Muscular Weakness; Palpitations; Sudden Hearing Loss; Vision Blurred	Azithromycin			S	Oral			Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15562492	NON-EXPEDITED			US-PFIZER INC-2018442657			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15562612	NON-EXPEDITED			US-PFIZER INC-2018440219		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Septra Ds			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2018	15563208	NON-EXPEDITED			US-PFIZER INC-2018442113			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Verapamil Hcl			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Bactrim			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	14347094	NON-EXPEDITED			US-PFIZER INC-2017555403		38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Z-Pak			S		Unk		Not Reported
	Albuterol			C		Unk		Not Reported
	Zyrtec			C		Unk		Not Reported
	Hydrocodone			C		Unk		Not Reported
	Protonix			C		Unk		Not Reported
	Zolpidem			C		Unk		Not Reported
	Xanax			C		Unk		Not Reported
	Celexa			C		Unk		Not Reported
	Motrin			C		Unk		Not Reported
	Lyrica			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15330784	EXPEDITED (15-DAY)		DE, HO	FR-PFIZER INC-2018341685		73 YR	Female	FRA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Pulmonary Oedema; Atrial Fibrillation; Autoimmune Hepatitis; Cerebrovascular Accident; Coma; Fall; Hepatic Failure; Multiple Organ Dysfunction Syndrome; Nausea; Osteoporosis; Pleurisy; Renal Failure; Respiratory Distress; Respiratory Failure; Vomiting	Neurontin			S	Oral	300 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Oxycodone			S	Oral	5 Mg, 1x/Day		Not Reported	
	Durogesic			S	Transdermal	12 Ug + 25 Ug		Not Reported	
	Instanyl			S	Nasal	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15544690	EXPEDITED (15-DAY)		HO	SI-ROCHE-2203663			Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Deep Vein Thrombosis; Drug Ineffective; Epistaxis; Hyperkalaemia; Neutropenia; Pneumonia; Renal Impairment; Staphylococcal Sepsis; Thrombocytopenia	Rituximab			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoksiklav			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15560924	NON-EXPEDITED			US-PFIZER INC- 2018431457			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564887	NON-EXPEDITED			US-PFIZER INC-2018440035			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15564963	EXPEDITED (15-DAY)		OT	US-ZYDUS-029305		68 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Factor V Inhibition	Voriconazole			S	Unknown			Zydus Pharm	
	Azithromycin			S	Unknown			Not Reported	
	Ertapenem/Ertapenem Sodium			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15565151	EXPEDITED (15-DAY)		DE, HO, LT	US-QILU PHARMACEUTICAL CO.LTD.-QLU-000780-2018		63 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Cefepime Hydrochloride			S	Unknown	Unk		Qilu Pharmaceutical	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown	Unk		Not Reported	
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	1 Mg/Kg, Bid		Not Reported	
	Pembrolizumab			C	Unknown	200 Mg, Every 3 Weeks		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15566472	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-969291		53 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Factor V Inhibition	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15566550	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-969286		68 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Factor V Inhibition	Azithromycin			S	Unknown			Not Reported	
	Voriconazole			S	Unknown			Teva	
	Ertapenem			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15566653	NON-EXPEDITED			US-TEVA-2018-US-968846			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-Oct-2018	15566961	EXPEDITED (15-DAY)		HO, OT	SI-FRESENIUS KABI-FK201811185			Male	SVN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Upper; Arthralgia; Asthenia; Blood Pressure Decreased; Body Temperature Decreased; Body Temperature Increased; Cough; Decreased Appetite; Dermatitis Exfoliative Generalised; Dyspnoea; Fatigue; Fibrosis; Flatulence; Haemoglobin Decreased; Haemophagocytic	Moxifloxacin (Manufacturer Unknown)			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lymphohistiocytosis;
Hypermetabolism;
Hypersensitivity;
Lymphadenopathy;
Lymphoma; Mobility
Decreased;
Myelodysplastic
Syndrome; Natural Killer
Cell Count Decreased;
Nausea; Night Sweats;
Oedema Peripheral;
Palpitations; Psoriatic
Arthropathy; Pyrexia;
Rales; Serum Ferritin
Increased; Skin
Exfoliation; Swelling;
Vomiting; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2018	15567559	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2018439128		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Naproxen (Naproxen Sodium)			S	Oral	Unk		Not Reported
	Cefpodoxime			S	Oral	200 Mg, 1x/Day		Not Reported
	Mabthera			S	Intravenous drip	1000 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	14683904	EXPEDITED (15-DAY)		OT	DE-AUROBINDO-AUR- APL-2018-016897		51 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury	Moxifloxacin			S	Oral	400 Mg, 5 Days		Aurobindo
	Moxifloxacin			S	Oral	400 Mg, 5 Days		Aurobindo
	Moxifloxacin			S	Oral	400 Milligram		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Repatha	S	Subcutaneous	140 Mg, Unk	Not Reported
Repatha	S	Subcutaneous	140 Milligram	Not Reported
Azithromycin	S	Unknown	1x ()	Not Reported
Restex	C	Oral	Unk	Not Reported
Restex	C	Oral	100 Mg/25 Mg	Not Reported
Restex	C	Oral	1 Dosage Form	Not Reported
Restex	C	Oral	100 Mg/25 Mg ()	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Valsartan	C		160 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15051414	EXPEDITED (15-DAY)		HO, OT	PHHY2018PT023189		65 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Drug Ineffective For Unapproved Indication; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Respiratory Failure; Therapeutic Response Decreased	Azithromycin			S	Unknown			Novartis	
	Lisinopril			S	Oral	Unk		Not Reported	
	Perindopril+Indapamide			S	Unknown	Unk (Dose Had Been Doubled)		Not Reported	
	Alendronate+Cholecalciferol			S	Unknown			Not Reported	
	Amoxicillin+Clavulanic Acid			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15569549	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-052865		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Naproxen			S	Oral	Unk		Aurobindo	
	Cefpodoxime			S	Oral	200 Milligram, Once A Day		Aurobindo	
	Mabthera			S	Intravenous drip	1000 Milligram, 9 Month		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2018	15571210	EXPEDITED (15-DAY)		HO	FR-BAYER-2018-198341		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Aleve			S	Oral	Unk		Bayer	
	Cefpodoxime			S	Oral	200 Mg, Unk		Not Reported	
	Azithromycine			S	Oral	250 Mg, Unk		Not Reported	
	Mabthera			S	Intravenous drip	1000 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15574266	EXPEDITED (15-DAY)		HO	FR-ZYDUS-029429		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Naproxene			S	Oral	()		Not Reported	
	Cefpodoxime/Cefpodoxime Proxetil			S	Oral			Not Reported	
	Azithromycin			S	Oral			Zydus Pharm	
	Rituximab			S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15574569	EXPEDITED (15-DAY)		DE	US-VIIV HEALTHCARE LIMITED-US2018GSK199040		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Duodenitis; Treatment Noncompliance	Dolutegravir			S				Viiv	
	Azithromycin			S				Glaxosmithkline	
	Co-Trimoxazole			S				Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15575557	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2018193069		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ageusia; Anosmia; Drug Interaction; Influenza	Flonase Sensimist Allergy Relief Otc Nasal Spray Azitromycin	S	Unk	Glaxosmithkline
		S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2018	15577092	EXPEDITED (15-DAY)		LT, OT	US-BAXTER-2018BAX026591		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Vancomycin Injection, Usp			S	Unknown			Baxter
	Azithromycin			S	Unknown	On Day 36		Not Reported
	Colistin			S	Unknown	On Day 36		Not Reported
	Meropenem			S	Unknown			Not Reported
	Tigecycline			S	Unknown			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Fluconazole			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15283277	EXPEDITED (15-DAY)		DE, HO, OT	FR-AUROBINDO-AUR-APL-2018-041198			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Pulmonary	Oxycodone			S	Oral	5 Milligram, Once A Day		Aurobindo
Oedema; Atrial Fibrillation;	Oxycodone			S	Oral	5 Milligram		Aurobindo
Autoimmune Hepatitis;	Neurontin			S	Oral	3 Dosage Form, Once A Day		Not Reported
Cerebrovascular Accident;	Durogesic			S	Transdermal	12 Microgram, 3 Times A Day		Not Reported
Coma; Death; Fall;	Durogesic			S	Transdermal	25 Microgram, 3 Times A Day		Not Reported
Hepatic Failure; Nausea;	Durogesic			S	Transdermal	12 Microgram, 3 Times A Day		Not Reported
Osteoporosis; Pleurisy;	Instanyl			S	Nasal	Unk		Not Reported
Renal Failure; Respiratory Distress; Respiratory Failure; Vomiting								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax			S	Oral	500 Milligram, Once A Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15576160	NON-EXPEDITED			US-PFIZER INC-2018434025			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15577275	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.-2018US22231			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Noncompliance	Emtricitabine			S	Unknown	Unk		Cipla	
	Tenofovir			S	Unknown	Unk		Cipla	
	Rilpivirine			S	Unknown	Unk		Not Reported	
	Raltegravir			S	Unknown	Unk		Not Reported	
	Trimethoprim Sulfamethoxazole			S	Unknown	Unk		Not Reported	
	Trimethoprim Sulfamethoxazole			S				Not Reported	
	Azithromycin			S	Unknown	Unk, Weekly		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15577924	NON-EXPEDITED			US-PFIZER INC-2018452511		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Cephalexin Hcl			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chloroquine			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15579070	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018446832		28 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Pneumonia; Vomiting	Azithromycin			S	Unknown	500 Mg, 1x/Day		Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Doxycycline Hyclate			S	Oral	100 Mg, 2x/Day		Pfizer	
	Cefprozil			S	Oral	500 Mg, 2x/Day		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	672 Mg, Unk (1 Every 8 Week(S))		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	672 Mg, Unk (1 Every 8 Week(S))		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	10 Mg/Kg, Unk (1 Every 8 Week(S))		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	672 Mg, Unk (1 Every 8 Week(S))		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15580493	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE-970775			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Ageusia; Aggression; Autophobia; Cardiovascular Disorder; Dizziness; Hallucination, Visual; Impaired Driving Ability; Indifference; Insomnia; Loss Of Personal Independence In Daily Activities; Muscular	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Weakness; Palpitations;
Sudden Hearing Loss;
Vision Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15580700	DIRECT		LT, OT			21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disorientation; Dizziness; Dizziness; Dyspnoea; Nausea; Pruritus; Tachycardia; Urticaria; Urticaria; Wheezing	Azithromycin 250 Mg			S	Oral	Quantity:6 Tablet(S);		Sandoz	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2018	15582349	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-971643		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Naproxene			S	Oral			Not Reported	
	Cefpodoxime			S	Oral	200 Milligram Daily;		Not Reported	
	Azithromycine Anhydre			S	Oral	250 Milligram Daily;		Not Reported	
	Mabthera			S	Intravenous drip			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2018	15582722	EXPEDITED (15-DAY)		OT	SK-TEVA-2018-SK-971668		29 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erection Increased	Sumamed			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2018	15583215	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2018-053100		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Factor V Inhibition	Azithromycin		S		Unknown		Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2018	15580731	DIRECT		OT				28 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Hypotension; Panic Attack	Z-Pak, Azithromycin				S		Quantity:1 Tablet(S);	4 DAY	Unknown	
	Lamictal				C				Not Reported	
	Trileptal				C				Not Reported	
	Lexapro				C				Not Reported	
	Wellbutrin				C				Not Reported	
	Metoprolol				C				Not Reported	
	Vyvanse				C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	13390382	NON-EXPEDITED				US-PFIZER INC- 2017135228		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
	Azithromycin				S		Unk		Pfizer	
	Erythromycin				S		Unk		Pfizer	
	Morphine Sulfate				S		Unk		Unknown	
	Chantix				S		Unk		Pfizer	
	Codeine				S		Unk		Not Reported	
	Darvocet-N				S		Unk		Not Reported	
	Tylenol				S		Unk		Not Reported	
	Metformin				S		Unk		Not Reported	
	Prozac				S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	14258387	NON-EXPEDITED				US-PFIZER INC- 2017514953		53 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Enbrel			S		Unk		Pfizer	
	Advil			S		Unk		Pfizer	
	Effexor Xr			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Sulfasalazine			S		Unk		Pfizer	
	Orencia			S		Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported	
	Leflunomide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15214809	NON-EXPEDITED			US-PFIZER INC-2018305338		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15286589	NON-EXPEDITED			US-PFIZER INC-2018332026			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Headache	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15508506	EXPEDITED (15-DAY)		HO	PHHY2018FR124722		74 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Toxic Epidermal Necrolysis	Azithromycin Monohydrate	S	Oral	Unk	Not Reported
	Ibuprofen	S	Oral	Unk	Novartis
	Olanzapine	C	Unknown	5 Mg, Qd	Not Reported
	Venlafaxine	C	Unknown	150 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15554973	EXPEDITED (15-DAY)	OT		PHHY2018UA136298		59 YR	Male	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Klebsiella Infection; Pneumonia; Respiratory Failure	Pantoprazole			S	Intravenous (not otherwise specified)	40 Mg, Unk		Novartis
	Azithromycin			S	Oral	0.5 Unk, Unk		Not Reported
	Ambroxol Hydrochloride			S	Intravenous (not otherwise specified)	2 MI, Unk		Not Reported
	Vancomycin Hydrochloride			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported
	Dexamethasone			S	Intravenous (not otherwise specified)	8 Mg-2ml		Not Reported
	Acetylcysteine			S	Oral	600 Mg, Qd		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported
	Linex			S	Oral	2 MI, Tid		Not Reported
	Levofloxacin			C	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Cefepime			C	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported
	Analgin (Metamizole Sodium)			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Rheosorbilact			C	Intravenous (not otherwise specified)	200 MI, Unk		Not Reported
	Glucose			C	Intravenous (not otherwise specified)	400 MI, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Insulin	C	Unknown	10 U, Unk	Not Reported
Nacl	C	Unknown	30 MI, Unk	Not Reported
K C L	C	Unknown	30 MI, Unk	Not Reported
Euphyllinum	C	Unknown	10 MI, Unk	Not Reported
Strophantin	C	Intravenous (not otherwise specified)	0.25 Mg,1 MI	Not Reported
Heparin	C	Intravenous (not otherwise specified)	2500 Mg, Unk	Not Reported
Drotaverine	C	Intravenous (not otherwise specified)	2 MI, Unk	Not Reported
Metoclopramide Hydrochloride	C	Intramuscular	2 MI, Unk	Not Reported
Liprazid	C	Oral	10 Mg, Unk	Not Reported
Ceftazidimum	C	Intravenous (not otherwise specified)	Unk	Not Reported
Amikacin	C	Intramuscular	0.5 G, Unk	Not Reported
Ornidazole	C	Intravenous (not otherwise specified)	500 Mg, 100 MI	Not Reported
Prednisolone	C	Unknown	30 Mg, Unk	Not Reported
Erdosteine	C	Oral	Unk Unk, Bid	Not Reported
Berodual	C	Unknown	Unk, Bid	Not Reported
Vitamiin C	C	Intravenous (not otherwise specified)	4 MI, Qd	Not Reported
Dextran	C	Intravenous (not otherwise specified)	200 MI, Qd	Not Reported
Famotidine	C	Intravenous (not otherwise specified)	40 Mg, Qd	Not Reported
Enoxaparin Sodium	C	Subcutaneous	0.4 Unk, Qd	Not Reported
Fresh Frozen Plasma	C	Intravenous (not otherwise specified)	300 MI, Qd	Not Reported
Albumin	C	Unknown	100 MI, Unk	Not Reported
Lioliv	C	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Acetylsalicylic Acid

C

Intravenous (not
otherwise specified)

200 Iu, Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15583471	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2018-053096		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Factor V Inhibition	Azithromycin			S	Unknown	Unk		Aurobindo
	Ertapenem			S	Unknown	Unk		Aurobindo
	Voriconazole			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15585149	EXPEDITED (15-DAY)		HO, OT	CA-ACCORD-090599		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Enterovirus Infection; Transplant Rejection	Mycophenolic Acid			S				Accord
	Tacrolimus			S		10-12 Ng/MI		Accord
	Prednisone			S		Dose Was Reduced To 10 Mg And Subsequently 5 Mg Daily		Not Reported
	Abacavir			S				Not Reported
	Dolutegravir			S				Not Reported
	Lamivudine			S				Not Reported
	Valganciclovir/Valganciclovir			S				Not Reported
	Hydrochloride							
	Trimethoprim			S				Not Reported
	Sulfamethoxazole/Sulfamethoxazole Sodium			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15585746	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2058382		49 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tinnitus	Azithromycin	S	Oral	Wockhardt					
	Multivitamin	C		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2018	15586639	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP023764		10 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250 Mg, Qd (250 Mg Dia)		Apotex	
	Salbutamol			C	Respiratory (inhalation)	Unk Unk, Unknown (2-2-2)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	9210346	EXPEDITED (15-DAY)		DS, HO, OT	FR-UCBSA-082025		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Eye Infection	Cimzia			S	Subcutaneous	Unk		Ucb	
Toxoplasmal;	Cimzia			S	Subcutaneous	Unk		Ucb	
Osteoarthritis; Rash	Novatrex			S	Oral	7 Df, Weekly (Qw)		Not Reported	
Erythematous	Cortancyl			S	Oral	2 Df, Once Daily (Qd)		Not Reported	
	Cortancyl			S		Daily Dose: 7.5 Mg For 15 Days		Not Reported	
	Cortancyl			S		Daily Dose: 5 Mg		Not Reported	
	Speciafoldine			C		Dose: 5 Mg, 3 Tablets Weekly, 15mg Weekly 48 Hours After Methootrexate		Not Reported	
	Fosavance			C		Dose: 70 Mg Weekly		Not Reported	
	Cacit D3			C		1 Df, Once Daily (Qd)		Not Reported	
	Dafalgan			C		Dose: 1gm Three Times Daily As Required If Pain		Not Reported	
	Piascledine			C				Not Reported	
	Mopral			C		Daily Dose: 20 Mg		Not Reported	
	Gaviscon			C		Dose: 3 Sachets Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Domperidone	C	Dose: 3 Times Daily	Not Reported
Sulfarlem	C	25 Mg, 3x/Day (Tid)	Not Reported
Celluvisc	C	12 Mg, Once Daily (Qd)	Not Reported
Bromazepam	C	1 Df, Once Daily (Qd)	Not Reported
Azilect	C	1 Mg, Once Daily (Qd)	Not Reported
Sinemet	C	Strength 150 Mg, Daily Dose: 450 Mg	Not Reported
Sinemet	C	200 Mg, 3x/Day (Tid)	Not Reported
Uvedose	C	Dose: 1 Phial Every 3 Months	Not Reported
Transipeg [Macrogol]	C	Dose: If Required	Not Reported
Inexium	C	Daily Dose: 20 Mg	Not Reported
Lacrigel	C	Dose: 3 To 4 Drops Daily In Both Eyes	Not Reported
Lacryvisc	C	Dose: 3 Times Daily In Both Eyes	Not Reported
Vitamin A	C	Dose: One Daily In Right Eye	Not Reported
Sterdex	C	Dose: One Drop Daily In Right Eye	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	13527924	NON-EXPEDITED			US-PFIZER INC- 2017197327			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Advil			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Dimetapp		Y	S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfasalazine	S	Unk	Pfizer
Terramycin	S	Unk	Pfizer
Zithromax	S	Unk	Pfizer
Aleve	S	Unk	Not Reported
Arava	S	Unk	Not Reported
Cipro /00697201/	S	Unk	Not Reported
Dilaudid	S	Unk	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Plaquenil /00072602/	S	Unk	Not Reported
Rocephin	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Valium	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15138446	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2018-035239		57 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Azithromycin			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Levofloxacin			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Olmotec Comp			C	Unknown	20 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15441661	NON-EXPEDITED			US-PFIZER INC- 2018393359		26 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Drug Hypersensitivity; Pyrexia; Swelling	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15589032	EXPEDITED (15-DAY)		HO, OT	IT-MACLEODS PHARMACEUTICALS US LTD- MAC2018018487			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Levofloxacin			S	Oral	500 Milligram, Qd		Macleods	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 Gram		Not Reported	
	Breva			C	Unknown	Unk		Not Reported	
	Clenil			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15589051	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR- APL-2018-053748		43 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Purpura; Rash Pruritic	Amoxicillin+Clavulanic Acid			S	Oral	2000 Milligram, Daily		Aurobindo	
	Azithromycin			S	Oral	500 Milligram, Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15589819	EXPEDITED (15-DAY)		HO, OT	IT-ALVOGEN-2018- ALVOGEN-097709		88 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Toxicity To Various Agents	Flecainide			S				Alvogen	
	Sulfamethoxazole/Trimethoprim			S				Not Reported	
	Amiodarone			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Acetylsalicylic Acid			C				Not Reported	
	Thiamazole			C				Not Reported	
	Amiodarone			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15590614	EXPEDITED (15-DAY)		HO	PT-PFIZER INC-2018451765		43 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Purpura; Rash Pruritic	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Amoxicillin And Clavulanate			S	Oral	2000 Mg, 1x/Day		Not Reported	
	Potassium								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15590684	EXPEDITED (15-DAY)		HO, LT	PHHY2018ES147493		365 DAY	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure	Paracetamol			S	Oral	12 Mg/Kg, Q6h		Not Reported	
	Azitromicina			S	Oral	10 Mg/Kg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15590688	EXPEDITED (15-DAY)		HO	PHHY2018IT147647		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Levofloxacin			S	Oral	500 Mg, Qd		Novartis	
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
	Clenil			C	Unknown			Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G, Qd		Not Reported	
	Breva			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15592062	NON-EXPEDITED			US-PFIZER INC-2018442999			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Clindamycin Hcl	S	Unk	Pfizer
	Erythromycin	S	Unk	Pfizer
	Ibuprofen	S	Unk	Pfizer
	Lincomycin Hcl	S	Unk	Pfizer
	Morphine Sulfate	S	Unk	Unknown
	Hydrocodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15592776	NON-EXPEDITED			US-PFIZER INC-2018445199			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15592853	EXPEDITED (15-DAY)		OT	PHHY2018PL143758			Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Liver Injury	Azithromycin			S	Unknown	500 Mg, Qd		Novartis
	Prednisone			S	Oral	40 Mg, Qd		Not Reported
	Pyrimethamine			S	Unknown	25 Mg, Unk		Not Reported
	Sulfadoxine			S	Unknown	500 Mg, Bid		Not Reported
	Sulfadoxine			S	Unknown	500 Mg, Qd		Not Reported
	Spiramycin			S	Unknown	3 Miu, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2018	15593629	NON-EXPEDITED			US-PFIZER INC-2018455215		13 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15592509	EXPEDITED (15-DAY)		OT	PHEH2018US046578			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxicity To Various Agents; Treatment Failure	Tobramycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	
	Linezolid			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15592637	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018FR148608			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Pyelonephritis; Bladder Cancer; Bladder Cancer Recurrent; Escherichia Pyelonephritis; Metastatic Carcinoma Of The Bladder	Neoral			S	Oral	140 Mg, Bid		Novartis	
	Cortancyl			S	Oral	20 Mg, Qd		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	1 Mg, Unk		Not Reported	
	Novatrex			S	Oral	10 Mg, Qw		Not Reported	
	Triatec (Ramipril)			C	Unknown			Not Reported	
	Glucophage			C	Unknown	850 Ot, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15592926	DIRECT		HO, LT, OT			48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia; Chest Pain; Decreased Appetite; Dysgeusia; Eye Swelling; Insomnia; Lymphoedema; Pain;	Z-Pak			S	Oral	Quantity:5 Tablet(S);	5 DAY	Not Reported	
	Seroquel			C				Not Reported	
	Trazodone			C				Not Reported	
	Gabapentin			C				Not Reported	
	Tizanidine			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Periorbital Disorder;	Diazepam	C	Not Reported
Peripheral Swelling;	Loratidine	C	Not Reported
Pyrexia; Seizure; Skin	Sudafed	C	Not Reported
Discolouration; Tinnitus;	Benadryl	C	Not Reported
Weight Decreased	Ibuprofen	C	Not Reported
	Extra Strength Excedrin	C	Not Reported
	Aspirin	C	Not Reported
	Tylenol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15594091	EXPEDITED (15-DAY)		OT	PHHY2018US142219		37 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure;	Piperacillin+Tazobactam			S	Unknown	Unk		Novartis
Escherichia Infection;	Azithromycin			S	Unknown			Not Reported
Septic Shock	Bevacizumab			C	Unknown			Not Reported
	Dexamethasone			C	Unknown			Not Reported
	Temozolomide			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15594222	EXPEDITED (15-DAY)		OT	DE-BAUSCH-BL-2018-030372		75 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood	Ofloxacin			S	Unknown			Bausch And Lomb
Pressure Increased; Chest	Gentamicin			S	Unknown	Unknown		Bausch And Lomb
Discomfort; Depressed	Prednisolone			S	Unknown			Not Reported
Mood; Dyspnoea	Lixiana			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Candesartan			C				Not Reported
	Bisoprolol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15595854	NON-EXPEDITED			PHEH2018US046308			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Azithromycin 250 Mg			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2018	15612511	DIRECT	Y				47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fat Tissue Increased	Azithromycin 600mg Lupin Pharmaceuticals			S	Oral			Lupin	
	Prezcobix 800/150mg Janssen Products			S	Oral	Other Dose:800/150mg;		Janssen	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	13492182	EXPEDITED (15-DAY)		OT		CA-ROCHE-1901737	51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Brain Hypoxia; Breath Odour; Crepitations; Drug Ineffective; Heart Rate Increased; Hypersensitivity; Insomnia; Lower Respiratory Tract Congestion; Malaise; Nasopharyngitis; Pulmonary Function Test Decreased; Pyrexia	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Ventolin			S	Unknown			Not Reported	
	Ventolin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ventolin	S	Unknown		Not Reported
Ventolin	S	Unknown		Not Reported
Ventolin	S	Unknown		Not Reported
Ventolin	S	Unknown		Not Reported
Ventolin	S	Respiratory (inhalation)		Not Reported
Ventolin	S	Unknown		Not Reported
Ventolin	S	Unknown		Not Reported
Zithromax	S	Unknown	250 Mg, Tiw (3 Times A Week, Monday, Wednesday And Friday)	Not Reported
Zithromax	S			Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown	50 Mg For Seven Days With Weaning Orders (10 Mg Every 3 Days)	Not Reported
Prednisone	S	Unknown	50 Mg For 4 Days (Tapered Dose)	Not Reported
Prednisone	S	Unknown	50 Mg For 5 Days	Not Reported
Prednisone	S	Unknown	50 Mg For Five More 5 Days And Then Tapered Dose	Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown	For Five Days	Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Will Be Tapered For 17 More Days	Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Advair	C	Respiratory (inhalation)	500 Ot	Not Reported
Advair	C	Respiratory (inhalation)	500 Ot, (1 Dose)	Not Reported
Diltiazem	C	Unknown		Not Reported
Alvesco	C	Unknown	2 Df, Qid	Not Reported
Spiriva	C	Unknown	2 Df, Qd	Not Reported
Zenhale	C	Unknown		Not Reported
Combivent	C	Unknown	20 Ug, Unk	Not Reported
Gaviscon (Calcium Carbonate/Sodium Alginate)	C	Oral	1 Df, Qid	Not Reported
Gaviscon (Calcium Carbonate/Sodium Alginate)	C	Oral	1 Df, Bid	Not Reported
Tums	C	Unknown	1 Df, Unk	Not Reported
Dexilant	C	Unknown	1 Df, Qd	Not Reported
Atrovent	C	Unknown	2 Df, Qid	Not Reported
Nexium	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	14778600	NON-EXPEDITED			US-PFIZER INC- 2018161026		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S				Unknown	
	Hydrocodone			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15213079	NON-EXPEDITED			US-PFIZER INC-2018305307			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15401724	NON-EXPEDITED			US-PFIZER INC-2018379380		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Drug Hypersensitivity; Pain; Peripheral Swelling	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15401802	NON-EXPEDITED			US-PFIZER INC-2018377315			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15597761	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1082038		88 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Amiodarone			S	Oral			Not Reported	
	Amiodarone			S	Unknown	200 Mg, Qd		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Flecainide			S	Unknown			Not Reported	
	Sulphamethoxazole/Trimethoprim			S	Unknown	160/800 Mg; Seven Days Treatment Was Prescribed		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetylsalicylic Acid	C	Unknown	100 Mg, Qd	Mylan
Verapamil	C	Intravenous (not otherwise specified)		Mylan
Verapamil	C	Intravenous (not otherwise specified)	Additional Dose	Mylan
Thiamazole	C	Unknown		Mylan
Ceftriaxone	C	Unknown		Mylan
Piperacillin W/Sulbactam	C	Unknown		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15599101	EXPEDITED (15-DAY)		HO	PHHY2018PT148798		84 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Diabetic Neuropathy; Fatigue; Oedema Peripheral; Orthopnoea; Palpitations	Metformin, Vildagliptin			S	Unknown	1 Df, Bid		Not Reported
	Azithromycin			S	Unknown	Unk		Novartis
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Not Reported
	Omeprazole			S	Unknown	20 Mg, Qd		Not Reported
	Amlodipine			S	Unknown	10 Mg, Qd		Not Reported
	Levothyroxine			C	Unknown	0.1 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15599626	NON-EXPEDITED			US-PFIZER INC-2018455220		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2018	15599800	EXPEDITED (15-DAY)		HO	FR-CANTON LABORATORIES, LLC-2058636		31 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Agranulocytosis	Naprosyn	S	Oral	Canton Laboratories
	Cefpodoxime	S	Oral	Not Reported
	Azithromycine Anhydride	S	Oral	Not Reported
	Mabthera	S	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15190179	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018293033		57 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Levofloxacin			S	Oral	1 Df, 1x/Day		Not Reported	
	Olmotec			C		20 Mg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15482922	NON-EXPEDITED			US-PFIZER INC-2018406312			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15600114	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2018-053802		365 DAY	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure	Paracetamol			S	Oral	12 Milligram/Kilogram, 6 Hour		Aurobindo	
	Azitromicin			S	Oral	10 Milligram/Kilogram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15600259	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-		60 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

APL-2018-053867

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Azithromycin			S	Unknown	500 Milligram, Daily		Aurobindo	
	Levofloxacin			S	Oral	500 Milligram, Daily		Aurobindo	
	Breva			C	Unknown	Unk		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 Gram		Not Reported	
	Clenil /00212602/			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15600711	EXPEDITED (15-DAY)		OT	BE-APOTEX- 2018AP023994			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Renal Failure	Azithromycin			S	Unknown	Unk		Apotex	
	Itraconazole			S	Unknown	Unk		Not Reported	
	Tildiem			S	Unknown	Unk		Not Reported	
	Crestor			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15603207	NON-EXPEDITED			US-PFIZER INC- 2018461689		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15604014	NON-EXPEDITED			PHEH2018US047067			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity	Azithromycin 250 Mg		S	Unknown		Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2018	15604038	NON-EXPEDITED			PHEH2018US046990			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Prednisone Tablets Usp			S	Unknown	Unk			Novartis
	Azithromycin 250 Mg			S	Unknown				Not Reported
	Darvocet			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2018	15604174	EXPEDITED (15-DAY)		HO	US-ABBVIE-18K-163-2543816-00		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease; Electrocardiogram Qt Prolonged; Rhinovirus Infection	Mavyret			S	Oral	100-40 Mg			Not Reported
	Azithro			S	Unknown				Not Reported
	Albuterol			C					Not Reported
	Levothyroxine			C					Not Reported
	Melatonin			C					Not Reported
	Metadone			C					Not Reported
	Multivitamin With Minerals			C					Not Reported
	Sennoside			C					Not Reported
	Tamsulosin			C					Not Reported
	Tiotropium			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	13526302	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-1641316		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Bilirubin Increased; Cardiac Arrest; Cough; Dyspnoea; Encephalitis	Bevacizumab			S	Intravenous (not otherwise specified)	Last Dose Prior To Sae: 13/Aug/2015; Total Dose: 2135 Mg.			Not Reported
	Ipilimumab			S	Intravenous (not	Last Dose Prior To Sae:			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified) 13/Aug/2015; Total Dose:
427 Mg.

Azithromycin	S	Unknown	Not Reported
Aspirin	C		Not Reported
Atorvastatin	C		Not Reported
Fenofibrate	C		Not Reported
Lasix	C		Not Reported
Lisinopril	C		Not Reported
Loratadine	C		Not Reported
Pseudoephedrine	C		Not Reported
Metformin	C		Not Reported
Slo-Niacin	C		Not Reported
Vitamin D3	C		Not Reported
Carvedilol	C		Not Reported
Sildenafil	C		Not Reported
Magnesium Oxide	C		Not Reported
Morphine	C		Not Reported
Melatonin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15172059	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-178941		57 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Azithromycin			S	Oral	1 Df, Daily		Sun
	Levofloxacin			S	Oral	1 Df, Daily		Ranbaxy
	Olmetec 20 Mg Comprese			C	Unknown	20 Mg, Unk		Not Reported
	Rivestite Con Film							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15403507	NON-EXPEDITED			US-PFIZER INC- 2018378471		7 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Odour Abnormal; Vomiting	Zithromax			S	Oral	Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15403508	NON-EXPEDITED			US-PFIZER INC-2018378470		5 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Odour Abnormal; Vomiting	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15406046	NON-EXPEDITED			US-PFIZER INC-2018378462		2 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Odour Abnormal; Vomiting	Zithromax			S	Oral	6 MI, Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15562775	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2018M1080660		58 YR	Male	NLD
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Depression; Suicidal Ideation	Azithromycin			S		250 Mg, Unk, 2.3 Day		Not Reported	
	Omeprazol /00661201/			C		20 Mg, Qd 1dd1		Mylan	
	Salbutamol /00139502/			C	Unknown	100 Mg, Unk Zn (5-10keer Per Week)		Mylan	
	Flutiform			C		2 Df, Bid, 2dd2, 12h		Mylan	
	Spiriva			C	Unknown	5 Mg, Qd 1dd2		Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Nov-2018	15605374	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2018-ES-974639		365 DAY	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Hepatic Failure	Paracetamol (12a)			S	Oral	12mg/Kg/6h		Not Reported	
	Azitromicina (7019a)			S	Oral	10 Mg/Kg Daily;		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

10mg/Kg/Dia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15605580	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP024317		85 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bronchospasm; Rash	Azithromycin			S	Oral	500 Mg, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15606349	EXPEDITED (15-DAY)		HO	FR-ACCORD-091675		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury; Off Label Use	Methotrexate			S	Intramuscular			Accord	
	Novatrex			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15607502	EXPEDITED (15-DAY)		HO, LT, OT	US-MYLANLABS-2018M1084080		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Levofloxacin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Mylan	
	Pembrolizumab			C	Unknown	200 Mg Every 3 Weeks		Mylan	
	Vancomycin			C	Unknown			Mylan	
	Cefepime			C	Unknown			Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15607670	DIRECT					6 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15607927	EXPEDITED (15-DAY)		HO	PT-TEVA-2018-PT-974129		43 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Rash Pruritic	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
	Amoxicilina + Ácido Clavulânico			S	Oral	2000 Milligram Daily;		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15608142	NON-EXPEDITED			US-PFIZER INC-2018456780		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15608307	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1084780		47 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Cefoxitin			S	Intravenous drip			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	Loading Dose		Mylan	
	Tigecycline			S	Intravenous (not otherwise specified)			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15608313	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2018M1084761		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Ototoxicity; Skin Hyperpigmentation	Cefoxitin	S	Intravenous (not otherwise specified)	Not Reported
	Azithromycin	S	Oral	Not Reported
	Clarithromycin	S	Oral	Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)	Mylan
	Tigecycline	S	Intravenous (not otherwise specified)	Mylan
	Amikacin	S	Intravenous (not otherwise specified)	Mylan
	Imipenem	S	Intravenous (not otherwise specified)	Mylan
	Clofazimine	S	Oral	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15608371	NON-EXPEDITED			US-PFIZER INC- 2018463773		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2018	15609265	EXPEDITED (15-DAY)		HO, LT	NL-BAUSCH-BL-2018- 030746		82 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angina Pectoris; Cardiac Failure; Condition Aggravated	Salbutamol			S	Unknown	Aerosol, 3 Inhalations Per Day, 100 Microgram/Dose		Bausch And Lomb
	Azitromycine			S	Unknown			Not Reported
	Irbesartan			C	Unknown			Not Reported
	Codeinefosfaat			C	Unknown	3dd1		Not Reported
	Isosorbidedinitraat Retard			C	Unknown	2dd0, 5 Tablet		Not Reported
	Nedios			C	Unknown	1dd1		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Dermovate	C		1dd	Not Reported
	Pravastatine	C	Unknown	1dd1	Not Reported
	Bumetanide	C	Unknown	1dd1	Not Reported
	Acenocoumarol	C	Unknown		Not Reported
	Calci Chew D3	C	Unknown	1dd1, 1g/800, Kauw Tablet 1000mg/800ie	Not Reported
	Nebivolol	C	Unknown	1dd0, 5 Tablet	Not Reported
	Carbamazepine	C	Unknown	1dd1	Not Reported
	Prednisolon	C	Unknown	1dd0,5 Tablet	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15556534	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018432668		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Ibuprofen			S	Oral	Unk		Pfizer
	Azithromycine			S	Oral	Unk		Pfizer
	Olanzapine			C		5 Mg, 1x/Day		Not Reported
	Venlafaxine			C		150 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15597267	EXPEDITED (15-DAY)		HO	PHHY2018PT144402		43 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Purpura; Rash Pruritic	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Amoxicillin Clavulanic Acid			S	Oral	2000 Mg, Qd		Not Reported
	Sandoz							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15610400	NON-EXPEDITED			US-ROCHE-2029838			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fear; Ill-Defined Disorder	Tamiflu	S	Oral	For 5 Days	Not Reported
	Azithromycin	S	Oral	On Day 1	Not Reported
	Azithromycin	S	Oral	For The Next 4 Days	Not Reported
	Albuterol	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15611366	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-190756		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Azithromycin			S	Unknown	500 Mg, Daily		Sun	
	Levofloxacin			S	Oral	500 Mg, Daily		Ranbaxy	
	Clenil			C	Unknown	()		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Breva			C	Unknown	()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15613056	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC- FRWYE247031AUG07		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Cancer Recurrent; Bladder Cancer Stage Iv; Cystitis Noninfective; Escherichia Pyelonephritis; Escherichia Pyelonephritis; Metastatic Carcinoma Of The Bladder	Novatrex			S	Oral	10 Mg, 1x/Wk		Pfizer	
	Neoral			S	Oral	140 Mg, 2x/Day		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	1 G, Unk		Not Reported	
	Cortancyl			S	Oral	20 Mg, 1x/Day		Not Reported	
	Glucophage			C		850 Mg, 1x/Day		Not Reported	
	Triatec [Ramipril]			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2018	15613614	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018450703		1 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Macule; Rash; Rash	Zithromax			S	Oral	1.2 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	8972850	EXPEDITED (15-DAY)		DE, HO, OT	FR-ROCHE-GNE247093		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Pyelonephritis; Bladder Cancer; Bladder Cancer Recurrent; Escherichia Pyelonephritis; Metastatic Carcinoma Of The Bladder	Rituximab			S	Intravenous (not otherwise specified)	1 G, Unk, Day 01		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Day- 15		Not Reported	
	Cortancyl			S	Oral	20 Mg, Qd		Not Reported	
	Novatrex			S	Oral	10 Mg, 1/Week		Not Reported	
	Neoral			S	Oral	140 Mg, Bid		Not Reported	
	Triatec (France)			C	Unknown			Not Reported	
	Glucophage			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	10654838	NON-EXPEDITED			US-PFIZER INC-2014343269		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Lopid			S		600 Mg, Unk		Pfizer	
	Potassium Bicarbonate			S		Unk		Not Reported	
	Tegretol			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Cytosan		S		Unk			Not Reported
		Immune Globulin Nos		S		Unk			Not Reported
		Imuran		S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	14196399	NON-EXPEDITED			US-PFIZER INC-2017492560			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15472573	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2018-06871		93 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Deafness; Product Use In Unapproved Indication	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Bid		Lupin	
	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin	
	Synthroid			C	Unknown	Unk		Not Reported	
	Losartan			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15615733	EXPEDITED (15-DAY)		HO, LT, OT	NL-AUROBINDO-AUR-APL-2018-055084		82 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Cardiac Failure; Condition Aggravated	Azithromycin Film Coated Tablet 500 Mg			S	Unknown	500 Milligram, Daily		Aurobindo	
	Salbutamol 100 Cfc-Free Inhaler			S	Unknown	100 Microgram Every 8 Hours (3 Inhalations Per Day)		Not Reported	
	Irbesartan			C	Unknown	150 Milligram, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeinefosfaat	C	Unknown	10 Milligram Every 8 Hours	Not Reported
Glyceryl Monooleate	C	Unknown	1 Dosage Form, Daily	Not Reported
Isosorbide Dinitrate	C	Unknown	10 Milligram, Two Times A Day	Not Reported
Nedios	C	Unknown	250 Milligram, Daily	Not Reported
Dermovate	C	Unknown	1 Dosage Form, Daily	Not Reported
Pravastatin	C	Unknown	40 Milligram, Daily	Not Reported
Bumetanide	C	Unknown	1 Milligram, Daily	Not Reported
Acenocoumarol	C	Unknown	Unk	Not Reported
Calci Chew D3	C	Unknown	1 Dosage Form, Daily	Not Reported
Nebivolol	C	Unknown	1 Milligram, Daily	Not Reported
Carbamazepine	C	Unknown	100 Milligram, Daily	Not Reported
Prednisolon /00016201/	C	Unknown	2 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15618346	NON-EXPEDITED			US-PFIZER INC-2018459594		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contusion; Tenderness	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15618639	NON-EXPEDITED			US-PFIZER INC-2018450176			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2018	15618662	NON-EXPEDITED			US-PFIZER INC-2018452210			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Clindamycin Hcl	S	Unk	Pfizer
	Hydrocortisone	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15272726	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018321767			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity; Faeces Discoloured; Melaena	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15550776	EXPEDITED (15-DAY)		HO, OT	PL-APOTEX-2018AP023149		2 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Auscultation; Blood Lactate Dehydrogenase Increased; Cough; Drug Ineffective; Dry Mouth; Electrolyte Imbalance; Hyponatraemia; Mucosal Dryness; Pneumonitis; Pyrexia; Renal Failure; Streptococcus Test Positive	Azithromycin			S	Unknown	Unk		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15554268	NON-EXPEDITED			US-PFIZER INC-2018435976			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15597705	EXPEDITED (15-DAY)		HO, LT, OT	NL- GLAXOSMITHKLINE- NL2018201695		82 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Cardiac Failure; Condition Aggravated	Salbutamol			S	Other	100 ?G, Tid		Glaxosmithkline	
	Azitromycine			S	Respiratory (inhalation)	500 Mg, Qd		Glaxosmithkline	
	Carbamazepine			C	Unknown	100 Mg, Qd		Glaxosmithkline	
	Pravastatine			C	Unknown	40 Mg, Qd		Glaxosmithkline	
	Dermovate			C	Unknown	1 Df, Qd		Glaxosmithkline	
	Calcichew D3			C	Unknown	1 Df, Qd		Glaxosmithkline	
	Irbesartan			C	Unknown	1dd1		Glaxosmithkline	
	Prednisolon			C	Unknown	2 Mg, Qd		Glaxosmithkline	
	Nebivolol			C	Unknown	1 Mg, Qd		Glaxosmithkline	
	Isosorbidedinitraat Retard			C	Unknown	10 Mg, Bid		Not Reported	
	Nedios			C	Unknown	250 Mg, Qd		Not Reported	
	Koelzalf			C	Unknown	1 Df, Qd		Not Reported	
	Bumetanide			C	Unknown	1 Mg, Qd		Not Reported	
	Acenocoumarol			C	Unknown	Unk		Not Reported	
	Codeinefosfaat			C	Unknown	3dd1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2018	15619809	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT- 975372		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Azithromycin			S		500 Milligram Daily;		Not Reported	
	Levofloxacin			S	Oral	500 Milligram Daily;		Teva	
	Clenil			C				Not Reported	
	Ceftriaxone			C	Intravenous (not	2 Gram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Brevia		C					otherwise specified)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Nov-2018	15620916	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2018462322			Unknown	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Oedema Peripheral; Pain In Extremity	Zithromac			S	Oral	Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Nov-2018	15621342	EXPEDITED (15-DAY)		DE, HO, LT	US-MYLANLABS-2018M1084753		69 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Amoebic Brain Abscess; Balamuthia Infection; Central Nervous System Necrosis; Cerebral Haemorrhage; Coma; Disease Progression; Drug Ineffective; Encephalitis Protozoal; Hemiplegia; Mental Status Changes	Dexamethasone			S	Unknown	Initial Dose Not Stated; Later The Dose Was Tapered		Not Reported		
	Fluconazole			S	Unknown	Administered In One Dose		Not Reported		
	Azithromycin			S	Unknown	Administered In One Dose		Not Reported		
	Miltefosine			S	Unknown	Thrice Daily		Mylan		
	Pentamidine			S	Unknown			Mylan		
	Sulfadiazine			S	Unknown			Mylan		
	Flucytosine			S	Unknown			Mylan		
	Lorazepam			C	Unknown			Mylan		
	Levetiracetam			C	Intravenous (not otherwise specified)			Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
15-Nov-2018	15623411	NON-EXPEDITED			US-GILEAD-2018-0373535			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Disease Susceptibility;	Cayston			S	Unknown			Gilead		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Interaction; Weight Increased	Azithromycin	S	Unknown	Not Reported
	Tobramycin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15554645	EXPEDITED (15-DAY)		OT	PL-HORIZON-PRE-0477-2018			Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Prednisone			S	Oral	Initial Dose 40 Mg In The Morning		Not Reported	
	Pyrimethamine/Sulfadoxine			S	Oral	25 Mg/500 Mg Bid For First 2 Days; Qd On Days 3-21		Not Reported	
	Spiramycin			S	Oral	3 M Iu Tid For 10 Days		Not Reported	
	Azithromycin			S	Oral	500 Mg Qd		Not Reported	
	Omeprazole			C	Oral			Not Reported	
	Ranitidine			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15554671	EXPEDITED (15-DAY)		OT	PL-HORIZON-PRE-0478-2018			Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Prednisone			S	Oral	Initial Dose 40 Mg In The Morning		Not Reported	
	Pyrimethamine/Sulfadoxine			S	Oral	25 Mg/500 Mg Bid For First 2 Days; Qd On Days 3-21		Not Reported	
	Spiramycin			S	Oral	3 M Iu Tid For 10 Days		Not Reported	
	Azithromycin			S	Oral	500 Mg Qd		Not Reported	
	Omeprazole			C	Oral			Not Reported	
	Ranitidine			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15566543	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-969327			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15582480	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201810-003822		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Mass; Abdominal Pain; Acute Kidney Injury; Cushing'S Syndrome; Deafness; Electrocardiogram Qt Prolonged; Glucose Tolerance Impaired; Mycobacterium Abscessus Infection; Obesity; Osteoporosis; Sleep Apnoea Syndrome	Hydroxychloroquine			S	Unknown				Concordia
	Hydroxychloroquine			S					Concordia
	Cellcept			S	Unknown				Not Reported
	Cellcept			S					Not Reported
	Prednisone			S	Unknown				Not Reported
	Prednisone			S					Not Reported
	Amikacin			S	Intravenous (not otherwise specified)	Every Monday, Wednesday And Friday			Not Reported
	Amikacin			S	Unknown	Instillation 250 Mg In 100 Ml Normal Saline Every Monday Wednesday, Friday Via Wound Vacuum For Appr			Not Reported
	Methylprednisolone			S	Unknown				Not Reported
	Methylprednisolone			S					Not Reported
	Imuran			S	Unknown				Not Reported
	Imuran			S					Not Reported
	Voriconazole			S	Unknown	Every Morning			Not Reported
	Voriconazole			S	Unknown	Every Evening			Not Reported
	Azithromycin			S	Oral				Not Reported
	Azithromycin			S	Oral				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	Not Reported
Azithromycin	S	Oral	Not Reported
Clofazimine	S	Oral	Not Reported
Clofazimine	S	Unknown	Not Reported
Clofazimine	S	Unknown	Not Reported
Isavuconazole	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15624760	EXPEDITED (15-DAY)		HO	PHHY2018US155361		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Product Use In Unapproved Indication	Omalizumab			S	Unknown			Not Reported
	Budesonide			S	Respiratory (inhalation)	Unk Unk, Bid		Not Reported
	Montelukast Sodium			S	Unknown	10 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	250 Mg, Q3w		Not Reported
	Salmeterol/Fluticasonpropionaat			S	Respiratory (inhalation)	500/50 One Puff Twice A Day		Not Reported
	Tiotropium			S	Respiratory (inhalation)	2 Df, Qd		Not Reported
	Albuterol			S	Respiratory (inhalation)			Not Reported
	Albuterol			S	Respiratory (inhalation)	Unk, Biw		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628240	EXPEDITED (15-DAY)		HO, LT	PHHY2018NL156194		82 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angina Pectoris; Cardiac Failure; Condition Aggravated	Azithromycin			S	Unknown	500 Mg, Qd		Novartis
	Salbutamol			S	Respiratory	100 Ug, Q8h (3x Per Dag)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		(inhalation)	1 Inhalatie)	
Irbesartan	C	Unknown	150 Mg, Qd	Not Reported
Codeinefosfaat	C	Unknown	3dd1	Not Reported
Isosorbidedinitraat	C	Unknown	10 Mg, Q12h	Not Reported
Nedios	C	Unknown	250 Mg, Qd	Not Reported
Dermovate	C	Unknown	1 Mg/L, Qd	Not Reported
Pravastatine	C	Unknown	40 Mg, Qd	Not Reported
Bumetanide	C	Unknown	1 Mg, Qd	Not Reported
Acenocoumarol	C	Unknown	Unk	Not Reported
Calci Chew D3	C	Unknown	1 Mg/L, Qd	Not Reported
Nebivolol	C	Unknown	1 Mg, Qd	Not Reported
Carbamazepine	C	Unknown	100 Mg, Qd	Not Reported
Prednisolone	C	Unknown	2 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628482	NON-EXPEDITED			US-PFIZER INC-2018470310		24 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Nov-2018	15628734	NON-EXPEDITED			US-PFIZER INC-2018469937			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2018	15630276	DIRECT		OT			49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Crying; Fatigue; Feeling Of Despair; Pulmonary Congestion; Suicidal Ideation; Therapy Cessation	Azithromycin Tablets Usp 250mg	S	Oral	2 Tablet(S); 2 Day 1, 1 Day 2-5	Lupin
	Verapamil Hcr Er	C			Not Reported
	Clonazepam	C			Not Reported
	Vitamin C	C			Not Reported
	Tylenol	C			Not Reported
	Benedryl	C			Not Reported
	Chlorpheniramine	C			Not Reported
	Dramamine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15214237	EXPEDITED (15-DAY)		OT	PHHY2018US055334		45 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dyspnoea Exertional; Hypoxia; Obstructive Airways Disorder; Product Use In Unapproved Indication	Budesonide, Formoterol Fumarate			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Novartis
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Albuterol			S	Unknown	Unk		Not Reported
	Tiotropium			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15388049	EXPEDITED (15-DAY)		HO	PL-AUROBINDO-AUR-APL-2018-045797		10 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Oral	Unk ()		Aurobindo
	Hydrocortisone			S	Topical	Unk		Not Reported
	Betamethasone Dipropionate W/Clotrimazole			S	Topical	Unk		Not Reported
	Betamethasone Dipropionate			S	Topical	Unk ()		Not Reported
	Betamethasone Dipropionate W/Gentamicin			S	Topical	Unk		Not Reported
	Betamethasone			S	Topical	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dipropionate;Clotrimazole;Genta
Sodium Chloride

C

Unknown

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15607459	EXPEDITED (15-DAY)		HO	US-IMPAX LABORATORIES, LLC- 2018-IPXL-03735		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma	Budesonide			S	Other	Unk, Twice A Day (Nebulizer)		Impax
	Salmeterol/Fluticasonpropionaat			S		500/50 Inhaler, One Puff, Twice A Day		Not Reported
	Tiotropium			S		Unk, Inhaler, Two Puffs, Daily		Not Reported
	Montelukast			S	Unknown	10 Milligram, Daily		Not Reported
	Albuterol /00139501/			S	Unknown	Unk, As Needed		Not Reported
	Albuterol /00139501/			S	Unknown	Unk, Inhaler, Less Than Twice A Week		Not Reported
	Azithromycin			S	Unknown	250 Milligram, 3 /Week		Not Reported
	Omalizumab			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15632469	DIRECT	Y				72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aggression; Anger; Anger; Personality Change	Azithromycin			S	Oral			Teva
	Diazepam			C				Not Reported
	Ventolin			C				Not Reported
	Levothyroxine			C				Not Reported
	Lisinopril/Hctz			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2018	15633055	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2059017			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea	Azithromycin			S	Oral			Wockhardt	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Nov-2018	15633548	NON-EXPEDITED			US-PFIZER INC-2018472507		17 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	14410061	NON-EXPEDITED			US-PFIZER INC-2018024338		62 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	14688093	NON-EXPEDITED			US-PFIZER INC-2018128223		50 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Nov-2018	15632664	NON-EXPEDITED			US-PFIZER INC-2018474654		56 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Protonix			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15635710	EXPEDITED (15-DAY)		HO, LT	NL-PFIZER INC-2018475706		82 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Cardiac Failure; Disease Progression	Azithromycin			S	Other	500 Mg, 1x/Day		Pfizer	
	Salbutamol			S	Other	100 Ug, 3x/Day		Not Reported	
	Salbutamol			S				Not Reported	
	Salbutamol			S				Not Reported	
	Codeine Phosphate			C		10 Mg, 3x/Day		Not Reported	
	Irbesartan			C	Respiratory (inhalation)	150 Mg, 1x/Day		Not Reported	
	Cold Cream Naturel			C		1 Df, 1x/Day		Not Reported	
	Isosorbide Dinitrate			C		10 Mg, 2x/Day		Not Reported	
	Nedios			C		250 Mg, 1x/Day		Not Reported	
	Dermovate			C		1 Df, 1x/Day		Not Reported	
	Pravastatin			C		40 Mg, 1x/Day		Not Reported	
	Bumetanide			C		1 Mg, 1x/Day		Not Reported	
	Acenocoumarol			C		Unk		Not Reported	
	Calci Chew D3			C		1 Df, 1x/Day		Not Reported	
	Nebivolol			C		1 Mg, 1x/Day		Not Reported	
	Carbamazepin			C		100 Mg, 1x/Day		Not Reported	
	Prednisolone			C		2 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15638146	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-977803		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Ototoxicity; Skin Hyperpigmentation	Amikacin			S	Intravenous (not otherwise specified)			Teva	
	Cefoxitin			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azithromycin	S	otherwise specified)						
	Tigecycline	S	Oral						Not Reported
			Intravenous (not otherwise specified)	Loading Dose					Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)						Not Reported
	Clarithromycin	S	Oral						Not Reported
	Imipenem	S	Intravenous (not otherwise specified)						Not Reported
	Clofazimine	S	Oral						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15639460	NON-EXPEDITED			US-PFIZER INC-2018477248		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Verapamil Hcl			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15639800	EXPEDITED (15-DAY)		HO	PHHY2018IT157603		18 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Delirium; Hallucinations, Mixed	Azitromicin Sandoz			S	Unknown	1 Df, Unk		Novartis	
	Azitromicin Sandoz			S	Unknown	1 Df, Unk		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15639802	EXPEDITED (15-DAY)		HO	PHHY2018FR158801		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Cefotaxime			S	Intravenous (not	3 G, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2018	15640435	NON-EXPEDITED			US-PFIZER INC-2018477020		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cipro [Ciprofloxacin Hydrochloride]			S		Unk		Not Reported	
	Cefdinir			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	13611349	NON-EXPEDITED			US-PFIZER INC-2017242047			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15384481	EXPEDITED (15-DAY)		HO	PL-009507513-1809POL003027		10 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Betamethasone Dipropionate			S	Topical	Unk		Merck	
	Betamethasone Dipropionate (+) Gentamicin Sulfate			S	Topical	Unk		Merck	
	Clotrimazole (+) Betamethasone Dipropionate			S	Topical	Unk		Merck	
	Betamethasone Dipropionate (+) Clotrimazole (+) Gentamicin Sulfate			S	Topical	Unk		Merck	
	Azithromycin			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15641597	EXPEDITED (15-DAY)		HO	PT-ASTRAZENECA-2018SF50544		84 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Diabetic Neuropathy; Fatigue; Oedema Peripheral; Orthopnoea; Palpitations	Omeprazole			S	Oral			Not Reported	
	Amoxicillin+Clavulanic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Amlodipine			S	Unknown	10 Mg, Qd		Not Reported	
	Metformin, Vildagliptin			S	Unknown	1 Df, Bid		Not Reported	
	Levothyroxine			C		0.1 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15643437	EXPEDITED (15-DAY)		HO, OT	PHHY2018ES159565		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azitromicina			S	Oral	500 Mg, Q24h		Novartis	
	Capoten			C	Oral	25 Mg, Q12h		Not Reported	
	Adiro			C	Oral	300 Mg, Q24h		Not Reported	
	Omeprazol			C	Unknown			Not Reported	
	Ibuprofen			C	Oral	Historia Actual De Informe De Alta De Medicina Interna: "Ha Estado Tomando 1-2cp Diarios En La Últim		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15644416	NON-EXPEDITED			US-PFIZER INC-2018476687		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Vistaril			S		Unk		Pfizer		
Morphine Sulfate			S		Unk		Unknown		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15644417	NON-EXPEDITED			US-PFIZER INC-2018479099			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Pruritus; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15644652	NON-EXPEDITED			US-PFIZER INC-2018479112			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15645743	EXPEDITED (15-DAY)		OT	PHEH2018US048988			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Neuritis; Night Sweats; Treatment Failure; Vision Blurred	Rifampin Capsules Usp			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2018	15646148	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2018-055919		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis	Azithromycin			S	Oral	500 Milligram, Daily		Aurobindo	
	Cefotaxime			S	Intravenous (not otherwise specified)	3 Gram, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15573280	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06448		75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Faeces Hard	Azithromycin Tablets, 250 Mg			S	Oral	500 Mg, Qd		Lupin	
	Azithromycin Tablets, 250 Mg			S	Oral	250mg Daily For 4 Days		Lupin	
	Metoprolol			C	Unknown	Unk		Not Reported	
	Hctz			C	Unknown	Unk		Not Reported	
	Baby Aspirin			C	Unknown	Unk		Not Reported	
	Ramipril			C	Unknown	Unk		Not Reported	
	Simvastatin			C	Unknown	Unk		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15646436	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2018-056188		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azithromycin 500 Mg Film- Coated Tablets			S	Oral	500 Milligram, Daily		Aurobindo	
	Capoten			C	Oral	25 Milligram, Two Times A Day		Not Reported	
	Adiro			C	Oral	300 Milligram, Daily		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
	Ibuprofen			C	Oral	Unk, Has Been Taking 1- 2cp Daily In The Last Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15646669	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR- APL-2018-056290		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatitis Fulminant; Liver Transplant	Azithromycin	S	Oral	Unk	Aurobindo
	Aciclovir	S	Oral	Unk	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15646844	EXPEDITED (15-DAY)	HO		PT-AUROBINDO-AUR-APL-2018-056362		84 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Diabetic Neuropathy; Fatigue; Oedema Peripheral; Orthopnoea; Palpitations	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Amlodipine			S	Unknown	10 Mg, Qd		Aurobindo
	Omeprazole			S	Unknown	20 Mg, Qd		Aurobindo
	Metformin W/Vildagliptin			S	Unknown	1 Df, Bid		Not Reported
	Levothyroxine			C	Unknown	0.1 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647109	EXPEDITED (15-DAY)	OT		FR-AUROBINDO-AUR-APL-2018-056394		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo
	Atarax /00058402/			S	Oral	Unk		Not Reported
	Emend /01627301/			S	Oral	Unk		Not Reported
	Lamprene /00224701/			S	Oral	100 Milligram, Daily		Not Reported
	Vogalene			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15647614	EXPEDITED (15-DAY)	HO		PT-PFIZER INC-2018480043		84 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetic Neuropathy; Fatigue; Oedema Peripheral; Orthopnoea;	Amlodipine Besilate			S	Unknown	10 Mg, 1x/Day		Pfizer
	Azithromycin			S	Unknown	Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Palpitations	Amoxicillin+Clavulanic Acid	S	Unknown	Unk	Not Reported
	Metformin/Vildagliptin	S	Unknown	1 Df, 2x/Day	Not Reported
	Omeprazole	S	Unknown	20 Mg, 1x/Day	Not Reported
	Levothyroxine	C	Unknown	0.1 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15648469	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2018-032139		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Prednisolone			S	Oral			Not Reported
	Hepatoum			S	Oral	Unspecified		Not Reported
	Azithromycine Anhydre			S	Oral			Not Reported
	Escitalopram			S	Oral			Not Reported
	Arestal			S	Oral			Not Reported
	Seresta			S	Oral			Not Reported
	Inorial			S	Oral			Not Reported
	Paracetamol			S	Oral			Not Reported
	Augmentin			S	Oral			Not Reported
	Cefpodoxime			S	Oral			Not Reported
	Trimebutine			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15648696	NON-EXPEDITED			PHEH2018US048752			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Flatulence	Azithromycin			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2018	15648793	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-TEVA-2018-US-977800		69 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balamuthia Infection; Central Nervous System Lesion; Drug Ineffective; Encephalitis Protozoal; Haemorrhage; Hemiplegia; Necrosis; Post Procedural Haemorrhage; Post Procedural Oedema	Dexamethasone			S	Unknown	Initial Dose Not Stated; Later The Dose Was Tapered		Actavis
	Azithromycin			S	Unknown	20 Mg/Kg Daily; Administered In One Dose		Teva
	Fluconazole			S	Unknown	12 Mg/Kg Daily; Administered In One Dose		Not Reported
	Pentamidine			S	Unknown	4 Mg/Kg Daily;		Not Reported
	Miltefosine			S	Unknown	Thrice Daily		Not Reported
	Sulfadiazine			S	Unknown	6 Gram Daily;		Not Reported
	Flucytosine			S	Unknown	150 Mg/Kg Daily;		Not Reported
	Levetiracetam			C	Intravenous (not otherwise specified)			Not Reported
	Lorazepam			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15634633	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC- 2018463110		26 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Dizziness; Electrocardiogram Abnormal; Headache; Loss Of Consciousness; Nausea; Palpitations; Vision Blurred	Azithromycin Dihydrate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650563	EXPEDITED (15-DAY)		HO	US-ROCHE-2217120		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma	Omalizumab			S	Unknown			Not Reported
	Budesonide			S	Respiratory			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		(inhalation)		
Montelukast Sodium	S	Unknown		Not Reported
Azithromycin	S	Unknown		Not Reported
Fluticasone Propionate/Salmeterol	S	Respiratory (inhalation)	500/50 One Puff Twice A Day	Not Reported
Tiotropium	S	Respiratory (inhalation)	2 Df, Qd	Not Reported
Albuterol	S	Respiratory (inhalation)		Not Reported
Albuterol	S	Respiratory (inhalation)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15650874	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR- APL-2018-055590		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balamuthia Infection; Coma; Condition Aggravated; Drug Ineffective; Encephalitis; Hypoaesthesia; Necrosis; Somnolence	Dexamethasone			S	Unknown	Unk		Aurobindo
	Dexamethasone			S		Dose Tapered		Aurobindo
	Azithromycin			S	Unknown	20 Milligram/Kilogram, Daily		Aurobindo
	Fluconazole			S	Unknown	12 Milligram/Kilogram, Every 6 Hours		Aurobindo
	Miltefosine			S	Unknown	50 Milligram, 3 Times A Day		Not Reported
	Pentamidine			S	Unknown	4 Milligram/Kilogram, Daily		Not Reported
	Sulfadiazine			S	Unknown	1.5 Gram, Every 6 Hours		Not Reported
	Flucytosine			S	Unknown	37.5 Milligram/Kilogram, Every 6 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15652932	EXPEDITED (15-DAY)		HO	PHHY2018FR159630		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cholestasis	Lamprene	S	Oral	1 Df, Qd	Novartis
	Zithromax	S	Oral	250 Mg, Qd	Not Reported
	Cefoxitine Panpharma	S	Intravenous (not otherwise specified)	4 G, Unk	Not Reported
	Dexambutol	S	Oral	1 Df, Qd	Not Reported
	Amikacine	S	Intravenous (not otherwise specified)	25 Mg/Kg, Q48h	Not Reported
	Imipenem Cilastatin Kabi	S	Intravenous (not otherwise specified)	1000 Mg, Qd	Not Reported
	Ansatipline	S	Oral	300 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2018	15652940	EXPEDITED (15-DAY)		OT	PHHY2018FR159753		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Vogalene			S	Oral	Unk		Not Reported
	Atarax			S	Oral	Unk		Not Reported
	Azithromycin Anhydrous			S	Oral	250 Mg, Qd		Not Reported
	Emend			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2018	15653574	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030651		75 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalitis	Azithromycin			S	Oral			Zydus Pharm
	Cefotaxime			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2018	15653687	EXPEDITED (15-DAY)		HO	PHHY2018PT164827		34 YR	Male	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoptysis; Mediastinitis; Pleural Effusion; Pneumonia	Azithromycin			S	Unknown			Novartis	
	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	12678011	EXPEDITED (15-DAY)		HO, LT	JP-PFIZER INC- 2016392599		75 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis	Pregabalin			S		75 Mg, 2x/Day		Pfizer	
	Azithromycin			S		500 Mg, Single		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	13995644	NON-EXPEDITED			US-PFIZER INC- 2017405269		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Demerol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Effexor Xr			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Verapamil Hcl			S		Unk		Pfizer	
	Oxycontin			S		Unk		Not Reported	
	Dilaudid			S		Unk		Not Reported	
	Allegra			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15206514	NON-EXPEDITED			US-PFIZER INC- 2018302700		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15494274	NON-EXPEDITED			US-PFIZER INC-2018411732			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15623218	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1853514US		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram Oxalate Unk			S	Oral	140 Mg, 1 Day		Allergan	
	Arestal			S	Oral	30 Mg, Total		Not Reported	
	Seresta			S	Oral	310 Mg, Total		Not Reported	
	Prednisolone			S	Oral	200 Mg, Total		Not Reported	
	Inorial			S	Oral	120 Mg, Total		Not Reported	
	Paracetamol			S	Oral	79 G, Total		Not Reported	
	Augmentin			S	Oral	6 G, 1 Day		Not Reported	
	Cefpodoxime			S	Oral	2000 Mg, Total		Not Reported	
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported	
	Hepatoum			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15654688	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP025053		71 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	250mg Single Dose In Total		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15655015	EXPEDITED (15-DAY)		DE	US-KNIGHT THERAPEUTICS (USA) INC.-2059254		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Impavido (Miltefosine) Capsules			S	Oral			Knight Therapeutics	
	Pentamidine			S				Not Reported	
	Sulfadiazine			S				Not Reported	
	Flucytosine			S				Not Reported	
	Fluconazole			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15655698	NON-EXPEDITED			US-TEVA-2018-US- 978024			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Behaviour Disorder; Eczema; Reaction To Excipient	Azithromycin			S	Unknown	Dose Strength: 200 Mg/5 ML		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15655894	EXPEDITED (15-DAY)		OT	PT- GLAXOSMITHKLINE- PT2018GSK211921		43 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Heavy Metal Abnormal; Metal Poisoning; Off Label Use; Pain In Extremity; Product Use In Unapproved Indication	Malarone			S		Unk		Glaxosmithkline	
	Zithromax			S	Oral	250 Mg, Qd		Not Reported	
	Fasigyn			S	Oral	500 Mg, Z, 2 To 3 Per Week		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15656345	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC- 2018480045		66 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant	Azithromycine			S	Oral	Unk		Pfizer	
	Aciclovir			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15656999	EXPEDITED (15-DAY)		OT	ZA-SAKK-2018SA148742AA			Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carditis; Depression; Dyslipidaemia; Renal Disorder; Rheumatic Fever	Arava			S		20 Mg, Qd		Sanofi	
	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi	
	Minocycline Hydrochloride			S		60 Mg, Qd		Not Reported	
	Methotrexate Sodium			S		25 Mg, Qw		Not Reported	
	Azithromycin			S		75 Mg, Qd		Not Reported	
	Enbrel			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15658186	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2018479993		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Cefotaxime			S	Intravenous (not otherwise specified)	3 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15658395	NON-EXPEDITED			US-PFIZER INC-2018484766		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2018	15658530	EXPEDITED (15-DAY)		HO	PHHY2018PT162826		87 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Hypercapnia; Hypothermia; Hypoventilation; Impaired Gastric Emptying; Pneumonia; Pupillary Reflex Impaired; Respiratory Failure; Vomiting	Amoxicillin + Clavulanate			S	Unknown	Unk		Novartis	
	Potassium			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	14070471	NON-EXPEDITED			US-PFIZER INC-2017436431		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Promethazine Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	14300235	NON-EXPEDITED			US-TEVA-819772ACC			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Has Taken Four Tablets Total		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	14931493	EXPEDITED (15-DAY)		HO	US-CIPLA (EU) LIMITED-2018US17872			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma	Budesonide	S	Nasal	Unk, Bid (Nebulizer Twice A Day)	Cipla
	Montelukast	S	Unknown	10 Mg, Daily	Cipla
	Fluticasone Propionate W/Salmeterol	S		Inhaler 50/500 One Puff Twice A Day, Bid	Not Reported
	Tiotropium	S		Unk, Inhaler Two Puffs Daily	Not Reported
	Albuterol /00139501/	S	Unknown	Unk, Prn (As Needed)	Not Reported
	Azithromycin	S	Unknown	250 Mg, Three Times A Week	Not Reported
	Omalizumab	S	Unknown	Unk, Injection	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15622093	NON-EXPEDITED			US-PFIZER INC-2018465316		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Epinephrine			S		Unk		Unknown	
	Lopid			S		600 Mg, Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Potassium Bicarbonate			S		Unk		Not Reported	
	Tegretol			S		Unk		Not Reported	
	Imuran [Azathioprine]			S				Not Reported	
	Cytosan			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15659240	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06624		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Myalgia; Off Label Use	Rosuvastatin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Fluticasone	C	Unknown	Unk				Not Reported	
	Montelukast	C	Unknown	Unk				Not Reported	
	Immunoglobulin /00025201/	C	Intravenous (not otherwise specified)	Unk				Not Reported	
	Rituximab	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15659504	NON-EXPEDITED			US-TEVA-2018-US-979239			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15659719	EXPEDITED (15-DAY)		HO, LT	FR-ZYDUS-030661		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant; Liver Transplant	Azithromycin			S	Oral				Not Reported
	Aciclovir			S	Oral				Zydus Pharm
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660379	EXPEDITED (15-DAY)		OT	CA-BAYER-2018-216153		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Cipro			S	Oral	Unk			Bayer
	Azithromycin			S	Unknown	Unk			Not Reported
	Cancidas			S	Unknown	Unk			Not Reported
	Montelukast			S	Oral	Unk			Not Reported
	Mycophenolate Mofetil			S	Oral	Unk			Not Reported
	Nifedipine			S	Oral	Unk			Not Reported
	Pantoprazole			S	Oral	Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Prednisone	S	Oral	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Oral	Unk	Not Reported
	Tacrolimus	S	Oral	Unk	Not Reported
	Voriconazole	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660794	NON-EXPEDITED			US-TEVA-2017-US-829299			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Distension; Constipation; Diarrhoea; Product Use In Unapproved Indication	Azithromycin			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660796	NON-EXPEDITED			US-TEVA-2018-US-873984			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Adverse Event	Azithromycin			S	Unknown				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660802	NON-EXPEDITED			US-TEVA-824058ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Vomiting	Azithromycin			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660803	NON-EXPEDITED			US-TEVA-2017-US-828904			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Hypoacusis	Azithromycin			S					Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660810	NON-EXPEDITED			US-TEVA-824711ACC			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Zithromax			S	Unknown			Not Reported
	Abilify			S	Unknown			Not Reported
	Geodon			S	Unknown			Not Reported
	Tegretol			S	Unknown			Not Reported
	Lyrica			S	Oral	450 Milligram Daily;		Not Reported
	Chnatix			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Montelukast			C				Not Reported
	Norco			C				Not Reported
	Paracetamol			C				Not Reported
	Nasonex			C				Not Reported
	Ventolin			C				Not Reported
	Metoclopramide			C				Not Reported
	Tramadol			C				Not Reported
	Flexeril			C				Not Reported
	Hydrochlorothiazide			C				Not Reported
	Topamax			C				Not Reported
	Levothyroxine			C				Not Reported
	Zyrtec			C				Not Reported
	Methylprednisolone			C				Not Reported
	Prozac			C				Not Reported
	Verapamil			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660812	NON-EXPEDITED			US-TEVA-2018-US-918917		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dizziness; Urticaria; Wheezing	Azithromycin			S	Unknown			Not Reported
	Epinephrine			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660821	NON-EXPEDITED			US-TEVA-2018-US-900735		20 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Maternal Exposure During Pregnancy; Normal Newborn	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660822	NON-EXPEDITED			US-TEVA-2017-US-839829			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypoaesthesia Oral; Infective Glossitis	Azithromycin			S	Oral	Strength: 200mg/5ml 22.5 MI			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660825	NON-EXPEDITED			US-TEVA-2017-US-841602			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Off Label Use	Azithromycin			S		3-4 Timer Per Week.			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660826	NON-EXPEDITED			US-TEVA-2017-US-832632			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Contusion; Eye Swelling	Azithromycin			S					Not Reported
	Lyrice			S					Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Nov-2018	15660827	NON-EXPEDITED			US-TEVA-825529ACC			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Confusional State; Inappropriate Schedule Of Product Administration	Azithromycin		S			500 Milligram Daily;		Not Reported	
	Azithromycin		S			250 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660830	NON-EXPEDITED			US-TEVA-2017-US-830290			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Influenza	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660831	NON-EXPEDITED			US-TEVA-2017-US-827000		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S		250 Milligram Daily;			Not Reported
	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660832	NON-EXPEDITED			US-TEVA-2017-US-833681			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Inappropriate Schedule Of Product Administration; Product Taste Abnormal	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15660836	NON-EXPEDITED			US-TEVA-2017-US-827202			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Chest Pain; Frequent Bowel	Azithromycin			S					Teva

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Movements; Irritable
Bowel Syndrome; Muscle
Spasms; Pain

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15661933	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2018483518		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Bronchitis; Frequent Bowel Movements; General Physical Health Deterioration; Inappropriate Schedule Of Product Administration; Off Label Use; Therapeutic Product Effect Decreased; Treatment Failure	Zithromax			S		Unk (Every 5 Day)		Pfizer
	Remicade			S	Intravenous (not otherwise specified)	475 Mg, Unk (1 Every 6 Week)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	475 Mg, Unk (1 Every 6 Week)		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	475 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	480 Mg, Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	480 Mg, Unk		Not Reported
	Questran			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15661937	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2018482944		58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Obstructive Pulmonary Disease; Electrocardiogram Qt Prolonged; Rhinovirus Infection	Azithromycin			S		Unk		Pfizer
	Mavyret			S	Oral	[Glecaprevir 100 Mg]/[Pibrentasvir 40 Mg], 100-40 Mg, 3 Tablet,1 In 1 D		Not Reported
	Albuterol			C		Unk		Not Reported
	Levothyroxine			C		Unk		Not Reported
	Melatonin			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metadone	C	Unk	Not Reported
Sennoside	C	Unk	Not Reported
Tamsulosin	C	Unk	Not Reported
Tiotropium	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15662340	EXPEDITED (15-DAY)		HO	PHHY2018IT166347		16 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Intentional Self-Injury; Substance Abuse	Azithromycin			S	Oral	1500 Mg, Unk		Novartis
	Paracetamol			S	Oral	1000 Mg, Unk		Not Reported
	Nimesulide			S	Oral	1500 Mg, Unk		Not Reported
	Amoxicillin+Clavulanic Acid			S	Oral	1 G, Unk		Not Reported
	Oki			S	Unknown	120 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2018	15662551	EXPEDITED (15-DAY)		OT	US-BAXTER- 2018BAX029188		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Ceftriaxone Injection, Usp (In Dextrose)			S	Unknown			Baxter
	Vancomycin Injection, Usp			S	Unknown			Baxter
	Vancomycin Injection, Usp			S				Baxter
	Azithromycin			S	Unknown			Not Reported
	Cefepime			C	Unknown			Not Reported
	Metronidazole			C	Unknown			Not Reported
	Escitalopram			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported
	Clonazepam			C	Unknown			Not Reported
	Plasminogen			C	Intrapleural			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Piperacillin/Tazobactam	C	Unknown					Not Reported	
	Amikacin	C	Unknown					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15022906	EXPEDITED (15-DAY)		OT	ZA-SA-2018SA150949		40 YR	Male	ZAF
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Carditis; Dyslipidaemia	Chloroquine (Salt Not Specified)			S		200 Mg, Qd		Sanofi	
	Etanercept			S		50 Mg, Qw		Not Reported	
	Azithromycin			S		75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15418217	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018381759		40 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acoustic Neuroma; Deafness Unilateral; Facial Paralysis; Ototoxicity; Product Use Issue	Amikacin Sulfate			S	Intravenous (not otherwise specified)	525 Mg, 2x/Day (Total Of 29.4 G)		Unknown	
	Amikacin Sulfate			S	Respiratory (inhalation)	500 Mg, 2x/Day (Nebulised)		Unknown	
	Amikacin Sulfate			S				Unknown	
	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day (Oral And Nebulised)		Pfizer	
	Azithromycin			S				Pfizer	
	Minocycline			S	Oral	100 Mg, 2x/Day		Not Reported	
	Minocycline			S				Not Reported	
	Minocycline			S				Not Reported	
	Imipenem			S		Unk (Stopped At Day 8)		Not Reported	
	Imipenem			S				Not Reported	
	Imipenem			S				Not Reported	
	Meropenem			C		2 G, 3x/Day		Not Reported	
	Meropenem			C				Not Reported	
	Meropenem			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Tigecycline	C		50 Mg, 2x/Day		Not Reported
	Tigecycline	C				Not Reported
	Tigecycline	C				Not Reported
	Clofazimine	C	Oral	100 Mg, 1x/Day		Not Reported
	Clofazimine	C				Not Reported
	Clofazimine	C				Not Reported
	Moxifloxacin	C		400 Mg, 1x/Day		Not Reported
	Moxifloxacin	C				Not Reported
	Moxifloxacin	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15663299	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-979284		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis	Azithromycine Anhydre			S	Oral	500 Milligram Daily;		Not Reported	
	Cefotaxime Base			S	Intravenous (not otherwise specified)	3 Gram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15666014	NON-EXPEDITED			US-PFIZER INC-2018483187			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15666241	NON-EXPEDITED			US-PFIZER INC-2018489073			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15666271	NON-EXPEDITED			US-PFIZER INC-2018488899			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2018	15667374	EXPEDITED (15-DAY)		DS, OT	JP-PFIZER INC-2018483783		38 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Keratitis; Toxic Epidermal Necrolysis; Visual Impairment	Zithromac 250mg			S		1 Df, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15256079	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2018304918		77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Colistin			S		Unk		Not Reported	
	Colistin			S				Not Reported	
	Rifampin			S		Unk		Not Reported	
	Rifampin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15588630	EXPEDITED (15-DAY)		HO, OT	PHEH2018US046856		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Dizziness; Leukopenia; Muscular Weakness;	Tigecycline			S	Intravenous (not otherwise specified)	50 Mg, Qd		Novartis	
Musculoskeletal Disorder;	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
Myasthenia Gravis;	Linezolid			S	Oral	600 Mg, Qd		Not Reported	
Nausea; Vomiting; Weight Decreased	Amikacin			S	Intravenous (not	700 Mg, Tid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imipenem			S		otherwise specified) Intravenous (not otherwise specified)		1 G, Q12h		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-Nov-2018	15603761	NON-EXPEDITED			US-PFIZER INC- 2018461678		40 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-Nov-2018	15606687	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT148176		88 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Hyperthyroidism	Amiodarone Hydrochloride			S	Oral	400 Mg, Unk		Novartis		
	Amiodarone Hydrochloride			S	Unknown	200 Mg, Qd		Novartis		
	Flecainide Acetate			S	Unknown	50 Mg, Bid		Not Reported		
	Azithromycin			S	Unknown	Unk		Not Reported		
	Sulfametoaxazol/Trimetoprim			S	Unknown	160/800 Mg, Bid		Not Reported		
	Sulfametoaxazol/Trimetoprim			S				Not Reported		
	Ceftriaxone			C	Unknown	Unk		Not Reported		
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported		
	Verapamil			C	Unknown	Unk		Not Reported		
	Verapamil			C				Not Reported		
	Acetylsalicylic Acid			C	Unknown	100 Mg, Unk		Not Reported		
Thiamazole			C	Unknown			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-Nov-2018	15668176	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-192198		75 YR	Male	FRA	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Cefotaxime			S	Intravenous (not otherwise specified)	3 Gram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15668589	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018483808		46 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oculomucocutaneous Syndrome; Stevens-Johnson Syndrome	Zithromac 250mg			S		1 Df, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15668745	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192179		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant; Liver Transplant	Aciclovir			S	Oral	()		Sun	
	Azithromycin			S	Oral	()		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15669171	EXPEDITED (15-DAY)		OT	UA-TEVA-2018-UA-980619		14 YR	Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Loss Of Consciousness; Rash	Sumamed			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15669807	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018485483		48 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Lower Respiratory Tract Infection; Off Label Use; Product Use Issue; Sinusitis	Zithromax			S	Unknown	Unk		Pfizer	
	Zithromax			S	Unknown	Unk		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, (1 Every 6 Weeks)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15670398	NON-EXPEDITED			US-PFIZER INC-2018489285			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15670402	NON-EXPEDITED			US-PFIZER INC-2018489083		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15670472	NON-EXPEDITED			US-PFIZER INC-2018490173			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S		500 Mg, Single (One Time Dose)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15670747	NON-EXPEDITED			US-PFIZER INC-2018490682			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unk	Pfizer
Ciprofloxacin	S	Unk	Unknown
Doxycycline Hyclate	S	Unk	Pfizer
Diflucan	S	Unk	Pfizer
Lidocaine Hcl	S	Unk	Pfizer
Metoprolol Tartrate	S	Unk	Unknown
Fosamax	S	Unk	Not Reported
Thorazine [Chlorpromazine Hydrochloride]	S	Unk	Not Reported
Biaxin	S	Unk	Not Reported
Codeine	S	Unk	Not Reported
Norco	S	Unk	Not Reported
Dilaudid	S	Unk	Not Reported
Boniva	S	Unk	Not Reported
Mobic	S	Unk	Not Reported
Nortriptyline	S	Unk	Not Reported
Acetaminophen	S	Unk	Not Reported
Sulfanilamide	S	Unk	Not Reported
Tizanidine	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15671011	NON-EXPEDITED			US-PFIZER INC-2018486831		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15673559	NON-EXPEDITED			US-PFIZER INC-2018482346			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax		S			Unk		Pfizer	
	Piroxicam		S			Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2018	15717946	DIRECT		HO			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Gastric	Warfarin			S	Oral			Not Reported	
Haemorrhage; International Normalised Ratio Increased	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	14927323	NON-EXPEDITED			US-PFIZER INC- 2018208762			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Throat Tightness	Zithromax			S	Oral	Unk (5 Day Treatment)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15562931	EXPEDITED (15-DAY)		OT	PHHY2018DE009990		51 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Moxifloxacin			S	Oral	400 Mg, Unk		Not Reported	
	Moxifloxacin			S	Oral	400 Mg, Unk		Not Reported	
	Moxifloxacin			S	Oral	400 Mg, 5 Days		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	1x		Not Reported	
	Repatha			S	Subcutaneous	140 Mg, Unk		Not Reported	
	Restex			C	Oral	100 Mg, (100/25 Mg)Unk		Not Reported	
	Valsartan			C	Unknown	160 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15572622	NON-EXPEDITED			US-PFIZER INC-2018442341		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Bactrim			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Alphagan-P			S		Unk		Not Reported
	Tizanidine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15590292	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2018-053019		88 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Hyperthyroidism; Toxicity To Various Agents	Amiodarone			S	Oral	400 Milligram, Unk		Aurobindo
	Amiodarone			S	Oral	200 Milligram, Once A Day		Aurobindo
	Amiodarone			S				Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Flecainide			S	Unknown	50 Milligram, Two Times A Day		Aurobindo
	Flecainide			S				Aurobindo
	Sulfamethoxazole And Trimethoprim			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	160/800 Mg, Bid		Not Reported
	Acetylsalicylic Acid			C	Unknown	100 Milligram, Daily		Not Reported
	Thiamazole			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Verapamil			C		Unknown		5 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Nov-2018	15667431	NON-EXPEDITED			US-PFIZER INC-2018478195		44 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Influenza	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer		
	Z-Pak			S		Unk		Not Reported		
	Prednisone			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Nov-2018	15670949	NON-EXPEDITED			US-PFIZER INC-2018486713			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Nov-2018	15673922	EXPEDITED (15-DAY)		HO, LT	NL-TEVA-2018-NL-979498		82 YR	Female	NLD	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Angina Pectoris; Cardiac Failure; Condition Aggravated	Salbutamol Aerosol, 100 Mg/Dosis (Microgram Per Dosis)			S	Unknown	3x Per Dag 1 Inhalatie		Barr		
	Azitromycine Tablet, 500 Mg (Milligram)			S		500 Milligram Daily;		Not Reported		
	Irbesartan 150mg			C		150 Milligram Daily;		Not Reported		
	Codeinefosfaat 10mg			C				Not Reported		
	Koelzalf Fna			C	Unknown	1 Dosage Forms Daily; 1dd		Not Reported		
	Isosorbidedinitraat Retard 20mg			C				Not Reported		
	Nedios 250mg			C		250 Milligram Daily; 1dd1		Not Reported		
	Dermovate Creme			C	Unknown	1 Dosage Forms Daily; 1dd		Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pravastatine 40mg	C	Unknown	40 Milligram Daily;	Not Reported
Bumetanide 1mg	C	Unknown	1 Milligram Daily; 1dd1	Not Reported
Acenocoumarol	C	Unknown		Not Reported
Calci Chew D3 1g/800	C	Unknown	1 Dosage Forms Daily; 1dd1	Not Reported
Nebivololol 2,5mg	C		1 Milligram Daily; 1dd0,5 Tablet	Not Reported
Carbamazepine 100mg	C		100 Milligram Daily; 1dd1	Not Reported
Prednisolon 5mg	C		2 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15675026	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-192377		65 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia	Azithromycin			S	Oral	250 Milligram, Qd		Sun
	Lamprene (Clofazimine)			S	Oral	100 Milligram, Qd		Not Reported
	Vogalene			S	Oral	Unk		Not Reported
	Atarax			S	Oral	Unk		Not Reported
	Emend			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15675467	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2018GSK215932		50 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Valtrex			S		Unk		Glaxosmithkline
Diarrhoea; Fatigue;	Otezla			S	Oral	30 Mg, Qd		Not Reported
Haemoglobin Decreased;	Pms-Azithromycin			S		Unk		Not Reported
Headache; Nausea	Purinethol			C	Oral	50 Mg, Unk		Glaxosmithkline
	Imatinib Mesilate			C	Oral	400 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Pantoprazole Sodium	C	Oral	40 Mg, Unk		Not Reported			
	Zofran	C		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15676015	NON-EXPEDITED			US-PFIZER INC-2018482598			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S		1000 Mg, Single (Two Tablets, Once)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15676614	NON-EXPEDITED			PHEH2018US049794			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased	Azithromycin 250 Mg			S	Unknown	250 Mg, Unk (Once)		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15676891	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2018-FR-980399		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant; Liver Transplant	Azithromycine Anhydre			S	Oral			Not Reported	
	Aciclovir			S	Oral			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15676972	EXPEDITED (15-DAY)		HO, OT	GB-BAUSCH-BL-2018-033522		22 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dermatitis Allergic; Vomiting	Doxycycline			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Ceftriaxone			S	Intramuscular	Stat; In Total Powder For Solution For Injection		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vials.

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15677039	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-980595		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia	Azithromycine Anhydre			S	Oral	250 Milligram Daily;		Not Reported	
	Lamprone 100 Mg, Capsule			S	Oral	100 Milligram Daily;		Not Reported	
	Molle(Clofazimine)			S	Oral			Not Reported	
	Vogalene			S	Oral			Not Reported	
	Atarax			S	Oral			Not Reported	
	Emend			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2018	15677130	NON-EXPEDITED			US-PFIZER INC-2018494616		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2018	15676956	NON-EXPEDITED			US-PFIZER INC-2018485134		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Dec-2018	15678261	EXPEDITED (15-DAY)		DE, OT	ES-HETERO CORPORATE-HET2017ES00465		49 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neoplasm Progression	Levofloxacin			S	Unknown	Unk		Hetero	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rifampicin	S	Unknown	600 Mg	Not Reported
Ethambutol	S	Unknown	600 Mg, Continued For Ten Months	Not Reported
Azithromycin	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
Ceftriaxone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2018	15678798	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT148775		88 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Electrocardiogram T Wave Inversion; Hyperthyroidism	Flecainide			S	Unknown	50 Mg, Bid		Not Reported
	Flecainide			S				Not Reported
	Azithromycin			S	Unknown	Unk		Novartis
	Amiodarone			S	Oral	400 Mg, Unk		Not Reported
	Amiodarone			S	Unknown	200 Mg, Qd		Not Reported
	Sulfamethoxazole And Trimethoprim			S	Unknown	160/800 Mg		Not Reported
	Tmp-Smx			S	Unknown	160/800 Mg, Bid 7 Day Treatment		Not Reported
	Thiamazole			C	Unknown	Unk		Not Reported
	Ceftriaxone			C	Unknown	Unk		Not Reported
	Piperacillin / Tazobactam			C	Unknown	Unk		Not Reported
	Verapamil			C	Unknown	5 Mg, Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	100 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	12921216	EXPEDITED (15-DAY)		OT	PHHY2016NL147770		33 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Complaint; Therapeutic Response	Azithromycin Sandoz			S	Oral	250 Mg, Qw3		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unexpected; Unintended Pregnancy	Etinilestradiolo E Levonorgestrel Mylan	S	Oral	1 Df, Unk	Not Reported
	Clarithromycin Ranbaxy	S	Oral	500 Mg, Bid (2 Keer Per Dag 1 Stuk(S))	Not Reported
	Omecat	C	Oral	40 Mg, Bid	Not Reported
	Diclofenac Sandoz	C	Oral	50 Mg, Unk (1dd 1-2 X Per Dag 1 Tablet)	Not Reported
	Desmopressine Acetaat	C	Oral	0.4 Mg, Qd	Not Reported
	Codeine Phosphate	C	Oral	20 Mg, Unk	Not Reported
	Vesicare	C	Oral	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15665746	EXPEDITED (15-DAY)	HO		PHHY2018FR166791		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Cefpodoxime			S	Oral	2000 Mg, Unk (Total)		Not Reported
	Escitalopram			S	Oral	140 Mg, Unk (One Day)		Not Reported
	Paracetamol			S	Oral	79 G, Unk (Total)		Not Reported
	Trimebutine			S	Oral	14000 Mg, Unk (Total)		Not Reported
	Prednisolon			S	Oral	200 Mg, Unk (Total)		Novartis
	Hepatoum			S	Oral	Unk		Not Reported
	Azithromycin Anhydrous			S	Oral	1500 Mg, Unk (Total)		Not Reported
	Arestal			S	Oral	30 Mg, Unk (Total)		Not Reported
	Seresta			S	Oral	310 Mg, Unk (Total)		Not Reported
	Inorial			S	Oral	120 Mg, Unk (Total)		Not Reported
	Augmentin			S	Oral	6 G, Unk (One Day)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15679390	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-057745		25 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lip Oedema	Azithromycin	S	Oral	Total	Aurobindo
	Cefalexin	S	Oral	Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15680331	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2018491261		67 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Bradycardia; Chest Pain; Drug Hypersensitivity; Hypertension	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Capoten			C	Oral	25 Mg, 2x/Day		Not Reported
	Adiro			C	Oral	300 Mg, 1x/Day		Not Reported
	Omeprazole			C		Unk		Not Reported
	Ibuprofen			C	Oral	1-2 Capsules; Daily In The Last Week)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15682415	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20181139007		2 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Crohn'S Disease	Epitomax			S	Oral			Not Reported
	Rivotril			S	Oral			Not Reported
	Inexium			S	Oral			Not Reported
	Sabril			S	Oral			Not Reported
	Oramorph			S	Oral			Not Reported
	Circadin			S	Oral			Not Reported
	Lioresal			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Laroxyl			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15682582	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018-0374040		22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cystic Fibrosis Respiratory Infection Suppression; Drug Intolerance; Pneumonia	Aztreonam Lysine			S	Respiratory (inhalation)	75 Mg		Gilead	
	Aztreonam Lysine			S				Gilead	
	Orkambi			S	Unknown	200mg/125mg Tablets		Not Reported	
	Azithromycin			S	Unknown	500 Mg		Not Reported	
	Sodium Chloride			S	Unknown	7% Vial		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2018	15682600	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2018M1088014		50 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Doxycycline			S	Unknown			Not Reported	
	Doxycycline			S				Not Reported	
	Doxycycline			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15330916	NON-EXPEDITED			US-PFIZER INC-2018347735			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15565244	EXPEDITED (15-DAY)		HO, OT	PHHY2018PL138154			Female	POL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Leukopenia; Thrombocytopenia	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported
	Prednisone			S	Oral	40 Mg Qd (In Morning)		Novartis
	Prednisone			S				Novartis
	Spiramycin			S	Unknown	3 Miu, Tid		Not Reported
	Spiramycin			S				Not Reported
	Sulfadoxine Pyrimine			S	Unknown	Pyrimethamine 25mg, Sulfadoxine 500 Mg, Qd(On Days 3--21)		Not Reported
	Sulfadoxine Pyrimine			S	Unknown	Pyrimethamine 25mg, Sulfadoxine 500 Mg, Bid		Not Reported
	Omeprazole			C	Unknown			Not Reported
	Ranitidine			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15683260	EXPEDITED (15-DAY)		HO, OT	ES-TEVA-2018-ES-981359		67 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azitromicina 500 Mg 3			S	Oral	500 Milligram Daily;		Not Reported
	Comprimidos			C	Oral			Not Reported
	Capoten			C	Oral			Not Reported
	Adiro 300mg 30 Comprimidos					300 Milligram Daily; In Medical History Of Primary Health Care Consists Adiro 300mg 1/24h		
	Gastrorresistentes Efg							
	Omeprazol (2141a)			C	Unknown			Not Reported
	Ibuprofeno (1769a)			C	Oral	Current History Of High Internal Medicine Report: "You've Been Taking 1- 2cp Daily In The Last Week		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15683760	EXPEDITED (15-DAY)		HO	FR-ROCHE-2222824		2 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crohn'S Disease	Rivotril			S	Oral	2.5 Mg/MI		Not Reported	
	Epitomax			S	Oral			Not Reported	
	Inexium			S	Oral			Not Reported	
	Sabril			S	Oral			Not Reported	
	Oramorph			S	Oral			Not Reported	
	Circadin			S	Oral			Not Reported	
	Lioresal			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Laroxyl			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15683952	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR- APL-2018-058398			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Renal Failure	Azithromycin Ab 500 Mg			S	Unknown	Unk		Aurobindo	
	Rosuvastatin			S	Unknown	Unk		Aurobindo	
	Itraconazole			S	Unknown	Unk		Not Reported	
	Diltiazem Hydrochloride			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15684566	EXPEDITED (15-DAY)		OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001- 18-086		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous	Penicillin			S	Unknown			Hikma	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15684723	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2018493006		1 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Decreased Appetite; Nausea; Vomiting	Zithromax			S	Oral	0.1 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15686375	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-ICU MEDICAL, INC.-ICU2018CA00157			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Morphine Sulfate Injection			S	Intravenous (not otherwise specified)	1 Every 10 Minutes		Icu Medical	
	Amiodarone			S		2.0 Day(S)		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	10 Milligram (1 Every 1 Hour) 3.0 Day		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Milligram (1 Every 4 Hours) 3.0 Day		Not Reported	
	Diltiazem Cd			S	Oral	180 Milligram (6.0 Day)		Not Reported	
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Milligram (1 Every 4 Hours) 6.0 Day		Not Reported	
	Doxorubicin			S	Intravenous (not otherwise specified)	106 Milligram (1 Every 14 Days) 43.0 Days		Not Reported	
	Enoxaparin			S	Subcutaneous	40 Milligram (1 Every 1 Day) 6.0 Day		Not Reported	
	Furosemide			S	Oral	40 Milligram (1 Every 1 Day) 3.0 Day		Not Reported	
	Hydralazine			S	Intravenous (not	10 Milligram (1 Every 4		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorphone	S	otherwise specified)	Hours)	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	4.0 Day	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	125 Milligram (1 Every 6 Hours) 4.0 Day	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Milligram (1 Every 6 Hours)	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	5.0 Milligram (1 Every 6 Hours)	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	297 Milligram(1 Every 14 Days) 1.0 Day	Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified)	8.0 Milligram (1 Every 1 Hour)	Not Reported
Procytox	S	Intravenous (not otherwise specified)	500 Milligram (1 Every 1 Day) 4.0 Days	Not Reported
Trastuzumab	S	Intravenous (not otherwise specified)	1060 Milligram (1.0 Day)	Not Reported
Ondansetron	C	Unknown		Not Reported
Metoclopramide	C	Oral	8.0 Milligram (2 Every 1 Day)	Not Reported
Gabapentin	C	Oral	10 Milligram (4 Every 1 Day)	Not Reported
Filgrastim	C	Oral	100 Milligram (3 Every 1 Day)	Not Reported
Dexamethasone	C	Subcutaneous	300 Microgram (! Every 1 Day)	Not Reported
Aprepitant	C	Oral	20 Milligram (1 Every 1 Day)	Not Reported
	C	Oral	125 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2018	15687254	EXPEDITED (15-DAY)		HO	JP-009507513-1812JPN000227		44 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oculomucocutaneous Syndrome	Montelukast Sodium	S	Oral	Unk	Merck
	Lamictal	S	Oral	Unk	Not Reported
	Zithromac	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15687324	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-057897		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Paracetamol			S	Oral	79 G, Total		Aurobindo
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported
	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Aurobindo
	Prednisolone			S	Oral	200 Mg, Total		Aurobindo
	Cefpodoxime			S	Oral	2000 Mg, Total		Aurobindo
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported
	Oxazepam			S	Oral	310 Mg, Total		Not Reported
	Amoxicillin Sodium And Clavulanate Potassium			S	Oral	6 G, 1 Day		Not Reported
	Loperamide Oxide			S	Oral	30 Mg, Total		Not Reported
	Bilastine			S	Oral	120 Mg, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15687629	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192662		67 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azithromycin			S	Oral	500 Milligram, Qd, (Azitro/24h 6d)		Sun
	Capoten			C	Oral	25 Milligram, Bid, (25mg/12h)		Not Reported
	Adiro 300mg 30 Comprimidos Gastrorresistentes Efg			C	Oral	300 Milligram, Qd, (0-1-0)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omeprazol (2141a)	C	Unknown	Unk	Not Reported
Ibuprofeno (1769a)	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15689020	EXPEDITED (15-DAY)		DS, OT	GB-BAYER-2018-175771		30 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acoustic Neuroma; Balance Disorder; Deafness Neurosensory; Deafness Unilateral; Facial Paralysis; Facial Paralysis; Fatigue; Insomnia; Nausea; Off Label Use; Ototoxicity; Product Use In Unapproved Indication; Vestibular Disorder	Moxifloxacin Oral			S		400 Mg, Qd		Bayer
	Meropenem			S	Intravenous (not otherwise specified)	2 G, Tid		Not Reported
	Azithromycin			S	Oral	500 Mg, Qd		Not Reported
	Azithromycin			S	Oral	250 Unk		Not Reported
	Minocycline			S	Oral	100 Mg, Bid		Not Reported
	Amikacin			S	Respiratory (inhalation)	500 Mg, Bid		Not Reported
	Amikacin			S	Intravenous (not otherwise specified)	525 Unk		Not Reported
	Lamprene (Clofazimine)			S		100 Mg, Qd		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	50 Mg, Bid		Not Reported
	Imipenem			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15689795	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2018492965		3 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Disorder; Lip Disorder; Lip Erythema; Lip Swelling; Macule; Ocular Hyperaemia; Rubella; Swelling	Zithromax			S	Oral	125 Mg, 1x/Day		Pfizer
	Zithromax			S				Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15689842	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018491282		3 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Seizure	Zithromac 10%			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15690166	EXPEDITED (15-DAY)		HO	IT-ANIPHARMA-2018-IT-000121		88 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Sulfamethoxazole & Trimethoprim (Non-Specific)			S		800/160 Mg Twice Daily		Ani	
	Flecainide Acetate (Non-Specific)			S		50 Mg Twice Daily		Ani	
	Azithromycin			S				Not Reported	
	Amiodarone			S	Oral	200 Mg Daily		Not Reported	
	Aspirin			C		100 Mg Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15690366	NON-EXPEDITED			US-PFIZER INC-2018500438			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15691129	EXPEDITED (15-DAY)		HO	PHHY2018PL173386		5 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea	Azithromycin			S	Unknown			Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2018	15691892	NON-EXPEDITED			US-PFIZER INC-2018499964		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15004328	NON-EXPEDITED			US-PFIZER INC-2018238058			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15552209	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018435876		88 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Electrocardiogram T Wave Abnormal; Hyperthyroidism	Amiodarone Hcl			S	Oral	400 Mg		Pfizer	
	Amiodarone Hcl			S	Unknown	200 Mg, Daily		Pfizer	
	Azithromycin			S	Unknown	Unk		Pfizer	
	Flecainide Acetate			S	Unknown	50 Mg, 2x/Day		Not Reported	
	Sulfamethoxazole/Trimethoprim			S	Unknown	160/800 Mg, Bid		Not Reported	
	Acetylsalicylic Acid			C		100 Mg, Daily		Not Reported	
	Verapamil			C	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported	
	Verapamil			C	Intravenous (not otherwise specified)	5 Mg, Unk, (Additional)		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Piperacillin/Tazobactam			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15607316	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018458886		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Prescribed Overdose; Respiratory Distress	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15693518	EXPEDITED (15-DAY)		HO	PL-AUROBINDO-AUR-APL-2018-058971		5 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S				Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15693734	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-058855		34 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoptysis; Mediastinitis; Pleural Effusion; Pneumonia	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15694477	EXPEDITED (15-DAY)		HO, OT	PHHY2018GB173895		22 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dermatitis Allergic; Vomiting	Ceftriaxone			S	Intramuscular	500 Mg, Total		Novartis	
	Doxycycline			S	Oral	200 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	250 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15695031	EXPEDITED (15-DAY)		DE, HO	AU-ASSERTIO THERAPEUTICS, INC.- ET-2018DEP001933			Unknown	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug-Induced Liver Injury	Diclofenac			S		Unk		Assertio Therapeutics	
	Isoniazid			S		Unk		Not Reported	
	Pyrazinamide			S		Unk		Not Reported	
	Rifampicin			S		Unk		Not Reported	
	Ethambutol			S		Unk		Not Reported	
	Pyridoxine			S		Unk		Not Reported	
	Heparin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Cimetidine			S		Unk		Not Reported	
	Metoclopramide			S		Unk		Not Reported	
	Paracetamol			S		Unk		Not Reported	
	Dexamethasone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15695319	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018496930		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Atenolol			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15695748	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT- 982171		50 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Atenolol			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15696785	NON-EXPEDITED			US-PFIZER INC-2018492754		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Metoclopramide Hcl			S		Unk		Pfizer	
	Nitroglycerin			S		Unk		Pfizer	
	Calan Sr			S		Unk		Pfizer	
	Verapamil Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Barium Sulfate			S		Unk		Not Reported	
	Benadryl Allergy [Cetirizine Hydrochloride]			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	
	Entocort Ec			S		Unk		Not Reported	
	Golytely			S		Unk		Not Reported	
	Keflex [Cefalexin]			S		Unk		Not Reported	
	Pentasa			S		Unk		Not Reported	
	Reglan [Metoclopramide]			S		Unk		Not Reported	
	Stadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2018	15697337	EXPEDITED (15-DAY)		HO, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-192862		88 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction;	Azithromycin	S	Unknown	()	Sun
Electrocardiogram Qt	Sulfamethoxazole/Trimethoprim	S	Unknown	160/800 Mg ()	Not Reported
Prolonged;	Amiodarone	S	Oral	400 Milligram, Daily	Not Reported
Electrocardiogram T Wave	Amiodarone	S	Oral	400 Mg, Unk	Not Reported
Abnormal;	Flecainide	S	Unknown	50 Mg, 2x/Day	Not Reported
Hyperthyroidism	Amiodarone Hcl	S	Unknown	200 Mg, Daily	Not Reported
	Verapamil	C	Unknown		Not Reported
	Ceftriaxone	C	Unknown		Not Reported
	Piperacillin/Tazobactam	C	Unknown		Not Reported
	Thiamazole	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown	100 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	14271764	NON-EXPEDITED			US-PFIZER INC-2017531029			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Meloxicam			S		Unk		Not Reported
	Tramadol Hydrochloride			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	14837466	NON-EXPEDITED			US-PFIZER INC-2018179485		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urticaria	Breo Ellipta	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15089782	EXPEDITED (15-DAY)	HO		PHHY2018CA014391		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Back Pain;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Headache; Herpes Zoster;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Lung Cancer Metastatic;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Lymphoma; Nasal	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Congestion;	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Nasopharyngitis; Poor	Xolair			S	Subcutaneous	375 Mg, Biw		Not Reported
Quality Sleep; Productive								
Cough; Skin Lesion	Azithromycin Sandoz			S	Oral	1 Df, Unk		Not Reported
	Diltiazem Hcl			S	Oral	1 Df, Qd		Novartis
	Esomeprazole			S	Oral	1 Df, Bid		Not Reported
	Symbicort			C	Respiratory (inhalation)	2 Df, Tid		Not Reported
	Spiriva			C	Respiratory (inhalation)	2 Df, Qd		Not Reported
	Ventolin			C	Respiratory (inhalation)	2 Df, Prn		Not Reported
	Singulair			C	Oral	1 Df, Qd		Not Reported
	Rhinocort			C	Nasal	4 Df, Bid		Not Reported
	Rhinocort			C				Not Reported
	Asa			C	Oral	1 Df, Qd		Not Reported
	Synthroid			C	Oral	1 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15617213	NON-EXPEDITED			US-PFIZER INC-2018468870			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15625615	EXPEDITED (15-DAY)		OT	PHEH2018US047942			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Dizziness; Dyspnoea; Feeling Abnormal; Headache; Heart Rate Abnormal; Hypoaesthesia; Loss Of Consciousness; Palpitations; Paraesthesia; Tremor; Vision Blurred	Azithromycin Sandoz			S	Unknown	1 Df, Qd		Novartis	
	Azithromycin Sandoz			S				Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15698302	NON-EXPEDITED			US-PFIZER INC- 2018498237		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Z-Pak			S		Unk		Not Reported	
	Herceptin			S		Unk		Not Reported	
	Augmentine [Amoxicillin;Clavulanic Acid]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15698336	NON-EXPEDITED			US-PFIZER INC- 2018498264		76 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15699307	EXPEDITED (15-DAY)		OT	ES-APOTEX- 2018AP026034		55 YR	Female	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mixed Liver Injury	Azithromycin			S	Oral	Unk		Apotex	
	Meiact			S	Oral	200 Mg, Every 8 Hours (200 Mg Thrice A Day For 6 Days And Twice A Day For One Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15699862	NON-EXPEDITED			US-PFIZER INC- 2018497314			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrasystoles	Zithromax			S		Unk, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2018	15701376	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR- 983383		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Azithromycine Anhydre			S	Oral			Not Reported	
	Escitalopram			S	Oral	140 Milligram Daily;		Ivax	
	Prednisolone			S	Oral			Actavis	
	Paracetamol			S	Oral			Not Reported	
	Cefpodoxime			S	Oral			Not Reported	
	Trimebutine			S	Oral			Not Reported	
	Hepatoum, Solution Buvable			S	Oral	Not Informed		Not Reported	
	Arestal 1 Mg, Comprimé			S	Oral			Not Reported	
	Seresta 10 Mg, Comprimé			S	Oral			Not Reported	
	Inorial 20 Mg, Comprimé			S	Oral			Not Reported	
Augmentin			S	Oral			Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Dec-2018	15701377	EXPEDITED (15-DAY)		HO	PL-TEVA-2018-PL-983252		72 YR	Male	POL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Erythema	Azithromycine			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Dec-2018	15701693	EXPEDITED (15-DAY)		OT	IT-TEVA-2018-IT-983666		25 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Lip Oedema	Azithromycin			S	Oral				Not Reported
	Cefalexin			S	Oral				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	11168131	NON-EXPEDITED			US-PFIZER INC-2015186940		39 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S	Oral	Unk			Pfizer
	Biaxin			S	Oral	Unk			Not Reported
	Flu Vaccine			S		Unk			Not Reported
	Influenza Virus Vaccine			S		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	14568757	NON-EXPEDITED			US-PFIZER INC-2018074788			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Cefaclor			S		Unk			Not Reported
	Augmentin			S		Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Avelox	S	Unk	Not Reported
Hydrocodone	S	Unk	Not Reported
Hydrocodone Bitartrate	S	Unk	Not Reported
Bactrim	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15121216	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2018-034588		65 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Cough; Drug Ineffective For Unapproved Indication; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Therapeutic Response Decreased	Azithromycin			S	Unknown	Unk, Unknown Freq		Aurobindo
	Azithromycin			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk, Unknown Freq.		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Lisinopril Tablet			S	Oral	Unk, Unknown Freq		Aurobindo
	Perindopril+Indapamide			S	Unknown	Dose Of Perindopril Had Been Doubled		Not Reported
	Alendronate Sodium W/Colecalciferol			S	Unknown	Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15330967	NON-EXPEDITED			US-PFIZER INC- 2018347265		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15439550	EXPEDITED (15-DAY)		CA, DS, HO	LV-LPDUSPRD- 20181739			Female	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Atresia; Foetal Exposure During Pregnancy	Ferinject (Ferric Carboxymaltose - Vifor) (Fer-Vifor-02)			S	Transplacental	50 Dosage Forms		Vifor
	Venofer (Iron Sucrose Injection-			S	Transplacental	100 Mg		Vifor

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vifor)					
Azithromycinum (Azithromycin)	S	Transplacental	500 Mg (500 Mg, 1 In 1 D)		Not Reported
Cefuroxime	S	Transplacental	1500 Mg (750 Mg, 2 In 1 D)		Not Reported
Penicillin G Benzathine	S	Transplacental	4 Gm (1 Gm, 4 In 1 D)		Not Reported
Paracetamol	S	Transplacental	1000 Mg (500 Mg, 2 In 1 D)		Not Reported
Maltofer (Ferric Hydroxidel Polymaltose Complex)	S	Transplacental	Unknown		Not Reported
Ferrum	S	Transplacental	100 Mg Three Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15659820	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-056616		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	140 Milligram, Once A Day		Aurobindo
	Escitalopram			S	Oral	10 Milligram, Once A Day (Overdose: 140 Mg, 1 Day)		Aurobindo
	Prednisolone			S	Oral	200 Milligram, In Total		Aurobindo
	Prednisolone			S	Oral	20 Milligram In Total (200 Mg, Total)		Aurobindo
	Paracetamol			S	Oral	79 Gram, In Total		Aurobindo
	Cefpodoxime			S	Oral	2000 Milligram, In Total		Aurobindo
	Cefpodoxime			S	Oral	100 Milligram In Total		Aurobindo
	Trimebutine			S	Oral	14000 Milligram, In Total		Not Reported
	Trimebutine			S	Oral	200 Milligram In Total (14000 Mg, Total)		Not Reported
	Azithromycin			S	Oral	1500 Milligram, Total		Aurobindo
	Azithromycin			S	Oral	250 Milligram Total (1500 Mg, Total)		Aurobindo
	Hepatoum			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Seresta	S	Oral	310 Milligram, Total	Not Reported
Seresta	S	Oral	10 Milligram Total (310 Mg, Total)	Not Reported
Arestal	S	Oral	30 Milligram, Total	Not Reported
Arestal	S	Oral	1 Milligram Total (30 Mg, Total)	Not Reported
Inorial	S	Oral	120 Milligram, Total	Not Reported
Inorial	S	Oral	20 Milligram, Total (120 Mg, Total)	Not Reported
Augmentin /00756801/	S	Oral	6 Gram, Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15669810	EXPEDITED (15-DAY)		HO, OT	HU-PFIZER INC-2018487224		48 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Amoxicillin			C		Unk		Not Reported	
	Amoxicillin			C				Not Reported	
	Amoxicillin			C				Not Reported	
	Amoxicillin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15699146	NON-EXPEDITED			US-PFIZER INC-2018504565		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Furosemide			S		Unk		Unknown	
	Crestor			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15699850	NON-EXPEDITED			US-PFIZER INC-2018501619		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Z-Pak			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15702907	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2018-08409		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Unknown	Unk		Lupin	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Finasteride			C	Unknown	Unk		Not Reported	
	Prazosin			C	Unknown	Unk		Not Reported	
	Sertraline			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15703461	NON-EXPEDITED			US-PFIZER INC-2018502456		57 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2018	15704528	NON-EXPEDITED			US-PFIZER INC-2018507030		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15705161	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018500471			Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Seizure	Zithromac			S				Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Dec-2018	15705788	NON-EXPEDITED			US-PFIZER INC-2018505766			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Dilantin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	13063689	NON-EXPEDITED			US-PFIZER INC-2016584875		27 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Drug Ineffective	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15704553	NON-EXPEDITED			US-PFIZER INC-2018505966			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Dec-2018	15708212	NON-EXPEDITED			US-PFIZER INC-2018504666			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15708254	NON-EXPEDITED			US-PFIZER INC-2018506762		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15709077	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2018AP026576		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Unknown	Unk		Apotex	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Finasteride			C	Unknown	Unk		Not Reported	
	Prazosin			C	Unknown	Unk		Not Reported	
	Sertraline			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2018	15709564	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2018507114		2 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angular Cheilitis; Erythema; Skin Exfoliation	Zitromax			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	11677511	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2015360014		46 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Reaction With Eosinophilia And Systemic Symptoms		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	11826341	NON-EXPEDITED			US-PFIZER INC-2015401509			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Pradaxa			S		Unk		Not Reported	
	Coumadin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	12213553	NON-EXPEDITED			US-PFIZER INC-2016136538			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	12905682	EXPEDITED (15-DAY)		OT	NL-SUN PHARMACEUTICAL INDUSTRIES LTD-2016RR-126998		33 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Complaint; Unintended Pregnancy	Claritromycine 500 Ranbaxy, Filmomhulde Tabletten 500 Mg			S	Oral	500 Mg, Bid		Sun	
	Ethinylestradiol/Levonorges Myl Tb Omh 0,03/0,15mg			S	Oral	Once Daily 1 Tablet For A Period Of 3 Weeks, Discontinue Treatment Afterwards For 1 Week		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azitromycine Sandoz Tablet Omhuld 250mg	S	Oral	3 Keer Per Week 1 Stuk(S), Extra Info: (Niet Gebruikt Tijdens Kuur Claritromycine	Not Reported
Omecat Capsule Msr 40mg	C	Oral	2 Dd 1	Not Reported
Diclofenac Natrium Sandoz Tablet Msr 50mg	C	Oral	1dd 1-2 X Per Day 1 Tablet	Not Reported
Desmopressine Acetaat Sandoz Tablet 0,2mg	C	Oral	1 Dd 2	Not Reported
Codeinefosfaat Rp Tablet 20mg	C	Oral	1 Dd 1 Vn Zn	Not Reported
Vesicare Tablet Filmomhuld 5mg	C	Oral	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	14403074	EXPEDITED (15-DAY)		HO, OT	PHEH2018US002149		50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Heart Rate Abnormal; Hepatic Enzyme Increased; Multiple Sclerosis Relapse; Nasopharyngitis	Gilenya			S	Unknown	Unk		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Unknown	Unk		Novartis
	Sudafed			S	Unknown	Unk		Not Reported
	Z-Pak			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15532699	EXPEDITED (15-DAY)		DE, OT	GR-MYLANLABS- 2018M1078396		65 YR	Male	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Death; Hepatic Cirrhosis	Vancomycin			S		Unk		Not Reported
	Piperacillin/Tazobactam			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Doxycycline			S		Unk		Not Reported
	Sulphamethoxazole/Trimethopri m			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem			S		Unk			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15711584	EXPEDITED (15-DAY)		HO	FR-ZYDUS-030940		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Somnolence; Toxicity To Various Agents; Vomiting	Paracetamol			S	Oral			Not Reported	
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported	
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported	
	Cefpodoxime/Cefpodoxime Proxetil			S	Oral			Not Reported	
	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Zydu Pharm	
	Inorial			S	Oral			Not Reported	
	Chloroform/Glycerol/Herbal Extract Nos/Isoamyl Acetate/Menthol [Hepatoum]			S	Oral			Not Reported	
	Loperamide			S	Oral			Not Reported	
	Oxazepam			S	Oral	310 Mg, Total		Not Reported	
	Amoxicillin Sodium/Clavulanate Potassium			S	Oral	6 G, 1 Day		Not Reported	
	Prednisolone			S	Oral	200 Mg, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15711767	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-059467		87 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Hypercapnia; Hypothermia; Hypoventilation; Impaired Gastric Emptying; Pneumonia; Pupillary Reflex Impaired; Respiratory Failure; Vomiting	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ceftazidime			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15712002	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2018-059664		93 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, In Total		Aurobindo	
	Pregabalin			C	Unknown	50 Milligram		Not Reported	
	Carvedilol			C	Unknown	6.25 Milligram		Not Reported	
	Apixaban			C	Oral	5 Milligram		Not Reported	
	Elopram /00582602/			C	Oropharyngeal	5 Gtt Drops		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15712096	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-984596		45 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Azithromycine Anhydre			S	Oral	500 Milligram Daily;		Not Reported	
	Zeclar 250 Mg, Comprimé Pelliculé			S	Oral	2 Dosage Forms Daily;		Not Reported	
	Nebilox			C	Oral	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15713556	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2018GSK220884		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Asthenia; Asthma; Balance Disorder; Bladder Disorder; Blood Glucose Abnormal; Blood Pressure Systolic Increased; Body Temperature Decreased;	Ventolin			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Ventolin			S				Glaxosmithkline	
	Ventolin			S				Glaxosmithkline	
	Ventolin			S				Glaxosmithkline	
	Diltiazem			S		1 Df, Qd		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Brain Hypoxia; Breath Odour; Breath Sounds	Prednisone	S		Unk	Not Reported
Abnormal; Bronchitis;	Prednisone	S			Not Reported
Carbon Dioxide Increased;	Prednisone	S			Not Reported
Chest Discomfort; Chest Pain; Cough; Crepitations;	Prednisone	S			Not Reported
Diarrhoea; Drug	Xolair	S	Subcutaneous	Unk	Not Reported
Ineffective; Dyspepsia;	Zithromax	S		250 Mg, Z	Not Reported
Dyspnoea; Dyspnoea	Zithromax	S			Not Reported
Exertional; Fall; Fatigue;	Zithromax	S			Not Reported
Feeling Abnormal; Forced Expiratory Volume	Advair	C	Respiratory (inhalation)	1 Df, Bid	Glaxosmithkline
Decreased; Frustration	Tums	C		1 Df, Unk	Glaxosmithkline
Tolerance Decreased;	Alvesco	C		2 Df, Qid	Not Reported
Gait Disturbance;	Atrovent	C		2 Df, Qid	Not Reported
Gastrooesophageal Reflux Disease; General Physical Health Deterioration;	Dexilant	C		1 Df, Qd	Not Reported
Haemarthrosis; Headache;	Ipratropium Bromide + Salbutamol Sulphate	C		20 Unk, Unk	Not Reported
Heart Rate Increased;	Spiriva	C		2 Df, Qd	Not Reported
Humidity Intolerance;	Zenhale	C		Unk	Not Reported
Hypersensitivity;					
Hypoventilation; Infection;					
Injury; Insomnia; Joint Swelling; Lung Disorder;					
Malaise; Memory Impairment; Muscle Disorder; Muscle Spasms;					
Musculoskeletal Discomfort;					
Nasopharyngitis;					
Odynophagia; Oral Candidiasis;					
Oropharyngeal Pain; Pain In Extremity;					
Paraesthesia; Peak Expiratory Flow Rate					
Abnormal; Peak Expiratory Flow Rate Decreased;					
Peripheral Swelling;					
Pneumonia; Pollakiuria;					
Poor Quality Sleep;					

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Productive Cough;
Pulmonary Function Test
Decreased; Pyrexia;
Respiratory Rate
Increased; Respiratory
Tract Congestion;
Rhinorrhoea; Seasonal
Allergy; Sputum
Discoloured; Stress;
Tendonitis; Tremor; Viral
Infection; Vomiting; Weight
Decreased; Wheezing

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15714883	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2018M1091455		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
	Cefixime			S	Unknown			Not Reported	
	Metronidazole			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15715022	EXPEDITED (15-DAY)		OT	PHEH2018US052495			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin 250 Mg			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15715389	EXPEDITED (15-DAY)		OT	PHEH2018US052236			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fatigue; Seizure	Tigecycline			S	Unknown	Unk		Novartis	
	Azithromycin Monohydrate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Bedaquiline		S	Unknown	Unk			Not Reported	
	Imipenem		S	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2018	15716836	DIRECT	Y				212 DAY	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dose Calculation Error; Incorrect Dose Administered; Intercepted Product Preparation Error; Product Reconstitution Quality Issue	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15687591	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-192631		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	140 Milligram		Not Reported	
	Cefpodoxime			S	Oral	In Total		Sun	
	Prednisolone			S	Oral	In Total		Taro	
	Trimebutine			S	Oral	In Total		Not Reported	
	Paracetamol		Y	S	Oral	In Total		Ohm Lab	
	Azithromycine			S	Oral	In Total		Sun	
	Hepatoum, Solution Buvable			S	Oral	Non Renseignee ()		Not Reported	
	Arestal 1 Mg, Comprime			S	Oral	In Total		Not Reported	
	Seresta 10 Mg, Comprime			S	Oral	In Total		Not Reported	
	Inorial 20 Mg, Comprime			S	Oral	In Total		Not Reported	
	Augmentin			S	Oral	6 Gram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15717206	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-193435		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Rash Maculo-Papular	Azithromycin			S	Oral	Unk		Sun	
	Extovyl, Gelule			S	Oral	Unk		Not Reported	
	Solupred (Prednisolone/Metasulfobenzoate Sodium)			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15719946	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2018505693		2 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crohn'S Disease	Zithromax			S	Oral	660 Mg, Weekly		Pfizer	
	Inexium			S	Oral	1 Df, 1x/Day		Unknown	
	Epitomax			S	Oral	30 Mg, 1x/Day		Not Reported	
	Rivotril			S	Oral	10 Gtt, 1x/Day		Not Reported	
	Sabril			S	Oral	600 Mg, 1x/Day		Not Reported	
	Oramorph			S	Oral	7.5 Mg, 1x/Day		Not Reported	
	Circadin			S	Oral	6 Mg, 1x/Day		Not Reported	
	Lioresal			S	Oral	1 Df, 1x/Day		Not Reported	
	Laroxyl			S	Oral	21 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15720483	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2018493834		10 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Pr Prolongation	Zithromax			S	Intravenous drip	0.4 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15720518	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018-0379747		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated	Aztreonam Lysine			S	Unknown	Unk		Gilead	
	Tezacaftor			S	Unknown	Unk		Not Reported	
	Ivacaftor			S	Unknown	Unk		Not Reported	
	Tobramycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2018	15790584	DIRECT		DS			75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness Unilateral; Hypacusis	Azithromycin 250mg	Y		S	Oral	Quantity:250 Mg Milligram(S);Other Frequency:6 Tabs (2 Tabs 1st;		Lupin	
	Lisinopril			C				Not Reported	
	Lipitor			C				Not Reported	
	Multi Vitamins			C				Not Reported	
	Fish Oil			C				Not Reported	
	Potassium Vitamin D Nos			C C				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15681890	EXPEDITED (15-DAY)		HO	IT-TEVA-2018-IT-981567		16 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Intentional Self-Injury; Substance Abuse	Paracetamol			S	Oral			Not Reported	
	Nimesulide			S	Oral			Not Reported	
	Amoxicillina/Acido Clavulanico			S	Oral			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	Not Reported
Oki 80 Mg Granulato Per Soluzione Orale	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15720932	EXPEDITED (15-DAY)		OT	PT-TEVA-2018-PT-985843		19 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Dizziness; Pruritus; Skin Exfoliation; Somnolence	Azitromicina Ratiopharm			S	Oral	1000 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15721136	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2018-GB-985945		22 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Dermatitis Allergic; Vomiting	Azithromycin			S	Oral			Teva
	Doxycycline			S	Oral	200 Milligram Daily;		Actavis
	Ceftriaxone			S	Intramuscular	Stat		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15721801	NON-EXPEDITED			US-PFIZER INC-2018513098		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Nitroglycerin			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15723555	EXPEDITED (15-DAY)		HO, OT	US-VERTEX PHARMACEUTICALS-2018-009280		22 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pneumonia	Orkambi	S	Oral	200/125 Mg Tablets	Vertex
	Aztreonam Lysine	S	Respiratory (inhalation)	75 Mg	Not Reported
	Azithromycin	S	Unknown	500 Mg	Not Reported
	Sodium Chloride	S	Unknown	7 %	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15723861	EXPEDITED (15-DAY)		HO	PHHY2018US180405		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Chest Discomfort	Azithromycin			S	Unknown	Unk		Novartis
	Atorvastatin			C	Unknown	Unk		Not Reported
	Finasteride			C	Unknown	Unk		Not Reported
	Prazosin			C	Unknown	Unk		Not Reported
	Sertraline			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15724139	EXPEDITED (15-DAY)		HO	CZ-MYLANLABS-2018M1092548		69 YR	Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aphthous Ulcer; Haemoglobin Decreased; Leukopenia; Thrombocytopenia; Tonsillitis	Azithromycin			S		Administered After Tonsillitis As Ae Treatment		Not Reported
	Leflunomide Medac			S	Oral	20 Milligram, 3xw		Mylan
	Meloxicam			C	Oral	15 Milligram, 3xw		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2018	15724929	EXPEDITED (15-DAY)		HO, LT	PT-BAUSCH-BL-2018-034733		94 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Laryngeal Oedema	Mestinon			S	Oral	60 Mg 6/6h		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin Basi	S	Intravenous (not otherwise specified)	Not Reported
Paracetamol	C	Intravenous (not otherwise specified)	Not Reported
Pantoprazole	C	Unknown	Not Reported
Amoxicillin/Clavulanic Acid	C	Intravenous (not otherwise specified)	Not Reported
Irbesartan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2018	15725474	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2018-059421		67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Chest Discomfort	Azithromycin			S	Unknown	Unk		Aurobindo
	Sertraline			C	Unknown	Unk		Not Reported
	Prazosin			C	Unknown	Unk		Not Reported
	Finasteride			C	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	13196303	NON-EXPEDITED			US-PFIZER INC-2017051878		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Emycin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Serotonin			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-Dec-2018	14259732	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2017521797		48 YR	Female	ITA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Throat Tightness	Azithromycin			S	Oral	1 Df, Single, (Total (1 Ug/Liter)		Pfizer		
	Omeprazole			C	Oral	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-Dec-2018	14478866	NON-EXPEDITED			US-PFIZER INC-2018043157			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-Dec-2018	14566125	NON-EXPEDITED			US-PFIZER INC-2018076820		77 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer		
	Amiodarone Hcl			S		Unk		Pfizer		
	Nitroglycerin			S		Unk		Pfizer		
	Cardizem [Diltiazem Hydrochloride]			S		Unk		Not Reported		
	Codeine			S		Unk		Not Reported		
	Coreg			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-Dec-2018	15616980	EXPEDITED (15-DAY)		LT, OT	CN-PFIZER INC-2018466890		34 YR	Male	CHN	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Fluconazole			S	Intravenous drip	800 Mg, Unk (Initial Dose)		Pfizer
	Fluconazole			S	Intravenous drip	400 Mg, 1x/Day		Pfizer
	Cefoperazone Sodium And Sulbactam			C	Intravenous drip	1.5 G, 2x/Day (Ivgtt)		Not Reported
	Cefoperazone Sodium And Sulbactam			C	Intravenous drip	3 G, 4x/Day		Not Reported
	Tigecycline			C	Intravenous drip	100 Mg, Unk (Initial Dose)		Not Reported
	Tigecycline			C	Intravenous drip	50 Mg, 2x/Day (Ivgtt, Initial Dose Of 100mg)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15701253	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018501330		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use In Unapproved Indication; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Inorial			S	Oral	120 Mg, Single		Not Reported
	Bilastine			S	Oral	120 Mg, Unk		Not Reported
	Azithromycine			S	Oral	1500 Mg, Single		Pfizer
	Trimebutine Maleate			S	Oral	14000 Mg, Single		Not Reported
	Hepatoum			S	Oral	Unk		Not Reported
	Escitalopram			S	Oral	140 Mg, 1x/Day		Not Reported
	Arestal			S	Oral	30 Mg, Single		Not Reported
	Seresta			S	Oral	310 Mg, Single		Not Reported
	Prednisolone			S	Oral	200 Mg, Single		Not Reported
	Paracetamol			S	Oral	79 G, Single		Not Reported
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S	Oral	6 G, 1x/Day		Not Reported
	Cefpodoxime			S	Oral	2000 Mg, Single		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15714698	EXPEDITED (15-DAY)		LT, OT	PT-TEVA-2018-PT-985665		94 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Anaphylactic Shock; Cyanosis; Hypertension; Malaise; Oxygen Saturation Decreased; Respiratory Failure; Tachycardia	Azitromicina Basi			S	Intravenous (not otherwise specified)	500 Mg		Pliva	
	Amoxicilina + Ácido Clavulánico			C	Intravenous (not otherwise specified)	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15726928	NON-EXPEDITED		HO, OT	DE-DCGMA-16172220		63 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Azithromycin			S	Oral	500 Mg,Unk,Unknown		Lupin	
	Ibuprofen			S	Oral	800 Mg,Unk,Unknown		Not Reported	
	Salbutamol			C	Respiratory (inhalation)	Unk Unk,Prn,		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15727838	NON-EXPEDITED			US-PFIZER INC-2018517271			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15728912	EXPEDITED (15-DAY)		OT	PHHY2018GB184286		79 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Lower	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Respiratory Tract Infection	Abatacept	S	Subcutaneous	125 Mg, Qw	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Carbocisteine	C	Unknown	Unk	Not Reported
	Rivaroxaban	C	Unknown	Unk	Not Reported
	Dexamethasone	C	Oral	500 Mg, Unk	Not Reported
	Furosemide	C	Unknown	Unk	Not Reported
	Atorvastatin	C	Unknown	Unk	Not Reported
	Digoxin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15729025	EXPEDITED (15-DAY)		HO	CN-MYLANLABS-2018M1091571		34 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Ventricular Arrhythmia; Ventricular Fibrillation	Azithromycin			S	Intravenous (not otherwise specified)	0.5 Gram, Qd		Not Reported
	Azithromycin			S				Not Reported
	Fluconazole			S	Intravenous (not otherwise specified)	First Dose		Not Reported
	Fluconazole			S	Intravenous (not otherwise specified)	400 Milligram, Qd		Not Reported
	Cefoperazone Sodium And Sulbactam Sodium			C	Intravenous (not otherwise specified)	1.5 Gram		Mylan
	Cefoperazone Sodium And Sulbactam Sodium			C	Intravenous (not otherwise specified)	3 Gram, Q6h		Mylan
	Tigecycline			C	Intravenous (not otherwise specified)	First Dose		Mylan
	Tigecycline			C	Intravenous (not otherwise specified)	50 Milligram		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15729602	NON-EXPEDITED			US-PFIZER INC-2018513254			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypoacusis; Pain; Product Use In Unapproved Indication		Zithromax	S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15731133	DIRECT	Y				29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Culture Positive; Pulmonary Function Test Decreased	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15731532	EXPEDITED (15-DAY)		OT	PHHY2018FR185950		31 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash Erythematous	Pantoprazole			S	Oral	20 Mg, Qd		Novartis	
	Azithromycin Monohydrate			S	Oral	250 Mg, Qd		Not Reported	
	Cefotaxim			S	Intravenous (not otherwise specified)	6 G, Qd		Not Reported	
	Bactrim			S	Intravenous (not otherwise specified)	12 Df, Qd		Not Reported	
	Stromectol			S	Oral	4 Df, Qd		Not Reported	
	Bactrim Forte			S	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15731727	EXPEDITED (15-DAY)		HO	GB-PFIZER INC-2018511646		22 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Dermatitis Allergic; Vomiting	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
	Ceftriaxone Sodium			S	Intramuscular	500 Mg, Single (Stat)		Pfizer	
	Doxycycline Monohydrate			S	Oral	200 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2018	15820496	DIRECT	Y				59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Rash	Zithromax			S	Oral	Other Frequency:2x1day 1x4 Days;		Not Reported	
	Hydrocodone Polistirex			S	Oral	Other Dose:4oz;Other Frequency:1tsp Q12hr;		Neos Therapeutics	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	9892166	NON-EXPEDITED			US-PFIZER INC- 2014036055			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15232081	NON-EXPEDITED			US-PFIZER INC- 2018309441		67 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Lyrica			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Metformin			S		Unk		Not Reported	
	Ativan			S		Unk		Not Reported	
	Lasix			S		Unk		Not Reported	
	Lovaza			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15734629	EXPEDITED (15-DAY)		OT	US-MYLANLABS- 2018M1091230		67 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Azithromycin			S	Unknown			Not Reported
	Atorvastatin			C	Unknown			Mylan
	Finasteride			C	Unknown			Mylan
	Prazosin			C	Unknown			Mylan
	Sertraline			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15734790	EXPEDITED (15-DAY)		DE, OT	PT-MYLANLABS-2018M1094180		56 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Haemoptysis	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported
	Itraconazole			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15735078	NON-EXPEDITED			US-TEVA-2018-US-988365			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Hypersensitivity; Rash	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15735395	DIRECT	Y				22 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Cystic Fibrosis	Azithromycin			S	Oral	Other Frequency:Every Other Day;		Not Reported
	Cyproheptadine Hcl			C				Not Reported
	Naproxen			C				Not Reported
	Dekas Plus			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sodium Chloride	C	Not Reported
Cetirizine Hcl	C	Not Reported
Creon	C	Not Reported
Escitalopram Oxalate	C	Not Reported
Dulera	C	Not Reported
Fish Oil	C	Not Reported
Lantus Solostar	C	Not Reported
Mephyton	C	Not Reported
Novolog Flexpen	C	Not Reported
Orkambi	C	Not Reported
Pulmozyme	C	Not Reported
Vitamin D3	C	Not Reported
Tobramycin	C	Not Reported
Montelukast Sodium	C	Not Reported
Omeprazole	C	Not Reported
Colistimethate Sodium	C	Not Reported
Levalbuterol Hcl	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15736298	NON-EXPEDITED			US-PFIZER INC-2018516135			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15736310	NON-EXPEDITED			US-PFIZER INC-2018516662			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Cough; Pyrexia; Respiratory Tract Congestion; Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15756332	DIRECT	Y					Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Wrong Patient Received Product	Phenergan With Codeine Z-Pak			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2018	15769924	DIRECT	Y					Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Incorrect Dose Administered; Product Dispensing Error	Zithromax			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15737586	NON-EXPEDITED			PHEH2018US051983			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Cough; Malaise; Sneezing; Weight Decreased	Azithromycin			S	Unknown	250 Mg, Qd		Novartis	
	Metformin			C	Unknown	100 Mg, Qd		Not Reported	
	Losartan			C	Unknown	25 Mg, Qd		Not Reported	
	Ruvastin			C		25 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2018	15737933	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-989118		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Finasteride			C	Unknown			Not Reported	
	Prazosin			C	Unknown			Not Reported	
	Sertraline			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15738543	NON-EXPEDITED			US-PFIZER INC-2018522143		68 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Fentanyl Citrate			S		Unk		Unknown	
	Vancomycin Hcl			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
	Chlorhexidine			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15738574	NON-EXPEDITED			US-PFIZER INC-2018516666			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Dec-2018	15740872	EXPEDITED (15-DAY)		OT	PHHY2018DE188196		31 YR	Female	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Lower; Loss Of Consciousness; Muscle Twitching; Myalgia; Nausea	Azithromycin			S	Oral	500 Mg, Qd (1 Mal 500mg An 3 Tagen)		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Dec-2018	12370763	EXPEDITED (15-DAY)		DE, OT	IN-CIPLA LTD.-2016IN04753			Unknown	IND

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Therapeutic Product Cross-Reactivity; Toxic Epidermal Necrolysis	Levofloxacin			S	Unknown	100 Mg, Per Day On Day 1		Cipla
	Levofloxacin			S	Unknown	500 Mg, Per Day On Day 2		Cipla
	Cetirizine			S	Unknown	20 Mg, 12 Hourly		Cipla
	Azithromycin			S	Unknown	500 Mg, 24 Hourly, Tablet		Not Reported
	Rabeprazole			S	Unknown	20 Mg, Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	100 Mg, On Day 3 (Tablet)		Not Reported
	Ethambutol			S	Unknown	800 Mg, On Day 4 (Tablet)		Not Reported
	Streptomycin			S	Unknown	125 Mg, On Day 5 (Injection)		Not Reported
	Streptomycin			S	Unknown	500 Mg, On Day 6 (Injection)		Not Reported
	Isoniazid			S	Unknown	Unk		Not Reported
	Rifampicin			S	Unknown	Unk		Not Reported
	Pyrazinamide			S	Unknown	Unk		Not Reported
	Asera P			S	Unknown	Unk, Tablet		Not Reported
	Asera P			S				Not Reported
	Tolperisone			S	Unknown	50 Mg, Tablet		Not Reported
	Tolperisone			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15156021	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2018FR039687		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Drug Interaction; Drug Level Above Therapeutic; Hepatocellular Injury; Hepatotoxicity; Off Label Use	Azithromycin			S	Unknown	250 Mg, From Day 3 To Day 9		Novartis
	Azithromycin			S	Unknown	500 Mg, On Day 2		Novartis
	Azithromycin			S	Unknown	250 Mg, Qd		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Voriconazole	S	Unknown	On Day 3	Not Reported
Voriconazole	S	Unknown	1 Df, Unk (400mg In The Morning And 200mg At Night)	Not Reported
Voriconazole	S	Unknown	On Day 9: Administered Only In The Morning	Not Reported
Voriconazole	S	Unknown	400 Mg, From Day 4 To Day 7	Not Reported
Voriconazole	S	Unknown	400 Mg, Bid (Morning And Night)	Not Reported
Voriconazole	S	Unknown	200 Mg, Qhs	Not Reported
Voriconazole	S	Unknown	400 Mg, Q.Am	Not Reported
Voriconazole	S	Unknown	400 Mg, Qhs	Not Reported
Voriconazole	S	Unknown	200 Mg, Q.Am	Not Reported
Voriconazole	S	Unknown	1 Df, Unk (400mg In The Morning And 200mg At Night)	Not Reported
Ponatinib	S	Unknown	45 Mg	Not Reported
Ponatinib	S	Unknown	45 Mg, Q. Af (45 Mg/Day At Noon)	Not Reported
Ponatinib	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15219991	NON-EXPEDITED			US-PFIZER INC-2018306178			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15719306	NON-EXPEDITED			US-PFIZER INC-2018512960		77 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity	Atorvastatin Calcium	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer
	Prednisone	S	Unk	Not Reported
	Crestor	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15742900	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08761		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Discomfort; Skin Exfoliation	Azithromycin Tablets			S	Oral	Unk Unk, Qd (2 Tablets On Day 1, Followed By One Tablet)		Lupin	
	Ativan			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15743060	EXPEDITED (15-DAY)		OT	DE-TEVA-2018-DE- 988383		31 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Loss Of Consciousness; Muscle Twitching; Myalgia; Nausea	Azithromycin			S	Oral	500 Milligram Daily; 1 By 500mg On 3 Days		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15743288	EXPEDITED (15-DAY)		OT	CZ-TEVA-2018-CZ- 988957		4 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conversion Disorder; Erythema; Lacrimation Increased; Oral Discomfort; Sudden Visual Loss	Sumamed Forte			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15744014	EXPEDITED (15-DAY)		OT	FR-TEVA-2018-FR-988950		31 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash Erythematous	Azithromycine Monohydratée			S	Oral	250 Milligram Daily;		Teva	
	Pantoprazole			S	Oral	20 Milligram Daily;		Teva	
	Cefotaxime Sodique			S	Intravenous (not otherwise specified)	6 Gram Daily;		Not Reported	
	Bactrim, Solution Injectable Pour Perfusion			S	Intravenous (not otherwise specified)	12 Dosage Forms Daily;		Not Reported	
	Stromectol 3 Mg, Comprimé			S	Oral			Not Reported	
	Bactrim Forte, Comprimé			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15746025	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2018523552		31 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Loss Of Consciousness; Muscle Twitching; Myalgia; Nausea	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15746162	NON-EXPEDITED			PHEH2018US052509			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Azithromycin			S	Oral	250 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2018	15747531	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-MK-6037566		21 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Kidney Injury;	Ibuprofen	S	Unknown	Unk	Not Reported
Arthropathy; Blood	Azithromycin	S	Unknown	Unk	Not Reported
Creatinine Increased;	Tobramycin	S	Intravenous (not	120 Mg,Tid	Not Reported
Blood Urea Increased;			otherwise specified)		
Creatinine Renal	Tobramycin	S	Intravenous (not	8 Milligram/Kilogram, Qd	Not Reported
Clearance Decreased;			otherwise specified)		
Drug Interaction;	Colomycin (Colistin)	S	Intravenous (not	2 Df,Tid	Mylan
Dyspepsia; Hypophagia;			otherwise specified)		
Influenza Like Illness; Off					
Label Use; Polyarthritis;					
Vomiting; Weight					
Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	10362747	NON-EXPEDITED			US-PFIZER INC-2014213190		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Erythromycin			S		Unk		Pfizer	
Rash	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	13909623	NON-EXPEDITED			US-PFIZER INC-2017369808		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer	
Urticaria									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15682411	EXPEDITED (15-DAY)		DE, OT	ET-PFIZER INC-2018494618		8 YR	Female	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia;	Zithromax			S	Oral	500 Mg (2 Tablets), Single		Pfizer	
Cardiovascular						(Stat, At Once)			
Insufficiency; Product Use									
Issue; Respiratory									
Depression; Trismus;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15727890	NON-EXPEDITED			US-PFIZER INC-2018518014		31 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15738630	NON-EXPEDITED			US-PFIZER INC-2018519343		64 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Talwin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Imitrex			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15747991	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-193984		35 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Clostridium Difficile Infection; Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Sun	
	Cefixime			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Dec-2018	15748447	NON-EXPEDITED			US-JNJFOC-20181141110		73 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Diflucan		Y	S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetaminophen	Y	S	Unknown	Not Reported
Acetaminophen		S	Unknown	Not Reported
Amoxicillin		S	Unknown	Not Reported
Azithromycin		S	Unknown	Not Reported
Ciprofloxacin		S	Unknown	Not Reported
Doxycycline Hyclate		S	Unknown	Not Reported
Lidocaine Hcl		S	Unknown	Not Reported
Metoprolol Tartrate		S	Unknown	Not Reported
Fosamax		S	Unknown	Not Reported
Thorazine		S	Unknown	Not Reported
Biaxin		S	Unknown	Not Reported
Codeine		S	Unknown	Not Reported
Norco		S	Unknown	Not Reported
Dilaudid		S	Unknown	Not Reported
Boniva		S	Unknown	Not Reported
Mobic		S	Unknown	Not Reported
Nortriptyline		S	Unknown	Not Reported
Sulfanilamide		S	Unknown	Not Reported
Tizanidine		S	Unknown	Not Reported
Tramadol		S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15749307	NON-EXPEDITED			US-PFIZER INC-2018525180			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2018	15750311	DIRECT		CA, DE, LT				Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Death; Heart Disease Congenital; Maternal Drugs Affecting Foetus; Maternal Exposure During Pregnancy	Zythromax	Y		S	Oral	Quantity:1 Tablet(S);		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2018	15753969	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2018M1095064		35 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Ineffective; Pulmonary Tuberculosis; Pyrexia	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2018	15756670	DIRECT					57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Pruritus; Pruritus; Skin Burning Sensation; Urticaria	Zithromax Z-Pack			S	Oral	Quantity:1 Tablet(S);	5 DAY	Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2018	15755720	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2018-08952		63 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia; Conjunctival Oedema; Eyelid Oedema; Hypersensitivity; Lacrimation Increased; Papillary Muscle Infarction; Rhinitis	Azithromycin			S	Topical	Unk (1.5% Ophthalmic Solution)		Lupin	
	Dexamethasone			C	Topical	Unk		Not Reported	
	Artificial Tear			C	Ophthalmic			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15756839	EXPEDITED (15-DAY)		OT	TR-LUPIN PHARMACEUTICALS INC.-2018-08970		67 YR	Male	TUR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Conjunctival Hyperaemia; Conjunctival Oedema; Eyelid Oedema; Hypersensitivity; Lacrimation Increased; Papillary Muscle Disorder; Rhinitis	Azithromycin			S	Topical	Unk (1.5% Ophthalmic Solution)		Lupin	
	Dexamethasone			C	Topical	Unk		Not Reported	
	Artificial Tear			C	Ophthalmic	Unk		Not Reported	
	Cyclosporin			C	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15757036	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018- 0381110		19 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bacterial Infection; Pulmonary Haemorrhage	Aztreonam Lysine			S	Respiratory (inhalation)	75 Mg		Gilead	
	Pulmozyme			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Dec-2018	15760180	DIRECT	Y					Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Dispensing Error	Azithromycin			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Dec-2018	15757698	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-061169		31 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pruritus; Rash Erythematous	Pantoprazole	S	Oral	20 Milligram, Once A Day	Aurobindo
	Azithromycin	S	Oral	250 Milligram, Once A Day	Aurobindo
	Cefotaxime Sodium	S	Intravenous (not otherwise specified)	6 Gram, Once A Day	Not Reported
	Bactrim F	S	Oral	1 Dosage Form, Once A Day	Not Reported
	Bactrim	S	Intravenous (not otherwise specified)	12 Dosage Form, Once A Day	Not Reported
	Stromectol	S	Oral	4 Dosage Form	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	15757915	EXPEDITED (15-DAY)		OT	ES-APOTEX-2018AP027701		58 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin			S	Oral	500 Mg, Qd(Once A Day)		Apotex	
	Ventolin /00139501/			C	Respiratory (inhalation)	Unk, Prn		Not Reported	
	Zaditen			C	Ophthalmic	As Necessary		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	15758722	EXPEDITED (15-DAY)		HO	PHHY2018FR193710		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Eosinophilia; Hepatocellular Injury	Lamprene			S	Oral	Unk		Novartis	
	Amikacine			S	Intravenous (not otherwise specified)	1 G, Qd (Every 2 Days)		Not Reported	
	Ansapipine			S	Oral	300 Mg, Qd		Not Reported	
	Zithromax			S	Oral	250 Mg, Qd		Not Reported	
	Tygacil			S	Intravenous (not otherwise specified)	50 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2018	15758803	EXPEDITED (15-DAY)		DE	PHHY2018IT193887		90 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Qd		Novartis	
	Azithromycin Dihydrate			S	Oral	500 Mg, Qd		Not Reported	
	Lercanidipine			C	Oral	5 Mg, Unk		Not Reported	
	Valsartan			C	Oral	80 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	13873750	EXPEDITED (15-DAY)		OT	US-AMGEN-USASP2017121302		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Blood Glucose Increased; Body Height Decreased; Diabetes Mellitus; Gastrointestinal Disorder; Hip Arthroplasty; Intervertebral Disc Protrusion; Lip Squamous Cell Carcinoma; Psoriasis; Skin Cancer	Enbrel			S	Unknown	Unk		Amgen	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Otezla			S	Unknown	Unk		Not Reported	
	Aza (Azithromycin Dihydrate)			S	Unknown	Unk		Not Reported	
	Xeljanz Xr			C	Oral	11 Mg, 4qd		Not Reported	
	Xeljanz Xr			C				Not Reported	
	Arava			C		Unk		Not Reported	
	Sulfasalazine			C	Unknown	Unk		Not Reported	
	Methotrexate			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	14295523	NON-EXPEDITED			US-PFIZER INC-2017538533			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Palpitations	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15156899	EXPEDITED (15-DAY)		DE	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-178637		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Drug Interaction; Drug Interaction; Drug Level Above Therapeutic; Hepatic Failure; Hepatocellular Injury; Hepatotoxicity; Off Label Use	Azithromycin			S	Unknown	500 Mg, Daily On Day 2		Sun	
	Azithromycin			S	Unknown	250 Mg, Daily From Day 3 To Day 9		Sun	
	Ponatinib			S	Unknown	45 Mg, Daily, From Day 1 To Day 9		Not Reported	
	Voriconazole			S		400 Mg, Daily, Night, On Day 3		Not Reported	
	Voriconazole			S		400 Mg, Daily, Morning- Night, From Day 4 To Day 7		Not Reported	
	Voriconazole			S	Unknown	400 Mg Morning 200 Mg Night, On Day 8		Not Reported	
	Voriconazole			S	Unknown	200 Mg, Daily, Morning, On Day 9		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15260232	NON-EXPEDITED			US-PFIZER INC- 2018321691			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15756677	NON-EXPEDITED			PHEH2018US054361			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin	S	Unknown	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760343	EXPEDITED (15-DAY)		DS, OT	CA-BAYER-2018-236755		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Cipro			S	Oral	500 Mg, Qd (1 Every 1 Day(S)		Bayer
	Cipro			S		Unk		Bayer
	Azithromycin			S	Unknown	Unk		Not Reported
	Quetiapine Fumarate			S	Oral	25 Mg, Bid (2 Every 1 Day)		Not Reported
	Quetiapine Fumarate			S	Oral	100 Mg, Qd (1 Every 1 Day)		Not Reported
	Risperidone			C	Unknown	Unk		Not Reported
	Valproate Semisodium			C	Unknown	Unk		Not Reported
	Zyprexa			C	Unknown	Unk		Not Reported
Amoxicillin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760866	NON-EXPEDITED			US-PFIZER INC-2018530681		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Augmentin [Amoxicillin;Clavulanic Acid]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15760971	NON-EXPEDITED			US-PFIZER INC-2018520378		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Celebrex	S	Unk	Pfizer
	Demerol	S	Unk	Pfizer
	Ibuprofen	S	Unk	Pfizer
	Tetracycline Hcl	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Aleve	S	Unk	Not Reported
	Aspirin	S	Unk	Not Reported
	Caffeine	S	Unk	Not Reported
	Claritin	S	Unk	Not Reported
	Rofecoxib	S	Unk	Not Reported
	Saccharin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15761006	NON-EXPEDITED			US-PFIZER INC-2018522439		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Dyspnoea; Fatigue	Azithromycin			S	Oral	500 Mg, Single		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2018	15761987	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2018M1094601		60 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Respiratory Failure	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Oseltamivir			S	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	10398750	NON-EXPEDITED			US-PFIZER INC-2014231486			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Percocet			S		Unk		Not Reported
	Vancocin Hydrochloride			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Zantac			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15763298	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-028057		85 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug Level Above Therapeutic; Labelled Drug-Drug Interaction Medication Error	Warfarin Sodium			S	Unknown	Unk		Bristol Myers Squibb
	Azithromycin			S	Unknown	Unk		Not Reported
	Cefuroxime			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15764519	EXPEDITED (15-DAY)		DE, HO, LT	NP-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-194702		56 YR	Male	NPL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacteraemia; Chest Discomfort; Condition Aggravated; Cough; Haemoptysis; Pulmonary Alveolar Haemorrhage; Strongyloidiasis	Prednisolone			S	Unknown	Unk		Taro
	Prednisolone			S				Taro
	Prednisone			S	Oral	60 Mg (GI^1)		Mutual
	Prednisone			S	Oral	5 Unk		Mutual
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Not Reported
	Ceftriaxone			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	500 Milligram, Qd	Sun
Azithromycin	S			Sun
Salbutamol	S		Unk	Sun
Salbutamol	S			Sun
Ipratropium	S	Unknown	Unk	Sun
Ipratropium	S			Sun
Methylprednisone	S	Unknown	40 Milligram, Tid	Not Reported
Methylprednisone	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15764783	EXPEDITED (15-DAY)		HO, LT, OT	NL-APOTEX-2018AP028220		82 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angina Pectoris; Cardiac Failure; Condition Aggravated	Azithromycin			S	Unknown	500 Mg, Qd (1x Per Dag 1 Tablet)		Apotex
	Salbutamol			S	Unknown	100 Mg, Tid (3x Per Dag 1 Inhalatie)		Not Reported
	Irbesartan			C	Unknown	150 Mg, Qd (1dd1)		Not Reported
	Codeinefosfaat			C	Unknown	10 Mg, Tid (3dd1)		Not Reported
	Isosorbidedinitraat			C	Unknown	10 Mg, Q.12h (2dd0,5 Tablet)		Not Reported
	Nedios			C	Unknown	250 Mg, Qd (1dd1)		Not Reported
	Dermovate			C	Unknown	1 Df, Qd (1dd)		Not Reported
	Pravastatine /00880401/			C	Unknown	40 Mg, Qd (1dd1)		Not Reported
	Bumetanide			C	Unknown	1 Mg, Qd (1dd1)		Not Reported
	Acenocoumarol			C	Unknown			Not Reported
	Calci Chew D3			C	Unknown	1 Df, Qd (1dd1)		Not Reported
	Nebivolol			C	Unknown	1 Mg, Qd (1dd0,5 Tablet)		Not Reported
	Carbamazepine			C	Unknown	100 Mg, Qd (1dd1)		Not Reported
	Prednisolon /00016201/			C	Unknown	2 Mg, Qd (1dd0,5 Tablet)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15766567	NON-EXPEDITED			US-PFIZER INC-2018532142			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Allergies	Azithromycin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15767968	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2018M1096186		68 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Disorientation; Hypotension; Pneumonia Necrotising;	Azithromycin			S	Unknown	Unk		Not Reported	
Pneumothorax; Rales; Staphylococcal Sepsis; Tachypnoea	Linezolid			S	Unknown	Unk		Not Reported	
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported	
	Clindamycin			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2018	15770174	DIRECT		OT			73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Diarrhoea Haemorrhagic; Muscle Spasms; Tremor; Tremor	Azithromycin Tablets Usp 250 Mg Ndc 50111-787-5 1			S	Oral	Quantity:2 Tablet(S);Other Frequency:2 Then 1 Per Day;		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	14360713	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1001422		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eosinophilia; Eosinophilic Pleural Effusion	Amoxicillin/Clavulanic Acid	S	Oral	1 Dosage Form, Tid (1.1.1)	Not Reported
	Azithromycin	S	Oral	500 Milligram, Qd (1 Cp)	Not Reported
	Levofloxacin	S	Oral	500 Milligram, Qd (500 Mg, Qd)	Not Reported
	Alopurinol	S	Oral	300 Milligram, Qd (1 Cp)	Mylan
	Hidroferol	C	Oral	Unk (1 Amp, 266)	Mylan
	Valsartan/Hct 1a Pharma	C	Oral	1-0-0 32/12.5	Mylan
	Valsartan/Hct 1a Pharma	C	Oral	Unk Unk, Qd (1-0-0)	Mylan
	Tamsulosina	C	Oral	Unk (1 Cp)	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15413334	NON-EXPEDITED			US-PFIZER INC- 2018382128		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15725571	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB- 988545			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Unilateral	Azithromycin			S	Unknown	For About 6/8 Months, On Monday, Wednesday And Fridays		Not Reported
	Carbocisteine			C	Unknown			Not Reported
	Nasonex Nasal Spray			C	Unknown	2/3 Times A Day		Not Reported
	Optics Eye Drops			C	Unknown	2/3 Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15770105	NON-EXPEDITED			US-PFIZER INC- 2018531360			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15770631	EXPEDITED (15-DAY)		OT	US-MYLANLABS- 2018M1096004		3 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterial Infection	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2018	15770774	EXPEDITED (15-DAY)		HO, OT	PHEH2018US054385		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Bone Marrow Failure; Drug Resistance; Treatment Failure	Azithromycin			S	Intravenous (not otherwise specified)	250 Mg, Qd		Novartis	
	Linezolid			S	Oral	600 Mg, Q24h		Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	50 Mg, Q12h		Not Reported	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Amikacin			S	Oral	700 Mg, Q24h		Not Reported	
	Amikacin			S	Respiratory (inhalation)	400 Mg, Bid		Not Reported	
	Bedaquiline			S	Intravenous (not otherwise specified)	400 Mg, Qd		Not Reported	
	Bedaquiline			S	Intravenous (not otherwise specified)	200 Mg, Qw3		Not Reported	
	Imipenem			S	Intravenous (not otherwise specified)	500 Mg, Q8h		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Ciprofloxacin		S	Unknown	Unk			Not Reported
		Sulfamethoxazole And Trimethoprim		S	Unknown	Unk			Not Reported
		Cefoxitin		S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15577597	EXPEDITED (15-DAY)		OT	MY-AUROBINDO-AUR-APL-2018-052700		39 YR	Male	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Disorganised Speech; Hallucination, Auditory; Irritability	Amoxicillin+Clavulanic Acid			S	Intravenous (not otherwise specified)	Unk			Aurobindo
	Azithromycin			S	Oral	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15759997	EXPEDITED (15-DAY)		DE, OT	IT-AUROBINDO-AUR-APL-2018-062372		90 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Azithromycin			S	Oral	500 Milligram, Daily			Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Daily			Aurobindo
	Lercanidipine			C	Oral	5 Milligram			Not Reported
	Valsartan			C	Oral	80 Milligram			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Dec-2018	15774546	EXPEDITED (15-DAY)		OT	GB-TEVA-2018-GB-992465		63 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Face	Azithromycin			S					Not Reported
	Femoston			C		As Directed By Doctor			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	9848221	NON-EXPEDITED			US-PFIZER INC-2014019668			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Buspirone			S		Unk		Not Reported	
	Chlorzoxazone			S		Unk		Not Reported	
	Tequin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Simvastatin			S		Unk		Not Reported	
	Tizanidine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	12597886	NON-EXPEDITED			US-PFIZER INC-2016359531		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	E-Mycin			S		Unk		Not Reported	
	Hycodan			S		Unk		Not Reported	
	Roxicet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	14795230	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2018159679		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxone Mylan

S

Intravenous (not
otherwise specified)

2 G, 1x/Day

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15171452	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2018290890		39 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash; Swelling Face	Azithromycin			S	Oral	Unk		Pfizer	
	Amoxicillin Trihydrate/Clavulanic Acid			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15672793	NON-EXPEDITED			US-PFIZER INC- 2018483242		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S	Ophthalmic	Unk		Pfizer	
	Amitriptyline			S		Unk		Not Reported	
	Divalproex Sodium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15775839	EXPEDITED (15-DAY)		OT	US-CELGENEUS-USA- 20181206871		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Blood Glucose Increased; Body Height Decreased; Diabetes Mellitus; Gastrointestinal Disorder; Hip Arthroplasty; Intervertebral Disc Protrusion; Lip Squamous Cell Carcinoma; Psoriasis; Skin Cancer	Otezla			S	Oral			Celgene	
	Humira			S	Subcutaneous			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
	Sulfasalazine			S	Unknown			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Tofacitinib Citrate			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tofacitinib Citrate			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15776299	NON-EXPEDITED		OT	US-TEVA-2018-US-991841			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Feeling Abnormal; Heart Rate Irregular; Palpitations; Product Dose Omission	Azithromycin			S	Unknown				Not Reported
	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15776352	NON-EXPEDITED			PHEH2018US055310			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Unknown				Novartis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15776660	NON-EXPEDITED			US-PFIZER INC-2018534233		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Quinapril Hcl			S		Unk			Pfizer
	Verapamil Hcl			S		Unk			Pfizer
	Zoloft			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15777035	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018530044		40 YR	Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Interaction; Epilepsy	Zithromac			S	Oral	500 Mg, 1x/Day			Pfizer
	Scopolia Extract			S	Oral	Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mucosolvan			S	Oral	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2018	15778448	NON-EXPEDITED			US-PFIZER INC-2018535960		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Erythema; Peripheral Swelling	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2019	12537973	NON-EXPEDITED			US-PFIZER INC-2016318401		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	
	Medent			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2019	15779753	NON-EXPEDITED			PHEH2018US055069			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Gastrointestinal Disorder; Heart Rate Abnormal; Liver Disorder; Malaise; Pyrexia	Azithromycin			S	Oral	250 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	14794311	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2018158430		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pleural Effusion	Azithromycin			S	Unknown	Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Amoxicillin Clavulanic Acid			S	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	14976381	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2018M1037309		82 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Hyponatraemia	Azithromycin			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15346500	NON-EXPEDITED			US-PFIZER INC-2018353140			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15605110	EXPEDITED (15-DAY)		OT	PT-PFIZER INC-2018437661		43 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Heavy Metal Abnormal; Metal Poisoning	Zithromax			S	Oral	250 Mg, 1x/Day			Pfizer
	Fasigyn			S	Oral	500 Mg, (2 To 3 X/Week)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15780544	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2018-061805		79 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Lower Respiratory Tract Infection	Azithromycin			S	Unknown	Unk			Aurobindo
	Abatacept			S	Subcutaneous	125 Milligram, Every Week			Not Reported
	Amlodipine			C	Unknown	Unk			Not Reported
	Atorvastatin			C	Unknown	Unk			Not Reported
	Carbocisteine			C	Unknown	Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Dexamethasone	C	Oral	500 Milligram		Not Reported			
	Digoxin	C	Unknown	Unk		Not Reported			
	Furosemide	C	Unknown	Unk		Not Reported			
	Rivaroxaban	C	Unknown	Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15781682	NON-EXPEDITED			US-PFIZER INC-2018533497			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Infection	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15782026	NON-EXPEDITED			US-PFIZER INC-2018536694		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15782496	EXPEDITED (15-DAY)		HO	PT-PFIZER INC-2018534910		14 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Rash; Vomiting	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2019	15783767	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018-0382660		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nasopharyngitis; Pulmonary Function Test Decreased	Aztreonam Lysine			S	Respiratory (inhalation)	75 Mg, Tid, 28 Days Then Off For 28 Days		Gilead	
	Creon			S	Unknown	24000 Df		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Kitabis Pak	S	Unknown	1 Df		Not Reported
	Pulmozyme	S	Respiratory (inhalation)	1 Mg		Not Reported
	Omeprazole Sodium	S	Unknown	20 Mg		Not Reported
	Azithromycin Monohydrate Hemihethanolate	S	Unknown	500 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15770123	NON-EXPEDITED			US-PFIZER INC-2018531032			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Cipro [Ciprofloxacin Hydrochloride]			S		Unk		Not Reported
	Keflex [Cefalexin]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15776888	NON-EXPEDITED			US-PFIZER INC-2018531799			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15785036	EXPEDITED (15-DAY)		DE, HO	KE-CIPLA LTD.-2016KE08316			Unknown	KEN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anaemia; Death; Lymphopenia; Pulmonary Tuberculosis	Efavirenz			S	Unknown	Unk		Cipla
	Sulfamethoxazole/Trimethoprim			S	Unknown	Unk		Not Reported
	Fluconazole			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rifampicin	S	Unknown	Unk	Not Reported
Isoniazid	S	Unknown	Unk	Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Ethambutol	S	Unknown	Unk	Not Reported
Acyclovir /00587301/	S	Unknown	Unk	Not Reported
Raltegravir	S	Unknown	Unk	Not Reported
Tenofovir	S	Unknown	Unk	Not Reported
Pyridoxine	C	Unknown	Unk	Not Reported
Vitamin A /00056001/	C	Unknown	Unk	Not Reported
Amoxyl	C	Unknown	Unk	Not Reported
Paracetamol	C	Unknown	Unk	Not Reported
Emtricitabine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15785057	NON-EXPEDITED			US-PFIZER INC-2017490162			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15785153	NON-EXPEDITED			US-PFIZER INC-2019002217		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15786519	NON-EXPEDITED			US-PFIZER INC-2019001464		87 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin		S	Unk	Pfizer
	Doxycycline Hyclate		S	Unk	Pfizer
	Erythromycin		S	Unk	Pfizer
	Guaifenesin	Y	S	Unk	Unknown
	Labetalol Hydrochloride		S	Unk	Unknown
	Entex		S	Unk	Not Reported
	[Guaifenesin;Phenylephrine Hydrochloride]				
	Corticaine [Hydrocortisone Acetate]		S	Unk	Not Reported
	Imdur		S	Unk	Not Reported
	Isosorbide		S	Unk	Not Reported
	Macrobid [Nitrofurantoin]		S	Unk	Not Reported
	Pseudoephedrine Hcl		S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15787466	EXPEDITED (15-DAY)		LT, OT	CN-PFIZER INC-2019000819		1 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest; Respiratory Arrest	Azithromycin			S	Intravenous drip	0.085 G, 1x/Day		Pfizer
	Dexamethasone Sodium Phosphate			C	Intravenous drip	5 Mg, 1x/Day		Not Reported
	Omeprazole Sodium			C	Intravenous drip	10 Mg, 1x/Day		Not Reported
	Jin Shuang Qi			C	Oral	1 G, 3x/Day		Not Reported
	Etamsylate			C	Intravenous drip	0.125 G, 2x/Day		Not Reported
	Vitamin K1			C	Intramuscular	5 Mg, 1x/Day		Not Reported
	Alanyl Glutamine			C	Intravenous drip	10 MI, 1x/Day		Not Reported
	Fat Soluble Vitamin For Injection li			C		1 Df, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15787611	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018-0369402		66 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hiatus Hernia; Liver Abscess; Procedural Complication	Aztreonam Lysine			S	Unknown	75 Mg, Tid Via Neb 28 Days On/Off		Gilead	
	Advair			S	Unknown			Not Reported	
	Albuterol [Salbutamol]			S	Unknown			Not Reported	
	Atorvastatin Calcium			S	Unknown			Not Reported	
	Azithromycin 0.5-Ethanol Monohydrate			S	Unknown			Not Reported	
	Bactrim Balsamico			S	Unknown			Not Reported	
	Losartan			S	Unknown			Not Reported	
	Pantoprazole Sodium			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15793136	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Packaging Confusion; Wrong Product Stored	Azithromycin			S	Intravenous (not otherwise specified)			Auromedics	
	Etomidate			S	Intravenous (not otherwise specified)			Auromedics	
	Pantoprazole Sodium			S	Intravenous (not otherwise specified)			Auromedics	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15798322	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intercepted Product Dispensing Error; Product Dispensing Error; Wrong Product Administered	Erythromycin Ethylsuccinate			S				Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2019	15798334	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Label Confusion; Product Packaging Confusion	Bupivacaine Hcl			S				Not Reported	
	Azithromycin			S				Not Reported	
	Pantoprazole Sodium			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15450282	NON-EXPEDITED			US-PFIZER INC- 2018389703		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Mouth Ulceration; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15634879	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2018- 0375067		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystic Fibrosis; Intentional Dose Omission; Pneumonia; Respiratory Tract Infection	Aztreonam Lysine			S	Respiratory (inhalation)	75 Mg, Tid, 28 Days On And 28 Days Off		Gilead	
	Advair			S	Unknown	Unk		Not Reported	
	Albuterol [Salbutamol]			S	Unknown	Unk		Not Reported	
	Atorvastatin Calcium			S	Unknown	Unk		Not Reported	
	Azithromycin [Azithromycin 0.5- Ethanol Monohydrate]			S	Unknown	Unk		Not Reported	
	Bactrim Balsamico			S	Unknown			Not Reported	
	Losartan			S	Unknown	Unk		Not Reported	
	Pantoprazole Sodium			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15789030	NON-EXPEDITED			US-PFIZER INC-2019002555			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15789167	NON-EXPEDITED			US-PFIZER INC-2019004874		9 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Rapamune			S	Oral	1.5 Mg, Daily		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15789234	NON-EXPEDITED			US-PFIZER INC-2018536133		80 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15789975	NON-EXPEDITED			US-PFIZER INC-2018493072			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Ampicillin Sodium			S		Unk		Unknown	
	Losartan			S		Unk		Not Reported	
	Pravastatin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15790079	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-001414		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Pruritus	Acetylsalicylic Acid(<=100 Mg)			S		Unk		Bayer	
	Amlodipine			C		Unk		Not Reported	
	Azithromycin			S	Oral	500 Df, Once		Not Reported	
	Bisoprolol			C				Not Reported	
	Cefazolin			S				Not Reported	
	Docusate			C				Not Reported	
	Eprex			C				Not Reported	
	Ergocalciferol			C				Not Reported	
	Fluticasone			C				Not Reported	
	Megestrol			C				Not Reported	
	Nepafenac			C				Not Reported	
	One Alpha			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Salbutamol			C				Not Reported	
	Sevelamer			C				Not Reported	
	Sodium Polystyrene Sulfonate			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jan-2019	15790658	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019000890		3 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Vomiting Projectile	Zithromax			S	Oral	0.2 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	10830430	NON-EXPEDITED			US-PFIZER INC-2015062777		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergic Reaction To Excipient	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15792318	NON-EXPEDITED			PHEH2018US055720			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15792935	EXPEDITED (15-DAY)		HO, OT	JP-LUPIN PHARMACEUTICALS INC.-2018-09203		94 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple-Drug Resistance	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Lupin	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown	Unk		Not Reported	
	Penicillin /00000901/			S	Unknown	Unk		Not Reported	
	Ampicillin			S	Unknown	Unk		Not Reported	
	Clindamycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15793628	EXPEDITED (15-DAY)		OT	CN- ELI_LILLY_AND_COMP ANY-CN201901000354		65 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Liver Function Test Abnormal; Nausea; Pneumonia	Zyprexa			S	Oral	2.5 Mg, Bid		Eli Lilly And Co	
	Cefin [Ceftriaxone Sodium]			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Sulperazone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Qi Xian			S	Intravenous (not otherwise specified)	0.5 G, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Risperidone	S	Oral	0.75 MI, Bid	Not Reported
Sulpiride	S	Oral	100 Mg, Daily	Not Reported
Olanzapine	C	Oral	5 Mg, Daily	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	250 MI, Daily	Not Reported
Sodium Chloride	C	Intravenous (not otherwise specified)	100 MI, Daily	Not Reported
Haloperidol	C	Intramuscular	2.5 MI, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15793695	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019004401		83 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Eosinophilia; Hepatocellular Injury	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Tygacil			S	Intravenous (not otherwise specified)	50 Mg, 1x/Day		Pfizer	
	Amikacin			S	Intravenous (not otherwise specified)	1 G, Alternate Day		Not Reported	
	Ansapine			S	Oral	300 Mg, 1x/Day		Not Reported	
	Lamprene [Clofazimine]			S	Oral	Unspecified		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794062	NON-EXPEDITED			PHEH2019US000805			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Unknown			Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794220	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019000897		66 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cough; Dyspnoea; Flushing; Hypersensitivity; Pruritus	Zithromax Zithromax		S S	Intravenous drip	500 Mg, 1x/Day		Pfizer Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15794304	EXPEDITED (15-DAY)		DE	IT-PFIZER INC- 2019006099		90 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Toxic Epidermal Necrolysis	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Daily		Not Reported	
	Lercanidipine			C	Oral			Not Reported	
	Valsartan			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2019	15795488	EXPEDITED (15-DAY)		OT	PHHY2019PT001445		19 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Angioedema; Respiratory Distress	Azithromycin			S	Oral			Novartis	
	Lepicortinolo			S	Oral			Not Reported	
	Maxilase			S	Oral			Not Reported	
	Lergonix			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15235410	NON-EXPEDITED			US-PFIZER INC- 2018313328		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Daypro			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Gentamycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zomig			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15712429	EXPEDITED (15-DAY)		HO	FR-TEVA-2018-FR-984898		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Rash Maculo-Papular	Azithromycin			S	Oral				Not Reported
	Betahistine Mesilate			S	Oral				Not Reported
	Betahistine Mesilate			S					Not Reported
	Solupred [Prednisolone Metasulfobenzoate Sodium]			S	Oral				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15797397	NON-EXPEDITED			US-PFIZER INC-2019008139		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Amoxicillin			S		Unk			Pfizer
	Codeine			S		Unk			Not Reported
	Propoxyphene			S		Unk			Not Reported
	Hydrocodone			S		Unk			Not Reported
	Tylenol [Paracetamol]			S		Unk			Not Reported
	K [Potassium]			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15798281	NON-EXPEDITED			US-PFIZER INC-2019010246			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
	Erythromycin			S		Unk			Pfizer
	Relafen			S		Unk			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2019	15803196	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission; Product Prescribing Error	Azithromycin Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	13994484	NON-EXPEDITED		OT	US-AMGEN- USASL2017140496		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Enbrel			S	Unknown	50 Mg, Qwk		Amgen	
Bronchitis; Gastrointestinal Disorder; Malaise;	Azithromycin			S	Unknown	Unk		Not Reported	
Musculoskeletal Discomfort;	Methotrexate			C	Unknown	Unk		Not Reported	
Nasopharyngitis; Neck Pain; Pain In Extremity; Rheumatoid Arthritis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15153460	EXPEDITED (15-DAY)		DE, OT	FR-MYLANLABS- 2018M1016171			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Level Increased; Hepatic Failure; Hepatitis; Off Label Use	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Bid		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported	
	Bisoc 5 Mg, Comprimé Pelliculé Sécable			S	Oral	5 Mg, Qd		Mylan	
	Iclusig			S	Oral	45 Mg, Qd		Mylan	
	Zyloric			S	Oral	100 Mg, Qd		Mylan	
	Zyloric			S	Oral	100 Mg, Qd		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zyloric	S	Oral	100 Mg, Bid	Mylan
Zyloric	S	Oral	200 Milligram, Qd	Mylan
Trimebutine Arrow	S	Oral	100 Mg, Bid	Mylan
Vfend	S	Intravenous (not otherwise specified)	400 Mg, Bid	Mylan
Vfend	S		200 Mg, Bid	Mylan
Hydrocortisone	S	Intravenous (not otherwise specified)	100 Mg, Qd	Mylan
Lasilix /00032601/	S	Oral	40 Mg, Qd	Mylan
Lasilix /00032601/	S	Oral	20 Mg, Qd	Mylan
Polaramine	S	Intravenous (not otherwise specified)	5 Mg, Qd	Mylan
Zithromax	S		500 Mg, Total	Mylan
Zithromax	S	Oral	250 Mg, Qd	Mylan
Hydrea	S	Oral	500 Mg, Bid	Mylan
Spasfon /00765801/	C		80 Mg, Prn	Mylan
Ataraxone /00058401/	C		12.5 Mg, Qd	Mylan
Renagel /01459901/	C		800 Mg, Bid	Mylan
Topalgic /00599202/	C		50 Mg, Prn	Mylan
Movicol	C		2 Df, Qd	Mylan
Cortancyl	C		40 Mg, Qd	Mylan
Fasturtec	C	Intravenous (not otherwise specified)	7.5 Mg, Total	Mylan
Stilnox	C		10 Mg, Prn	Mylan
Polyethylene Glycol 3350	C		Unk	Mylan
Sodium Hydrogen Carbonate	C		Unk	Mylan
Potassium Chloride	C		Unk	Mylan
Phloroglucinol	C		80 Milligram, Prn	Mylan
W/Trimethylphloroglucinol				

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15750714	NON-EXPEDITED		LT	US-PFIZER INC-2018520067			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Azithromycin			S		250 Mg, Took 2 On Day1 And Took Another One For A Total Of 3 Tablets		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15802645	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19S-163-2613716-00		17 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nasopharyngitis; Pulmonary Function Test Decreased	Creon			S	Oral			Not Reported	
	Aztreonam Lysine			S	Respiratory (inhalation)			Not Reported	
	Kitabis Pak			S	Unknown			Not Reported	
	Dornase Alfa			S	Unknown			Not Reported	
	Omeprazole Sodium			S	Unknown			Not Reported	
	Azithromycin Monohydrate Hemiethanolate			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15803194	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019010480		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extravasation; Injection Site Erythema; Injection Site Pain; Injection Site Swelling; Product Use Issue	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 4x/Day		Pfizer	
	Solumedrol			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15803205	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019010799		23 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Sinus Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Acetaminophen			C		Unk		Not Reported	
	Ciprofloxacin			C		Unk		Not Reported	
	Cyanocobalamin			C		Unk		Not Reported	
	Dimenhydrinate			C		Unk		Not Reported	
	Echinacea			C		Unk		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Ibuprofen			C		Unk		Not Reported	
	Nat Osetamivir			C		Unk		Not Reported	
	Piperacillin/Tazobactam			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2019	15804646	NON-EXPEDITED			US-PFIZER INC-2019005151		69 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		Unk		Pfizer	
	Methylprednisolone			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15764755	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2018AP028051		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azithromycin			S	Oral	500 Mg, Qd, (Azitro/24h 6d)		Apotex	
	Capoten			C	Oral	25 Mg, Q.12h, (25mg/12h)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Adiro	C	Oral	300 Mg, Qd, (0-1-0. En Historia Clínica Electrónica De Atención Primaria Consta Adiro 300mg 1/24h)	Not Reported
Omeprazol /00661201/	C	Unknown	Unk	Not Reported
Ibuprofeno	C	Oral	Unk, (Historia Actual De Informe De Alta De Medicina Interna: "Ha Estado Tomando 1-2cp Diarios En La	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15805207	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-994595		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Mycophenolate Mofetil			S	Unknown			Teva	
	Prednisone			S	Unknown			Actavis	
	Azithromycin			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15805227	EXPEDITED (15-DAY)		OT	PT-TEVA-2019-PT-996904		19 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Angioedema; Respiratory Distress	Azithromycin			S	Oral			Teva	
	Lepicortinolo			S	Oral			Not Reported	
	Maxilase			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15805450	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-000170		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperkalaemia; Hypoacusis; Metabolic Acidosis; Renal Injury	Azithromycin	S	Oral	500 Milligram, Daily	Aurobindo
	Azithromycin	S			Aurobindo
	Amikacin	S	Intravenous (not otherwise specified)	600 Milligram (Every 48–72 H Dosed After Dialysis)	Not Reported
	Amikacin	S			Not Reported
	Tigecycline	C	Intravenous (not otherwise specified)	50 Milligram, Daily	Not Reported
	Tigecycline	C			Not Reported
	Acetylcysteine	C	Unknown	Unk	Not Reported
	Acetylcysteine	C			Not Reported
	Linezolid	C	Oral	600 Milligram, Unk	Not Reported
	Linezolid	C			Not Reported
	Clofazimine	C	Oral	50 Milligram, Daily	Not Reported
	Clofazimine	C			Not Reported
	Tedizolid	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15806229	NON-EXPEDITED			US-PFIZER INC- 2019012846			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Keflex			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15806396	NON-EXPEDITED			US-PFIZER INC- 2019012257		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amlodipine Besilate			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Celecoxib			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Minocycline	S	Unk	Pfizer
Hydrochlorothiazide	S	Unk	Not Reported
Lisinopril	S	Unk	Not Reported
Losartan Potassium	S	Unk	Not Reported
Albuterol Hfa	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2019	15807770	EXPEDITED (15-DAY)		DS, OT	FR-MYLANLABS-2019M1001970		61 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoaesthesia;	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
Neuropathy Peripheral;	Zyvoxid			S	Oral	600 Milligram, Qd		Mylan
Paraesthesia								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15629669	NON-EXPEDITED			US-UNITED THERAPEUTICS-UNT-2018-018616		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Orenitram			S	Oral	0.125 Mg, Tid		Not Reported
Diarrhoea; Fluid	Orenitram			S	Oral	0.25 Mg, Tid		Not Reported
Retention; Flushing;	Orenitram			S	Oral	1 Mg, Tid		Not Reported
Headache; Nausea;	Orenitram			S	Oral	2.5 Mg, Tid		Not Reported
Oedema; Upper	Orenitram			S	Oral	0.125 Mg, Tid		Not Reported
Respiratory Tract Infection	Orenitram			S	Oral	0.25 Mg, Tid		Not Reported
	Orenitram			S	Oral	1 Mg, Tid		Not Reported
	Orenitram			S	Oral	2.5 Mg, Tid		Not Reported
	Orenitram			S	Oral	0.125 Mg, Tid		Not Reported
	Orenitram			S	Oral	0.25 Mg, Tid		Not Reported
	Orenitram			S	Oral	1 Mg, Tid		Not Reported
	Orenitram			S	Oral	2.5 Mg, Tid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orenitram	S	Oral	0.125 Mg, Tid	Not Reported
Orenitram	S	Oral	0.25 Mg, Tid	Not Reported
Letairis	S	Unknown	5 Mg, Qd	Not Reported
Letairis	S	Unknown	10 Mg, Qd	Not Reported
Z-Pak	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15811184	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-997143		40 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hyperaemia; Periorbital Swelling	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
	Gentalyn			S	Topical			Not Reported	
	Brufen 600 Mg Granulato Effervescente			S	Oral	600 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15811413	EXPEDITED (15-DAY)		HO	IT-ASTRAZENECA-2019SE03132		83 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Dyskinesia; Pyrexia	Crestor			S	Oral			Astrazeneca	
	Azitromicina Doc			S	Oral			Not Reported	
	Cardirene			C		160 Mg		Not Reported	
	Mirapexin			C				Not Reported	
	Giant			C		40 Mg/5 Mg		Not Reported	
	Dibase			C		25.000 U.I./2,5 MI		Not Reported	
	Atenolol			C				Not Reported	
	Seebri			C				Not Reported	
	Talofen			C		4 G/100 MI		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15811675	NON-EXPEDITED			US-PFIZER INC-2019015731		63 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Metformin			S		Unk		Not Reported	
	Zyrtec			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15811697	NON-EXPEDITED			US-PFIZER INC-2019011614			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eyelid Margin Crusting; Ocular Hyperaemia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15812275	EXPEDITED (15-DAY)		OT	PHHY2019AT002306			Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Adrenal Insufficiency; Adverse Food Reaction; Agonal Rhythm; Alopecia; Arthralgia; Arthralgia; Astenia; Constipation; Depression; Diarrhoea; Dry Eye; Dysgeusia; Fatigue; Flatulence; Gait Disturbance; Gastrointestinal Pain; Headache; Hormone Level Abnormal; Hypoaesthesia; Hypoaesthesia; Incontinence; Injection Site Pain; Joint Ankylosis; Joint Swelling; Menstruation Irregular;	Azithromycin			S	Unknown	1 Ot, Qd		Novartis	
	Itraconazole			S	Unknown	200 Mg, Qd		Not Reported	
	Itraconazole			S	Unknown	400 Mg, Bid		Not Reported	
	Avelox			S	Unknown	Unk		Not Reported	
	Gadoteridol			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Gadoteridol			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Diflucan			S	Unknown	Unk, Qod		Not Reported	
	Diflucan			S	Unknown	Unk		Not Reported	
	Ivermec			S	Unknown	Unk Unk, Qod		Not Reported	
	Ivermec			S	Unknown	Unk		Not Reported	
	Cortisone			S	Unknown	1 Df, Qd		Not Reported	
	Moxifloxacin Krka			S	Unknown	1 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metabolic Disorder; Mitochondrial Toxicity; Mucosal Dryness; Muscle Injury; Muscle Spasticity; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Nervous System Disorder; Neuralgia; Neuropathy Peripheral; Pain; Pain In Extremity; Panic Attack; Paraesthesia; Paraesthesia; Photopsia; Skin Irritation; Suicidal Ideation; Suicide Attempt; Swelling; Temperature Intolerance; Tendon Injury; Vein Rupture; Vertigo; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Anaerobex Pantelmin Pantoloc Pantoloc	S C C C	Unknown Unknown Unknown Unknown	Unk Unk, Bid Unk Unk, Bid Unk 40 Mg, Qd	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15812713	EXPEDITED (15-DAY)		DE, OT	PT-SA-2019SA006861		56 YR	Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Failure; Multiple Organ Dysfunction Syndrome	Ethambutol			S		Unk		Not Reported
	Rifampicin			S		Unk		Sanofi
	Azithromycin			S		Unk		Not Reported
	Piperacillin/Tazobactam			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15813258	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2019003025		11 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort; Cardiac Failure; Gastrointestinal Disorder; Heart Rate Increased; Nausea; Product Use Issue		Azithromycin	S	Intravenous drip	0.5 G, 1x/Day		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2019	15814651	NON-EXPEDITED			US-SA-2019SA008349		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune System Disorder	Dupixent			S	Subcutaneous	300 Mg, Qow		Sanofi	
	Z-Pak			S		Unk Unk, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15714959	EXPEDITED (15-DAY)		OT	PHHY2018HU175939		17 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Epstein-Barr Virus Infection; Fatigue; Hepatic Function Abnormal; Leukocytosis; Lymphadenitis; Lymphocytosis; Malaise; Product Use In Unapproved Indication; Pyrexia	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15779037	EXPEDITED (15-DAY)		HO	PHHY2018UA197913			Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Cyanosis; Drug Ineffective; Dyspnoea; General Physical Health	Ambroxol Hydrochloride			S	Intravenous (not otherwise specified)	14 Mg, Bid		Not Reported	
	Azithromycin			S	Oral	500 Mg, Qd		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deterioration; Poisoning; Product Use In Unapproved Indication; Respiratory Failure	Acetylcysteine	S	Oral	600 Mg, Qd	Not Reported
	Paracetamol	S	Unknown		Not Reported
	Cefoperazonum	S	Intravenous (not otherwise specified)	1 G, Bid	Not Reported
	Lisinopril	C	Unknown	5 Mg, Qd	Not Reported
	Lisinopril	C			Not Reported
	Carvedilol	C	Unknown	6.25 Mg, Qd	Not Reported
	Carvedilol	C			Not Reported
	Acetylsalicylic Acid	C	Unknown	100 Mg, Qd	Not Reported
	Acetylsalicylic Acid	C			Not Reported
	Tienam	C	Intravenous (not otherwise specified)	1000 Mg, Tid	Not Reported
	Enoxaparin	C	Subcutaneous	0.8 MI, Unk	Not Reported
	Avelox	C	Intravenous (not otherwise specified)	400 Mg, Unk	Not Reported
	Solu Medrol	C	Intravenous (not otherwise specified)	1000 Mg, Unk	Not Reported
	Fluimucil	C	Respiratory (inhalation)		Not Reported
	Dopamine	C	Intravenous drip	Unk	Not Reported
	Rheosorbilact	C	Intravenous (not otherwise specified)	200 MI, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2019	15815522	EXPEDITED (15-DAY)	CA		PHHY2019DK003758		365 DAY	Male	DNK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Tachycardia; Supraventricular Extrasystoles	Azithromycin Sandoz			S	Transplacental	Maternal Dose: 500 Mg, Qd		Novartis
	Ampicillin			S	Transplacental	Maternal Dose: 3000 Mg, Qd		Not Reported
	Pentrexyl			S	Transplacental	Maternal Dose: 4 G, Qd		Not Reported
	Seloken			C	Transplacental	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15821025	EXPEDITED (15-DAY)		HO, OT	US- GLAXOSMITHKLINE- US2019GSK002131		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Condition Aggravated; Cystic Fibrosis; Intentional Dose Omission; Pneumonia; Productive Cough; Respiratory Tract Infection	Fluticasone			S		Unk		Glaxosmithkline	
	Propionate+Salmeterol								
	Xinafoate								
	Albuterol			S		Unk		Glaxosmithkline	
	Atorvastatin Calcium			S		Unk		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Aztreonam Lysine			S		75 Mg, Tid		Not Reported	
	Losartan			S		Unk		Not Reported	
	Pantoprazole Sodium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15821634	NON-EXPEDITED			US-PFIZER INC- 2019014584		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Depakote			S		Unk		Not Reported	
	Fluarix			S		Unk		Not Reported	
	Sumatriptan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15821699	EXPEDITED (15-DAY)		HO	JP-PFIZER INC- 2019012889		31 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutrophil Count Decreased	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
	Ceftriaxone [Ceftriaxone Sodium]			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Carbocisteine	C	Unk	Not Reported
	Hustazol [Cloperastine Fendizoate] Sp Troches	C	Unk	Not Reported
		C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15821732	NON-EXPEDITED			US-PFIZER INC-2019014303			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Clindamycin Hcl			S		Unk		Pfizer	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15822575	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019009132		35 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Exfoliative	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day (0.5 G Of Azithromycin In 250 MI Of 5% Glucose)		Pfizer	
	Etimicin Sulfate			S	Intravenous drip	0.3 G, 1x/Day		Not Reported	
	Edaravone			C	Intravenous drip	30 Mg, 2x/Day		Not Reported	
	Alprostadil			C	Intravenous (not otherwise specified)	10 Ug, 1x/Day		Not Reported	
	Aspirin [Acetylsalicylic Acid]			C	Oral	100 Mg, 1x/Day		Not Reported	
	Glucose			C	Intravenous drip	Unk (Of 0.5 G Of Azithromycin In 250 MI Of 5% Glucose)		Not Reported	
	Sodium Chloride			C	Intravenous drip	Unk (0.3 G Etimicin Sulfate In 250 MI Of 0.9% Sodium Chloride Injection)		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2019	15823478	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2018M1097945		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Oedema Peripheral; Pruritus	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Amoxicillin/Clavulanic Acid			S	Oral	2 Dosage Form, Qd		Not Reported	
	Lyrica			C	Oral	1 Dosage Form		Mylan	
	Pantorc			C	Oral	1 Dosage Form		Mylan	
	Gentalyn Beta			C	Cutaneous	1 Dosage Form		Mylan	
	Norvasc			C	Oral	1 Dosage Form		Mylan	
	Cymbalta			C	Oral	1 Dosage Form		Mylan	
	Zyllt			C	Oral	1 Dosage Form		Mylan	
	Lasix /00032601/			C	Oral	1 Dosage Form		Mylan	
	Simvastatin			C	Oral	1 Dosage Form		Mylan	
	Lexotan			C	Oral	1 Dosage Form		Mylan	
	Norapril			C	Oral	1 Dosage Form		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15231201	EXPEDITED (15-DAY)		OT	PHHY2018GB060332		21 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Arthropathy; Blood Creatinine Increased; Blood Urea Increased; Creatinine Renal Clearance Decreased; Drug Interaction; Dyspepsia; Hypophagia; Influenza Like Illness; Off Label Use; Polyarthritis; Vomiting; Weight	Azithromycin			S	Unknown	Unknown		Novartis	
	Tobramycin			S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd		Not Reported	
	Tobramycin			S	Intravenous (not otherwise specified)	120 Mg, Tid		Not Reported	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Colomycin (Colistin)			S	Intravenous (not otherwise specified)	2 Miu, Tid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15728899	EXPEDITED (15-DAY)		OT	PHHY2018FR179978		35 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Gestational Diabetes; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Systemic Inflammatory Response Syndrome	Azithromycin			S	Unknown			Novartis
	Azithromycin			S	Unknown			Novartis
	Metronidazole			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Cefixime			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15744489	NON-EXPEDITED			US-PFIZER INC-2018523244		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Doxycycline Hyclate			S		Unk		Pfizer
	Phenoxymethylpenicillin			S		Unk		Pfizer
	Potassium Azithromax			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Sulfur			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15822032	NON-EXPEDITED		OT	US-PFIZER INC-2019011576			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Rocephin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15824476	EXPEDITED (15-DAY)		HO	CN-JNJFOC-20190108244		10 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Pruritus; Urticaria	Motrin Childrens Suspension/Fever Liquid 100ml		Y	S	Oral	Approval No. National Medicine Permission Number H19991011		Not Reported	
	Motrin Childrens Suspension/Fever Liquid 100ml			S	Oral			Not Reported	
	Azithromycin			S	Intravenous drip	Approval No. National Medicine Permission Number H19991011		Not Reported	
	Lactobacillus Acidophilus Compound			S	Oral			Not Reported	
	Glucose			C	Intravenous drip			Not Reported	
	Glucose			C	Intravenous drip			Not Reported	
	Glucose			C	Intravenous drip			Not Reported	
	Cefaclor			C	Oral			Not Reported	
	Methylprednisolone			C	Intravenous drip			Not Reported	
	Methylprednisolone			C	Intravenous drip			Not Reported	
	Ofloxacin			C	Intraocular			Not Reported	
	Cetirizine Hydrochloride			C	Oral			Not Reported	
	Dexamethasone Sodium Phosphate			C	Intramuscular			Not Reported	
	Dexamethasone Sodium Phosphate			C	Intramuscular			Not Reported	
	Chlorphenamine Maleate			C	Oral			Not Reported	
	Calamine			C	Topical			Not Reported	
	Cetirizine Hydrochloride			C	Oral			Not Reported	
	Cetirizine Hydrochloride			C	Oral			Not Reported	
	Promethazine Hydrochloride			C	Intramuscular			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15824570	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019002978		6 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Nausea; Pyrexia; Vomiting	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15825131	NON-EXPEDITED			US-PFIZER INC-2019017770		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Meperidine Hcl			S		Unk		Unknown	
	Acetaminophen/Asa/Caffeine			S		Unk		Not Reported	
	Amoxicillin And Clavulanate			S		Unk		Not Reported	
	Potassium Sulfamethoxazole			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15826159	EXPEDITED (15-DAY)		OT	PHHY2018HU195245		48 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Eye Inflammation; Rash Erythematous; Skin Ulcer	Azithromycin			S	Oral	Unk		Novartis	
	Azithromycin			S				Novartis	
	Azithromycin			S				Novartis	
	Azithromycin			S				Novartis	
	Azithromycin			S				Novartis	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Amoxicillin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15826206	EXPEDITED (15-DAY)		OT	CA-GILEAD-2019-0384072			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Viread			S	Transdermal	300 Mg, Qd		Gilead
	Abacavir			S	Transplacental	300 Mg, Qd		Not Reported
	Acyclovir [Aciclovir]			S	Transplacental			Not Reported
	Bactrim			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Intelence			S	Transplacental	200 Mg, Qd		Not Reported
	Lamivudine			S	Transplacental	150 Mg		Not Reported
	Prezista			S	Transplacental	600 Mg, Qd		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Mg		Not Reported
	Ritonavir			S	Transplacental	100 Mg		Not Reported
	Zidovudine			S	Transplacental	300 Mg		Not Reported
	Folic Acid			C				Not Reported
	Iron			C				Not Reported
	Magnesium Gluconate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15826606	EXPEDITED (15-DAY)		OT	CA-GILEAD-2019-0384068			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Viread			S	Transdermal	300 Mg		Gilead
	Acyclovir [Aciclovir]			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Bactrim			S	Transplacental			Not Reported
	Intelence			S	Transplacental	200 Mg, Qd		Not Reported
	Lamivudine			S	Transplacental	150 Mg		Not Reported
	Prezista			S	Transplacental	600 Mg		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Mg		Not Reported
	Ritonavir			S	Transplacental	100 Mg		Not Reported
	Zidovudine			S	Transplacental	300 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abacavir	C	Transplacental	300 Mg	Not Reported
Folic Acid	C	Unknown		Not Reported
Iron	C			Not Reported
Magnesium Gluconate	C			Not Reported
Multi Vitamin & Mineral	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15827135	EXPEDITED (15-DAY)		OT	PHHY2019FR004479		35 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection; Live Birth; Maternal Exposure During Pregnancy	Metronidazole			S	Unknown			Novartis
	Azithromycin			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15827560	NON-EXPEDITED			US-PFIZER INC-2019019442			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2019	15828543	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2019-0384898		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Pneumonia	Aztreonam Lysine			S	Respiratory (inhalation)	75 Mg, Tid, For 28 Days Off Then 28 Days On. Repeat.		Gilead
	Kalydeco			S	Oral	150 Mg, Bid		Not Reported
	Pulmozyme			S	Unknown	Unk		Not Reported
	Azithromycin Monohydrate Hemihydrate			S	Unknown	Unk		Not Reported
	Tobramycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	13903345	NON-EXPEDITED			US-PFIZER INC-2017365419			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Asa			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	14326137	NON-EXPEDITED			US-PFIZER INC-2017545669		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Stomatitis	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	14585629	NON-EXPEDITED			US-PFIZER INC-2018085001		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Levaquin			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	14933873	NON-EXPEDITED			US-PFIZER INC-2018210880		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity;	Azithromycin	S	Unk	Pfizer
Nausea; Vomiting	Morphine Sulfate	S	Unk	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15112190	EXPEDITED (15-DAY)		OT	GB-PFIZER INC- HQWYE257420SEP07		21 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Drug Interaction; Dyspepsia; Hypophagia; Vomiting; Weight Decreased	Anadin Ibuprofen			S		Unknown		Pfizer
	Anadin Ibuprofen			S				Pfizer
	Azithromycin			S		Unknown		Pfizer
	Tobramycin			S	Intravenous (not otherwise specified)	120 Mg, 3x/Day		Unknown
	Tobramycin			S				Unknown
	Colomycin (Colistin)			S	Intravenous (not otherwise specified)	2 Df, 3x/Day		Not Reported
	Colomycin (Colistin)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15832583	NON-EXPEDITED			PHEH2019US001947			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S	Unknown			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15832752	EXPEDITED (15-DAY)		OT	CA-VIIV HEALTHCARE LIMITED- CA2019006515			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Viread			S	Transdermal	300 Mg, Qd		Glaxosmithkline
	Abacavir			S	Transplacental	300 Mg, Qd		Viiv
	Acyclovir			S	Transplacental	Unk		Glaxosmithkline
	Bactrim			S	Transplacental	Unk		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Transplacental	Unk	Glaxosmithkline
Lamivudine	S	Transplacental	150 Mg	Glaxosmithkline
Zidovudine	S	Transplacental	300 Mg	Viiv
Intelence	S	Transplacental	200 Mg, Qd	Not Reported
Prezista	S	Transplacental	600 Mg, Qd	Not Reported
Raltegravir Potassium	S	Transplacental	400 Mg	Not Reported
Ritonavir	S	Transplacental	100 Mg	Not Reported
Folic Acid	C	Unknown	Unk	Glaxosmithkline
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15833019	DIRECT		DS			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pruritus; Rash	Azithromycin	Y		S	Oral	Quantity:1 Tablet(S);		Wockhardt
	Hyzaar			C				Not Reported
	Amlodipine			C				Not Reported
	Latanoprost			C				Not Reported
	Vitamin-C			C				Not Reported
	B-Complex			C				Not Reported
	Vitamin E			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Low Dose Aspirin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15833080	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019006515			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Viread			S	Transdermal	300 Mg, Qd		Glaxosmithkline
	Abacavir			S	Transplacental	300 Mg, Qd		Viiv
	Acyclovir			S	Transplacental	Unk		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactrim	S	Transplacental	Unk	Glaxosmithkline
Azithromycin	S	Transplacental	Unk	Glaxosmithkline
Lamivudine	S	Transplacental	150 Mg	Glaxosmithkline
Zidovudine	S	Transplacental	300 Mg	Viiv
Intelence	S	Transplacental	200 Mg, Qd	Not Reported
Prezista	S	Transplacental	600 Mg, Qd	Not Reported
Raltegravir Potassium	S	Transplacental	400 Mg	Not Reported
Ritonavir	S	Transplacental	100 Mg	Not Reported
Folic Acid	C	Unknown	Unk	Glaxosmithkline
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15833725	EXPEDITED (15-DAY)		HO	US-GILEAD-2019-0384907		30 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated	Aztreonam Lysine			S	Respiratory (inhalation)	75 Mg, Tid, For 28 Days On And 28 Days Off, Repeat		Gilead	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Omeprazole Sodium			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2019	15931999	DIRECT	Y	LT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Swelling Face	Zithromax 250mg Pfizer			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15836813	EXPEDITED (15-DAY)		OT	US-TEVA-2018-US-990345			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Dyspnoea	Azithromycin Teva			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15838869	NON-EXPEDITED			US-PFIZER INC-2019021512		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15838886	NON-EXPEDITED			US-PFIZER INC-2019022556		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Photophobia; Pruritus	Azithromycin			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15838920	NON-EXPEDITED			US-PFIZER INC-2019017622		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Rash; Swollen Tongue	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839334	NON-EXPEDITED		OT	US-ALEXION PHARMACEUTICALS INC.-A201900603			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Dyspnoea; Eyelid Ptosis; Myasthenia Gravis Crisis;	Soliris			S	Unknown			Alexion	
	Zithromax			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Nasopharyngitis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839358	EXPEDITED (15-DAY)		OT	CA-VIIV HEALTHCARE LIMITED- CA2019006529			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Exposure During Pregnancy	Viread			S	Transdermal	300 Mg		Glaxosmithkline	
	Aciclovir			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline	
	Bactrim			S	Transplacental	Unk		Glaxosmithkline	
	Lamivudine			S	Transplacental	150 Mg		Glaxosmithkline	
	Zidovudine			S	Transplacental	300 Mg		Viiv	
	Intelence			S	Transplacental	200 Mg, Qd		Not Reported	
	Prezista			S	Transplacental	600 Mg		Not Reported	
	Raltegravir Potassium			S	Transplacental	400 Mg		Not Reported	
	Ritonavir			S	Transplacental	100 Mg		Not Reported	
	Abacavir			C	Transplacental	300 Mg		Viiv	
	Folic Acid			C	Unknown	Unk		Glaxosmithkline	
	Iron			C	Unknown	Unk		Not Reported	
	Magnesium Gluconate			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839385	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019006529			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Exposure During Pregnancy	Viread			S	Transdermal	300 Mg		Glaxosmithkline	
	Aciclovir			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline	
	Bactrim			S	Transplacental	Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lamivudine	S	Transplacental	150 Mg	Glaxosmithkline
Zidovudine	S	Transplacental	300 Mg	Viiv
Intelence	S	Transplacental	200 Mg, Qd	Not Reported
Prezista	S	Transplacental	600 Mg	Not Reported
Raltegravir Potassium	S	Transplacental	400 Mg	Not Reported
Ritonavir	S	Transplacental	100 Mg	Not Reported
Abacavir	C	Transplacental	300 Mg	Viiv
Folic Acid	C	Unknown	Unk	Glaxosmithkline
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839489	NON-EXPEDITED			US-TEVA-2018-US-991363		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839580	EXPEDITED (15-DAY)		HO	PHHY2019IT009393		152 DAY	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medication Error; Vomiting	Azithromycin			S	Oral	7.5 MI, Qd		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839676	NON-EXPEDITED			US-PFIZER INC-2019022339			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		1500 Mg, Unk (6 Tabs X 250mg)		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839730	NON-EXPEDITED			US-PFIZER INC-2019021586		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Meperidine Hcl			S		Unk		Unknown	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Amoxicillin & Clav. Potassium			S		Unk		Not Reported	
	Acetylsalicylic Acid W/Caffeine/Paracetamol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15839804	NON-EXPEDITED			US-PFIZER INC-2019020591		81 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2019	15840004	NON-EXPEDITED			US-PFIZER INC-2018536892			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Contraindicated Product Prescribed; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15727729	EXPEDITED (15-DAY)		OT	US-ABBVIE-18K-163-2591022-00		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Disorder; Body Height Decreased; Diabetes Mellitus; Drug	Humira			S	Subcutaneous			Not Reported	
	Humira			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Gastrointestinal Disorder; Hip Arthroplasty; Intervertebral Disc Protrusion; Lip Squamous Cell Carcinoma; Psoriasis; Skin Cancer	Enbrel	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Aza (Azithromycin Dihydrate)	S	Unknown	Not Reported
	Sulfasalazine	S	Unknown	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Xeljanz Xr	S	Oral	Not Reported
	Xeljanz Xr	S		Not Reported
	Arava	S	Unknown	Not Reported
	Rituxan	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15841652	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR- APL-2019-000624		19 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Respiratory Distress	Azithromycin			S	Oral	Unk		Aurobindo	
	Lepicortinolo /00016201/			S	Oral	Unk		Not Reported	
	Maxilase			S	Oral	Unk		Not Reported	
	Lergonix			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2019	15843150	NON-EXPEDITED			US-INSMED, INC.-US- INS-18-00442		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Nausea	Arikayce			S	Respiratory (inhalation)			Insmmed	
	Lamira Nebulizer System			S				Insmmed	
	Pepto Bismol			S				Not Reported	
	Pepto Bismol			S				Not Reported	
	Rifampin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Ethambutol			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2019	12989565	EXPEDITED (15-DAY)		OT	GB-BRISTOL-MYERS SQUIBB COMPANY- BMS-2016-091103		79 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Lower Respiratory Tract Infection	Abatacept			S	Subcutaneous	125 Mg, Qwk		Bristol Myers Squibb	
	Azithromycin			S	Unknown			Not Reported	
	Dexamethasone			C	Oral	500 Mg, Unk		Not Reported	
	Rivaroxaban			C	Unknown			Not Reported	
	Amlodipine			C	Unknown			Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Carbocisteine			C	Unknown			Not Reported	
	Digoxin			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2019	15845788	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2019-001966		40 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hyperaemia; Periorbital Swelling	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Gentalyn			S	Topical	1 Dosage Form, As Necessary		Not Reported	
	Brufen /00109201/			S	Oral	600 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	11282446	EXPEDITED (15-DAY)		DE, HO, OT	GB-ROCHE-1607618			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anxiety;	Esbriet			S	Oral			Not Reported	
	Esbriet			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Asthenia; Breast Pain; Cataract; Cataract; Cellulitis; Chest Pain; Chest Pain; Condition Aggravated; Cough; Death; Depressed Mood; Depression; Drug Ineffective; Dyspnoea; Dyspnoea; Erythema; Fatigue; Fatigue; Flushing; Frequent Bowel Movements; Gastrointestinal Disorder; Gastrointestinal Pain; Gastrooesophageal Reflux Disease; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Haemoptysis; Headache; Heart Rate Increased; Hiatus Hernia; Hypotension; Increased Upper Airway Secretion; Inguinal Hernia; Insomnia; Jaw Cyst; Lethargy; Lower Respiratory Tract Infection; Lower Respiratory Tract Infection; Malaise; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nasopharyngitis; Osteomyelitis; Osteomyelitis; Oxygen Saturation Decreased; Panic Attack; Pneumonia; Pneumonia; Productive Cough; Pruritus; Pruritus; Pulmonary Function Test Decreased; Pulmonary Oedema; Pulmonary Pain;	Esbriet Azithromycin	S S	Oral Unknown	Full Dose	Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rash; Seasonal Allergy;
Seborrhoea; Skin Irritation;
Skin Ulcer; Sunburn;
Swelling; Tearfulness;
Therapeutic Product Effect
Decreased; Tinnitus;
Tooth Injury; Total Lung
Capacity Decreased;
Tremor; Ulcer; Upper-
Airway Cough Syndrome;
Vertigo; Viral Infection;
Weight Decreased; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	14328287	NON-EXPEDITED			US-PFIZER INC- 2017548756		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Lodine			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Trazodone Hcl			S		Unk		Not Reported	
	Ultram Er			S		Unk		Not Reported	
	Acihexal [Aciclovir Sodium]			S		Unk		Not Reported	
	Disalcid			S		Unk		Not Reported	
	Domperidone			S		Unk		Not Reported	
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	
	Actonel			S		Unk		Not Reported	
	Plavix			S		Unk		Not Reported	
	Dilaudid			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15711221	NON-EXPEDITED			US-PFIZER INC-2018506365		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Prescribing Error; Upper Respiratory Tract Infection	Zithromax			S		Unk		Pfizer	
	Xeljanz Xr			S	Oral	11 Mg, Daily (1 Tablet Daily)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15847739	EXPEDITED (15-DAY)		DE, OT	PHHY2019PT011909		56 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Failure; Multiple Organ Dysfunction Syndrome	Azithromycin			S	Unknown	Unk		Novartis	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Piperacillin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15848372	NON-EXPEDITED			US-PFIZER INC-2019026404			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pre-Existing Condition Improved; Therapeutic Response Unexpected	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15848886	EXPEDITED (15-DAY)		OT	AT-BRACCO-2018AT06772			Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Adrenal Insufficiency; Adverse	Prohance			S	Intravenous (not otherwise specified)	Unk Unk, Single		Bracco	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Food Reaction; Agonal Rhythm; Alopecia; Arthralgia; Arthralgia; Arthralgia; Asthenia; Constipation; Depression; Diarrhoea; Dry Eye; Dysgeusia; Fatigue; Flatulence; Gait Disturbance; Gastrointestinal Pain; Headache; Hormone Level Abnormal; Hypoaesthesia; Hypoaesthesia; Incontinence; Injection Site Pain; Joint Ankylosis; Joint Swelling; Menstruation Irregular; Metabolic Disorder; Mitochondrial Toxicity; Mucosal Dryness; Muscle Injury; Muscle Spasticity; Muscular Weakness; Musculoskeletal Pain; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Nervous System Disorder; Neuralgia; Neuropathy Peripheral; Pain; Pain In Extremity; Panic Attack; Paraesthesia; Paraesthesia; Photopsia; Skin Irritation; Suicidal Ideation; Suicide Attempt; Swelling; Temperature Intolerance; Tendon Injury; Vein Rupture; Vertigo; Vision Blurred; Visual Impairment; Vomiting; Weight Decreased	Prohance Itraconazole Itraconazole Azithromycin Avelox /01453202/ Diflucan Diflucan Ivermec Ivermec Cortisone Moxifloxacin Krka Anaerobex Pantelmin Pantoloc /01263204/ Pantoloc /01263204/	S S S S S S S S S S S S C C C	Intravenous (not otherwise specified)	Unk Unk, Single 200 Mg 200 Mg, Bid Unk Unk, Qd Unk Unk, Qd Unk Unk, Every Other Day (Qod) Unknown Unk Unk, Every Other Day (Qod) Unk 1 Df, Per Day 1 Df, 1x Per Day Unk Unk, Bid Unk Unk, Bid 40 Mg, 1x Per Day Unk, 280mg Cumulative Dose	Bracco Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15850213	NON-EXPEDITED			US-PFIZER INC-2019024240		42 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15850214	NON-EXPEDITED			US-PFIZER INC-2019024299		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15850233	NON-EXPEDITED			US-PFIZER INC-2019022272		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Benzympenicillin Potassium			S		Unk		Pfizer	
	Benzathine Benzympenicillin			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Phenoxyethylpenicillin Potassium			S		Unk		Pfizer	
	Baclofen			S		Unk		Not Reported	
	Ibu			S		Unk		Not Reported	
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2019	15850530	NON-EXPEDITED			US-PFIZER INC-2019024227		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Diclofenac Potassium			S		Unk		Not Reported	
	Glucosamine			S		Unk		Not Reported	
	Acetaminophen;Hydrocodone			S		Unk		Not Reported	
	Naproxen			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	10511006	NON-EXPEDITED			US-PFIZER INC-2014275816			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Protonix			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Pantoprazole			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	
	Elavil			S		Unk		Not Reported	
	Victoza			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trintellix	S	Unk	Not Reported
Valsartan	S	Unk	Not Reported
Levomenol	S	Unk	Not Reported
Bupropion	S	Unk	Not Reported
Escitalopram	S	Unk	Not Reported
Vortioxetine	S	Unk	Not Reported
Liraglutide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	13063793	NON-EXPEDITED			US-PFIZER INC-2016585307		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	14057494	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-VALIDUS PHARMACEUTICALS LLC-US-2017VAL001404		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Drug Ineffective; Lung Opacity; Lymphopenia; Off Label Use; Pneumocystis Jirovecii Pneumonia; Pneumomediastinum; Respiratory Failure; Sepsis; Syncope	Furosemide			S	Unknown	Unk		Validus	
	Dexamethasone			S	Oral	4 Mg, Qid		Not Reported	
	Dexamethasone			S	Unknown	Tapered Dose Unk		Not Reported	
	Temozolomide			S	Oral	150 Mg/M2, On Day 7-11qd		Not Reported	
	Temozolomide			S				Not Reported	
	Methotrexate			S	Intravenous (not	8 Mg/M2, On Day 1 And		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	15		
Piperacillin/Tazobactam	S	Unknown	Unk		Not Reported
Azithromycin	S	Unknown	Unk		Not Reported
Dexamethasone	S	Unknown	4 Mg, Bid		Not Reported
Vancomycin	S	Unknown	Unk		Not Reported
Bactrim	S	Intravenous (not otherwise specified)	Unk		Not Reported
Rituximab	S	Intravenous (not otherwise specified)	375 Mg/M2, On Days 3, 10, 17, 24		Not Reported
Rituximab	S				Not Reported
Folinic Acid	S	Unknown	Unk		Not Reported
Levetiracetam	C		Unk		Not Reported
Coumadin	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	14316750	NON-EXPEDITED			US-PFIZER INC-2017542747		95 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Theophylline			S		Unk		Pfizer
	Vibramycin			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Levoquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	14739945	NON-EXPEDITED			US-PFIZER INC-2018145965		12 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15411322	NON-EXPEDITED			US-PFIZER INC-2018383075		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cefuroxime			S		Unk		Unknown
	Doxepin Hcl			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Vancomycin Hcl			S		Unk		Pfizer
	Amitriptyline			S		Unk		Not Reported
	Atenolol			S		Unk		Not Reported
	Methadone			S		Unk		Not Reported
	Nortriptyline			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15767056	EXPEDITED (15-DAY)			JP-OTSUKA-2018_039913		11 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis Mycoplasmal; Drug Dose Titration Not Performed; Hepatic Enzyme Increased	Abilify 3mg			S	Oral	1 Tablet (3 Mg), Qd		Otsuka
	Abilify 3mg			S	Oral	0.5 Tablet (1.5 Mg), Qd		Otsuka
	Abilify 3mg			S	Oral	0.5 Tablet (1.5 Mg), Qd		Otsuka
	Abilify 1mg			S	Oral	1 Tablet (1 Mg), Qd		Otsuka
	Zithromac			S	Oral	Unk		Not Reported
	Midodrine Hydrochloride			C	Oral	2 Df, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15848861	NON-EXPEDITED			US-PFIZER INC-2019024407		60 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Penicillin V Potassium			S		Unk		Not Reported	
	Plavix			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15851036	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001833		33 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Rigidity; Nausea; Syncope; Urticaria; Vomiting	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	
	Ciprodex			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15852881	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT009166		23 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Condition Aggravated; Granulomatosis With Polyangiitis; Haemoptysis	Azithromycina			S	Unknown			Novartis	
	Ceftriaxona			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855073	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-V-DE-2007-1532		52 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Respiratory Disorder	Tobi (Tobramycin Inhalation Solution, Usp)			S				Mylan	
	Tobramycin			S	Intravenous (not otherwise specified)	9mg/Kg/Day (120 Mg, Freq: Tid)		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Colomycin /00013203/	S	Intravenous (not otherwise specified)	2 Df, Unk (120 Mg, 2 Megaunits)	Mylan
Colomycin /00013203/	S			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2019	15855237	EXPEDITED (15-DAY)		HO	PHHY2019PT012565		24 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemoglobin Decreased; Lung Infiltration	Ceftriaxone			S	Unknown	2 G, Unk		Novartis
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	14122454	EXPEDITED (15-DAY)		OT	PHHY2017CA117227		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Animal Bite;	Azithromycin Sandoz			S	Oral	250 Mg, Tiw		Novartis
Blood Pressure Systolic	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported
Increased; Dyspnoea; Gait	Xolair			S	Subcutaneous	Unk		Not Reported
Inability; Ligament	Xolair			S	Subcutaneous	Unk		Not Reported
Rupture; Mobility	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Patella	Xolair			S	Subcutaneous	Unk		Not Reported
Fracture; Stress; Tibia	Xolair			S	Subcutaneous	Unk		Not Reported
Fracture	Xolair			S	Subcutaneous	Unk		Not Reported
	Ventolin			C	Respiratory (inhalation)	Pn		Not Reported
	Spiriva			C	Respiratory (inhalation)	1 Df, Qd		Not Reported
	Symbicort			C	Respiratory (inhalation)	3 Df, Bid		Not Reported
	Prednisone			C	Unknown			Not Reported
	Prednisone			C	Unknown	1 Df, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856540	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1001839		75 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Cough; Decreased Appetite; Diarrhoea; Diarrhoea; Diarrhoea; Diarrhoea; Drug Interaction; Dry Mouth; Dysphonia; Eye Colour Change; Feeling Abnormal; Intercepted Product Prescribing Error; Labelled Drug-Drug Interaction Medication Error; Myocardial Infarction; Nasopharyngitis; Oral Fungal Infection; Oxygen Therapy; Pneumonia; Pneumonia; Productive Cough; Stent Placement; Tremor	Azithromycin Ofev Ofev Ofev Ofev Loperamide Ultram			S S S S S C C	Unknown Oral Oral Oral Oral Unknown Unknown	200 Milligram Daily; 200 Milligram Daily;		Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856914	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-998930			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Unilateral; Hot Flush; Paraesthesia; Sensory Disturbance	Azi-Teva 500 Mg Filmtabletten			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15856962	EXPEDITED (15-DAY)		HO, OT	PT-ROCHE-2247556		23 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Respiratory Failure; Condition Aggravated;	Oseltamivir	S	Unknown	Not Reported
Granulomatosis With	Azitromicina	S	Unknown	Not Reported
Polyangiitis; Haemoptysis	Ceftriaxona [Ceftriaxone]	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15857545	EXPEDITED (15-DAY)		HO	US-ROCHE-2248702		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Pneumonia	Pulmozyme			S	Unknown			Not Reported
	Cayston			S	Respiratory (inhalation)	28 Day Off Then 28 Day On		Not Reported
	Kalydeco			S	Oral			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Tobramycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858010	NON-EXPEDITED			US-TEVA-2018-US-994121			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthralgia; Myalgia; Product Substitution Issue	Azithromycin			S				Not Reported
	Prednisone			C				Not Reported
	Tylenol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858405	NON-EXPEDITED			US-PFIZER INC-2019029802		86 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Symbicort			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858416	NON-EXPEDITED			US-PFIZER INC-2019029363		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ultram [Tramadol Hydrochloride]			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858454	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1005092		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastritis; Gastrointestinal Haemorrhage; Maternal Exposure During Pregnancy; Normal Newborn	Azithromycin			S	Unknown			Not Reported	
	Dexamethasone			S	Unknown			Not Reported	
	Ampicillin			C	Unknown			Mylan	
	Gentamicin			C	Unknown			Mylan	
	Clindamycin			C	Unknown			Mylan	
	Etoposide			C	Unknown	Weekly		Mylan	
	Etoposide			C	Other	Discharged With Etoposide Outpatient Infusion (Week 6 Of HIh Protocol)		Mylan	
	Etoposide			C	Unknown	Restarted HIh-94 Protocol; Twice Weekly		Mylan	
	Ganciclovir			C	Unknown			Mylan	
	Rituximab			C	Unknown	On Day 15 Of Readmission		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858508	NON-EXPEDITED			US-PFIZER INC-2019024070		59 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858866	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK007778		85 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Above Therapeutic; Drug Interaction; Peripheral Swelling	Cefuroxime Axetil			S		Unk		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Warfarin			S		Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15858870	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2019GSK010872		60 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatitis Acute; Hepatocellular Injury	Nucala			S		Unk		Glaxosmithkline	
	Zithromax			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2019	15859272	NON-EXPEDITED			US-PFIZER INC-2019023245			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	13844741	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017342005		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amnesia; Balance Disorder; Dizziness; Headache; Heart Rate Irregular; Irritability; Social Avoidant Behaviour; Suicidal Ideation; Tinnitus; Vertigo	Zithromax	S		Unk	Pfizer
	Zithromax	S		500 Mg, 1x/Day (250 Mg, Two Pills)	Pfizer
	Lisinopril	C	Oral	20 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15322973	EXPEDITED (15-DAY)		DE	PHHY2018BE078080			Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Decreased; Off Label Use; Respiratory Failure; Therapeutic Product Ineffective For Unapproved Indication	Mycophenolate Mofetil			S	Unknown			Novartis
	Azithromycin			S	Unknown			Not Reported
	Montelukast Sodium			S	Unknown			Not Reported
	Mabthera			S	Unknown			Not Reported
	Pirfenidone			S	Unknown	2403 Mg, Qd		Not Reported
	Azathioprine			C	Unknown			Not Reported
	Ciclosporin A			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15563966	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2018RR-189245		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Azithromycin			S	Oral	Unk		Sun
	Ibuprofen		Y	S	Oral	Unk		Ranbaxy
	Olanzapine			C	Unknown	5 Mg, Daily		Not Reported
	Venlafaxine			C	Unknown	150 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15793878	EXPEDITED (15-DAY)		CA, DS, HO	LV-AMREGENT-20181739			Female	LVA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Atresia; Duodenal Atresia; Female Genital Tract Fistula; Foetal Exposure During Pregnancy; Oesophageal Atresia; Respiratory Distress; Spine Malformation	Ferinject (Ferric Carboxymaltose - Vifor) (Fer-Vifor-02)			S	Transplacental	Unknown		Vifor
	Venofer (Iron Sucrose Injection-Vifor)			S	Transplacental	100 Mg		Vifor
	Azithromycinum (Azithromycin)			S	Transplacental	500 Mg (500 Mg, 1 In 1 D)		Not Reported
	Cefuroxime			S	Transplacental	1500 Mg (750 Mg, 2 In 1 D)		Not Reported
	Penicillin G Benzathine			S	Transplacental	4 Gm (1 Gm, 4 In 1 D)		Not Reported
	Paracetamol			S	Transplacental	1000 Mg (500 Mg, 2 In 1 D)		Not Reported
	Maltofer (Iron Polymaltose)			S	Transplacental	Unknown		Not Reported
	Ferrum			S	Transplacental	100 Mg Three Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15843862	EXPEDITED (15-DAY)		OT	AT-JNJFOC-20190111032			Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Adrenal Insufficiency; Adverse Food Reaction; Agonal Rhythm; Alopecia; Arthralgia; Arthralgia; Arthralgia; Asthenia; Constipation; Depression; Diarrhoea; Dry Eye; Dysgeusia; Fatigue; Flatulence; Gait Disturbance; Gastrointestinal Pain; Headache; Hormone Level Abnormal; Hypoaesthesia; Hypoaesthesia; Incontinence; Injection Site Pain; Joint Ankylosis; Joint Swelling;	Itraconazole			S	Unknown	200 Mg, 2x Per Day		Not Reported
	Itraconazole			S	Unknown			Not Reported
	Itraconazole			S	Unknown			Not Reported
	Diflucan			S	Unknown			Not Reported
	Diflucan		Y	S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Avelox			S	Unknown			Not Reported
	Ivermec			S	Unknown			Not Reported
	Ivermec			S	Unknown			Not Reported
	Gadoteridol			S	Unknown			Not Reported
	Gadoteridol			S	Unknown			Not Reported
	Cortisone			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Menstruation Irregular;	Moxifloxacin	S	Unknown		Not Reported
Metabolic Disorder;	Anaerobex	S	Unknown	2x Per Day	Not Reported
Mitochondrial Toxicity;	Pantoloc	C	Unknown		Not Reported
Mucosal Dryness; Muscle	Pantoloc	C	Unknown		Not Reported
Injury; Muscle Spasticity;	Pantoloc	C	Unknown		Not Reported
Muscular Weakness;	Pantelmin	C	Unknown	2x Per Day	Not Reported
Musculoskeletal Pain;					
Musculoskeletal Pain;					
Musculoskeletal Stiffness;					
Nausea; Nervous System					
Disorder; Neuralgia;					
Neuropathy Peripheral;					
Pain; Pain In Extremity;					
Panic Attack;					
Paraesthesia; Photopsia;					
Skin Irritation; Suicidal					
Ideation; Suicide Attempt;					
Swelling; Temperature					
Intolerance; Tendon Injury;					
Vein Rupture; Vertigo;					
Vision Blurred; Visual					
Impairment; Vomiting;					
Weight Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15861567	EXPEDITED (15-DAY)		HO	FR-ZYDUS-032731		74 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Flagyl			S	Oral	()		Not Reported
Diarrhoea; Rectal	Deroxat			S		()		Not Reported
Haemorrhage	Azithromycin			S	Oral			Zydus Pharm
	Candesartan Cilexetil			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15861885	NON-EXPEDITED			US-PFIZER INC-2019027818		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Pruritus; Rash		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15861893	NON-EXPEDITED			US-PFIZER INC- 2019025114			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Lorazepam			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Piroxicam			S		Unk		Pfizer	
	Inderal			S		Unk		Pfizer	
	Trazodone Hcl			S		Unk		Not Reported	
	Metformin Hcl			S		Unk		Not Reported	
	Penicillin V Potassium			S		Unk		Not Reported	
	Sulfamethoxazole			S		Unk		Not Reported	
	Duloxetine Hcl			S		Unk		Not Reported	
	Macrobid [Nitrofurantoin]			S		Unk		Not Reported	
	Prochlorperazine Edisylate			S		Unk		Not Reported	
	Cipro [Ciprofloxacin Hydrochloride Monohydrate]			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
	Lovastatin			S		Unk		Not Reported	
	Prednisolone Sodium Phosphate			S		Unk		Not Reported	
	Oxycodone Hcl			S		Unk		Not Reported	
	Methadone Hcl			S		Unk		Not Reported	
	Nystatin			S		Unk		Not Reported	
	Pseudoephedrine Hcl			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyoscyamine	S	Unk	Not Reported
Tetanus Vaccine	S	Unk	Not Reported
Aluminium Magnesium Silicate	S	Unk	Not Reported
Remeron	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15862627	DIRECT					33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Auditory; Hallucination, Visual	Azithromycin Tablets, Usp			S	Oral	Quantity:1 Tablet(S);		Sandoz	
	Dysum			C				Not Reported	
	Acetaminophen			C				Not Reported	
	Ibuprofen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15863303	EXPEDITED (15-DAY)		OT	PHHY2019US010755			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental			Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15863693	NON-EXPEDITED			US-BAUSCH-BL-2019-001130		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Metronidazole			S	Unknown			Not Reported	
	Ramipril			S	Unknown			Not Reported	
	Verapamil Hydrochloride			S	Unknown			Not Reported	
	Morphine Sulfate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Hydrochlorothiazide With			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Triamterene				
Hyoscyamine	S	Unknown		Not Reported
Azithromycin	S	Unknown		Not Reported
Hepatitis B Vaccine	S	Unknown		Not Reported
Sulfadiazine Silver	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15864237	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019028936		28 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Insomnia	Azithromycin			S	Oral	250 Df, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2019	15864421	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2019028697			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Zithromac			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	11277787	EXPEDITED (15-DAY)		HO, OT	US-JNJFOC-20150711612		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Blood Electrolytes Abnormal; Cough; Electrocardiogram Qt Prolonged; Hypoxic-Ischaemic	Imbruvica			S	Oral			Not Reported
Encephalopathy; Leukocytosis; Rib Fracture; Ventricular Fibrillation	Azithromycin			S	Unknown			Not Reported
	Zyrtec		Y	S	Unknown			Not Reported
	Zyrtec			S	Unknown			Not Reported
	Synthroid			C				Not Reported
	Losartan/Hydrochlorothiazide			C				Not Reported
	Metformin			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	14134212	EXPEDITED (15-DAY)		OT	CA-ROCHE-2014167		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accident; Animal Bite; Blood Pressure Systolic Increased; Dyspnoea; Gait Inability; Ligament Rupture; Mobility Decreased; Patella Fracture; Stress; Tibia Fracture	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Azithromycin Sandoz			S	Oral			Not Reported
	Ventolin			C	Respiratory (inhalation)			Not Reported
	Symbicort			C	Respiratory (inhalation)			Not Reported
	Prednisone			C	Unknown			Not Reported
	Spiriva			C	Respiratory (inhalation)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	14347489	NON-EXPEDITED			US-PFIZER INC-2017554124			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	14420474	EXPEDITED (15-DAY)		DE, HO, LT	US-ROCHE-1990454		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Respiratory Distress Syndrome; Drug Ineffective; Lung Opacity; Lymphopenia; Pneumocystis Jirovecii Pneumonia; Pneumomediastinum; Respiratory Failure; Sepsis; Syncope; Urinary Tract Infection	Bactrim	S	Intravenous (not otherwise specified)		Not Reported
	Rituximab	S	Intravenous (not otherwise specified)	On Days (3, 10, 17, 24).	Not Reported
	Vancomycin	S	Unknown		Not Reported
	Leucovorin	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Temozolomide	S	Oral	On Days 7 And 11	Not Reported
	Furosemide	S	Unknown		Not Reported
	Methotrexate	S	Intravenous (not otherwise specified)	On Day 1 And 15	Not Reported
	Decadron (United States)	S	Unknown		Not Reported
	Piperacillin/Tazobactam	S	Unknown		Not Reported
	Piperacillin/Tazobactam	S			Not Reported
	Piperacillin/Tazobactam	S			Not Reported
	Levetiracetam	C			Not Reported
	Coumadine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	14461708	NON-EXPEDITED			US-ACORDA-ACO_143711_2017		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Diarrhoea	Ampyra			S	Unknown	10 Mg, Q 12 Hrs		Acorda	
	Z-Pak			S	Unknown	Unk		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Nifedipine			C	Unknown	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Carvedilol			C	Unknown	Unk		Not Reported	
	Vesicare			C	Unknown	Unk		Not Reported	
	Ventolin			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	C	Unknown	Unk	Not Reported
Tramadol	C	Unknown	Unk	Not Reported
Clotrimazole And Betamethasone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	14705570	EXPEDITED (15-DAY)	HO		PHHO2017US014037		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Chronic Obstructive Pulmonary Disease; Gastritis; Hypoxia; Myocardial Ischaemia	Azithromycin			S	Unknown	Unk		Novartis
	Entresto			S	Oral	24/26 Mg Bid		Not Reported
	Entresto			S	Oral	49/51 Mg Bid		Not Reported
	Entresto			S	Oral	49/51 Mg Bid		Not Reported
	Entresto			S	Oral	97/103 Bid		Not Reported
	Warfarin Sodium			C	Oral	5 Mg, Qd, 1 Tb Qd With Food		Not Reported
	Coumadin			C	Unknown	Unk		Not Reported
	Potassium Chloride			C	Oral	20 Ug, Qd, 1 Tb		Not Reported
	Digoxin			C	Oral	250 Ug, (0.25 Mg)		Not Reported
	Carvedilol			C	Oral	6.25 Mg, Qd, 1 Tb		Not Reported
	Carvedilol			C				Not Reported
	Enalapril Maleate			C	Oral	2.5 Mg, Qd, 1tb		Not Reported
	Enalapril Maleate			C				Not Reported
	Furosemide			C	Oral	40 Mg, Qd		Not Reported
	Percocet			C	Oral	10-325 Mg 1 Tb Q4 Hrs Prn		Not Reported
	Percocet			C				Not Reported
	Albuterol			C	Respiratory (inhalation)	Inhaler Q4 Hrs Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15814310	EXPEDITED (15-DAY)	OT		PT-PFIZER INC- 2019013341		19 YR	Male	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Angioedema; Respiratory Distress	Azithromycin			S	Oral	Unk		Pfizer	
	Lergonix			S	Oral	Unk		Not Reported	
	Lepicortinolo [Prednisolone]			S	Oral	Unk		Not Reported	
	Maxilase			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15843232	EXPEDITED (15-DAY)		HO, OT	US-VERTEX PHARMACEUTICALS- 2019-000397		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infective Pulmonary Exacerbation Of Cystic Fibrosis; Pneumonia	Kalydeco			S	Oral	150 Mg, Bid		Vertex	
	Cayston			S	Respiratory (inhalation)	75 Mg, Tid For 28 Days On And 28 Days Off		Not Reported	
	Pulmozyme			S	Unknown	Unk		Not Reported	
	Azithromycin Monohydrate Hemiethanolate			S	Unknown	Unk		Not Reported	
	Tobramycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15866176	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-197180		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin			S	Oral	()		Sun	
	Flagyl			S	Oral	()		Not Reported	
	Deroxat			S	Unknown	()		Not Reported	
	Candesartan Cilexetil			C	Unknown	8 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15866236	NON-EXPEDITED			US-PFIZER INC- 2019034811		88 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15866277	NON-EXPEDITED			US-PFIZER INC- 2019033634		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15867837	EXPEDITED (15-DAY)		OT	PHEH2019US002733			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease	Azithromycin			S	Oral	250 Mg, Unk		Novartis	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Mucinex			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15867909	EXPEDITED (15-DAY)		HO	PHHY2019FR012493		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin Monohydrate			S	Oral	Unk		Novartis	
	Deroxat			S	Unknown	Unk		Not Reported	
	Flagyl			S	Oral	Unk		Not Reported	
	Candesartan Cilexetil			C	Unknown	8 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15867932	EXPEDITED (15-DAY)		OT	PHHY2019CA015501			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematemesis	Azithromycin Sandoz			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15868823	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1006538			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Arthralgia; Large Intestinal Stenosis; Oral Herpes; Rash; Tonsillitis	Azithromycin			S	Unknown	Unk		Not Reported	
	Entyvio			S	Intravenous (not otherwise specified)	300 Mg, Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15869578	EXPEDITED (15-DAY)		OT	PHEH2019US003605			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Mycobacterium Avium Complex Infection; Pathogen Resistance	Azithromycin			S	Unknown	Unk		Novartis	
	Rifabutin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Amikacin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15869682	NON-EXPEDITED			US-PFIZER INC-2019036336			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hypertension	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2019	15869751	NON-EXPEDITED			US-PFIZER INC-2019027900			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2019	14413469	NON-EXPEDITED			US-TAKEDA-2016TEU001693		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Protonix			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Trintellix			S	Unknown	Unk		Takeda
	Vortioxetine			S	Unknown	Unk		Takeda
	Lexapro			S	Unknown	Unk		Not Reported
	Victoza			S	Unknown	Unk		Not Reported
	Wellbutrin			S	Unknown	Unk		Not Reported
	Elavil /00002202/			S	Unknown	Unk		Not Reported
	Levaquin			S	Unknown	Unk		Not Reported
	Lipitor			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Dilantin /00017401/			S	Unknown	Unk		Not Reported
	Valsartan			S	Unknown	Unk		Not Reported
	Levomenol			S	Unknown	Unk		Not Reported
	Bupropion			S	Unknown	Unk		Not Reported
	Escitalopram			S	Unknown	Unk		Not Reported
	Liraglutide			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2019	15876499	EXPEDITED (15-DAY)		HO	PHHY2019US011053		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection; Infective Aneurysm; Malaise; Pyrexia	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	9919772	NON-EXPEDITED			US-PFIZER INC-2014048244			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Elavil			S		Unk		Not Reported	
	Desyrel			S		Unk		Not Reported	
	Polymyxin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	13989068	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2017US-150130		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Drug Ineffective; Lung Opacity; Lymphopenia; Off Label Use; Pneumocystis Jirovecii Pneumonia; Pneumomediastinum; Respiratory Failure; Sepsis; Syncope	Temozolomide			S	Oral	150 Mg/M2 Milligram(S)/Sq. Meter, Days 7-11		Novartis	
	Temozolomide			S	Oral	150 Mg/M2 Milligram(S)/Sq. Meter, Days 7-11		Novartis	
	Dexamethasone			S	Oral	On Reduced Dose (Dose Tapered)		Sun	
	Dexamethasone			S	Oral	4 Milligram, Daily		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexamethasone	S	Unknown	4 Milligram, Daily, Trade Name: Decadron	Sun
Dexamethasone	S	Unknown	4 Milligram, Daily, Trade Name: Decadron	Sun
Dexamethasone	S	Unknown	Tapered Dose ()	Sun
Dexamethasone	S	Oral	4 Milligram, Daily	Sun
Dexamethasone	S	Unknown	Tapered Dose ()	Sun
Dexamethasone	S	Oral	4 Milligram, Daily	Sun
Rituximab	S	Intravenous (not otherwise specified)	375 Mg/M2 Milligram(S)/Sq. Meter, Days (3,10,17,24)	Not Reported
Rituximab	S	Intravenous (not otherwise specified)	375 Mg/M2 Milligram(S)/Sq. Meter, Days (3,10,17,24)	Not Reported
Leucovorin	S	Unknown		Not Reported
Levetiracetam	C	Unknown	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	Mg/M2 Milligram(S)/Sq. Meter, Day 1 And 15	Sun
Vancomycin	S	Unknown	Unk	Not Reported
Bactrim	S	Intravenous (not otherwise specified)	Unk	Mutual
Coumadin	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Sun
Piperacillin/ Tozobactam	S	Unknown	Unk	Not Reported
Furosemide	S	Unknown	Unk	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	14221218	NON-EXPEDITED			US-PFIZER INC-2017505512		40 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	14327132	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2015GB177427			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Azithromycin			S	Unknown	Unk		Novartis
Abdominal Pain Upper;	Pirfenidone			S	Oral	801 Mg, Qd		Not Reported
Alopecia; Anxiety;	Pirfenidone			S	Oral	801 Mg, Qd		Not Reported
Asthenia; Breast Pain;	Pirfenidone			S	Oral	Full Dose		Not Reported
Cataract; Cellulitis; Chest Pain; Condition	Esbriet			S	Oral	2403 Mg, Unk		Not Reported
Aggravated; Cough;	Esbriet			S	Oral	2403 Mg, Unk		Not Reported
Death; Depressed Mood; Depression; Drug Ineffective; Dyspnoea; Erythema; Fatigue; Flushing; Frequent Bowel Movements; Gastrointestinal Disorder; Gastrointestinal Pain; Gastrointestinal Pain; Gastroesophageal Reflux Disease; General Physical Health Deterioration; Haemoptysis; Headache; Heart Rate Increased; Hiatus Hernia; Hypotension; Increased Upper Airway Secretion; Inguinal Hernia; Insomnia; Jaw Cyst; Lethargy; Lower Respiratory Tract Infection; Malaise; Musculoskeletal Stiffness; Nasopharyngitis; Osteomyelitis; Oxygen Saturation Decreased; Panic Attack; Pneumonia; Pneumonia; Productive Cough; Pruritus; Pulmonary Function Test								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Decreased; Pulmonary
Oedema; Pulmonary Pain;
Rash; Seasonal Allergy;
Seborrhoea; Skin Irritation;
Skin Ulcer; Sunburn;
Swelling; Tearfulness;
Therapeutic Product Effect
Decreased; Tinnitus;
Tooth Injury; Total Lung
Capacity Decreased;
Tremor; Ulcer; Upper-
Airway Cough Syndrome;
Vertigo; Viral Infection;
Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	14557274	EXPEDITED (15-DAY)		HO, OT	NL-MYLANLABS-2018M1010876		65 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Appetite Disorder; Back Pain; Bone Pain; Chronic Obstructive Pulmonary Disease; Dehydration; Dizziness; Fatigue; Headache; Hypersensitivity; Malaise; Myalgia; Nausea; Pneumonia; Sense Of Oppression; Vomiting; Weight Decreased	Azithromycin			S		Unk		Not Reported	
	Adenuric			S		Unk, Unknown		Mylan	
	Teriparatide			S	Subcutaneous	20 Microgram, Qd		Not Reported	
	Teriparatide			S	Subcutaneous	20 Microgram, Qd		Not Reported	
	Teriparatide			S	Subcutaneous	20 Microgram, Qd		Not Reported	
	Teriparatide			S	Subcutaneous	20 Microgram, Qd		Not Reported	
	Nebusal			S	Respiratory (inhalation)	2 Df, Qd		Mylan	
	Spironolacton			C	Oral	1 Df, Qd		Mylan	
	Beclometasone Dipropionate W/Formoterol Fumar			C	Oral	6 Df, Qd (2 Df, Tid)		Mylan	
	Budesonide			C	Oral	Unk		Mylan	
	Pantoprazol			C	Oral	2 Df, Qd		Mylan	
	Itraconazol			C	Oral	1 Df, Bid		Mylan	
	Macrogol			C	Oral	Unk		Mylan	
	Benzbromaron			C	Oral	1 Df, Daily		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Benzbromaron	C	Oral	0.5 Df, Qd	Mylan
Levothyroxine	C	Oral	3 Df, Qd	Mylan
Levothyroxine	C		1 Df, Qd	Mylan
Paracetamol	C	Oral	1 Df, Qid	Mylan
Paracetamol	C	Oral	1 Df, Tid	Mylan
Hidroxocobalamina	C	Subcutaneous	Unk	Mylan
Kaliumchloride	C	Oral	3d1t	Mylan
Oxicodona	C	Oral	8 Df, Qd (2 Df, Qid)	Mylan
Colchicine	C	Oral	2 Df, Qd (1 Df Bid)	Mylan
Codeine	C	Oral	3 Df, Qd (1 Df, Tid)	Mylan
Azitromycine	C	Oral	3 Df, Unk	Mylan
Azitromycine	C	Oral	1 Df, 3/W	Mylan
Sodium Chloride	C	Subcutaneous	1 Df, Monthly (1/M)	Mylan
Paracetamol Codeine	C	Rectal	Unk	Mylan
Acetylcysteine	C	Oral	1 Df, Daily	Mylan
Calciumcarbonaat	C	Oral	2 Df, Qd	Mylan
Ipratropium W/Salbutamol	C	Oral	Unk	Mylan
Algeldrate W/Magnesium Hydroxide	C	Oral	30 MI, Qd	Mylan
Fentanyl	C	Topical	Unk	Mylan
Oxycodon	C	Oral	Unk	Mylan
Labetalol	C	Oral	1 Df, Daily	Mylan
Sumatriptan	C	Oral	Unk	Mylan
Desloratadine	C	Oral	2 Df, Qd	Mylan
Metoclopramide	C	Oral	1 Df, Prn	Mylan
Colistine	C	Oral	2 Df, Qd (1 Df, Bid)	Mylan
Ezetimibe W/Simvastatin	C	Oral	1 Df, Qd	Mylan
Pregabaline	C	Oral	3 Df, Bid	Mylan
Salbutamol	C	Respiratory (inhalation)	Unk	Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nystatine	C	Oral	5 MI, Qid	Mylan
Colecalciferol	C	Oral	2 Df, Unk	Mylan
Moxifloxacin	C	Oral	1 Df, Qd	Mylan
Carbasalaatcalcium	C	Oral	1 Df, Qd	Mylan
Metoclopramide	C	Rectal	1 Df, Prn	Mylan
Metformine	C	Oral	2 Df, Qd (1 Df, Bid)	Mylan
Prednisolon /00016201/	C		1 Df, Qd	Mylan
Tiotropium	C	Oral	2 Df, Qd	Mylan
Nortriptyline	C	Oral	Unk	Mylan
Bumetanide	C	Oral	2 Df, Qd (1 Df, Bid)	Mylan
Fluticasone Furoate	C	Nasal	2 Df, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15778890	EXPEDITED (15-DAY)		DE	ET-PFIZER INC-2018533409		7 YR	Female	ETH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Product Use Issue; Vomiting	Zithromax			S	Oral	500 Mg, Stat (At Once)		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15848975	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2019023066			Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Adrenal Insufficiency; Adverse Food Reaction; Agonal Rhythm; Alopecia;	Diflucan			S	Unknown	Unk Unk, Qod		Pfizer	
Arthralgia; Arthralgia;	Diflucan			S	Unknown	Unk		Pfizer	
Arthralgia; Asthenia;	Azithromycin			S	Unknown	1 Df, 1x/Day		Pfizer	
Constipation; Depression;	Itraconazole			S		400 Mg, Daily (200 Mg, 2xday)		Not Reported	
Diarrhoea; Dry Eye;	Itraconazole			S		400 Mg, Daily (200mg)		Not Reported	
Dysgeusia; Fatigue;	Avelox			S	Unknown	Unk		Not Reported	
Flatulence; Gait Disturbance;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastrointestinal Pain;	Ivermec	S	Unknown	Unk, Qod	Not Reported
Headache; Hormone Level	Ivermec	S	Unknown	Unk	Not Reported
Abnormal; Hypoaesthesia;	Prohance [Gadoteridol]	S	Unknown	Unk	Not Reported
Hypoaesthesia;	Prohance [Gadoteridol]	S		Unk	Not Reported
Incontinence; Injection	Cortisone	S	Unknown	1 Df, 1x/Day (1 Df, Per Day)	Not Reported
Site Pain; Joint Ankylosis;	Moxifloxacin Krka	S	Unknown	1 Df, 1x/Day (1 Df, 1x Per Day)	Not Reported
Joint Swelling;	Anaerobex	S	Unknown	2 Unknown Unit, Daily (Unk, 2x Per Day)	Not Reported
Menstruation Irregular;	Pantoloc [Pantoprazole]	C		40 Mg, 1x Per Day	Not Reported
Metabolic Disorder;	Pantoloc [Pantoprazole]	C	Unknown	Unk	Not Reported
Mitochondrial Toxicity;	Pantelmin	C	Unknown	Unspecified, 2x Per Day	Not Reported
Mucosal Dryness; Muscle					
Injury; Muscle Spasticity;					
Muscular Weakness;					
Musculoskeletal Pain;					
Musculoskeletal Pain;					
Musculoskeletal Stiffness;					
Nausea; Nervous System					
Disorder; Neuralgia;					
Neuropathy Peripheral;					
Pain; Pain In Extremity;					
Panic Attack;					
Paraesthesia;					
Paraesthesia; Photopsia;					
Skin Irritation; Suicidal					
Ideation; Suicide Attempt;					
Swelling; Temperature					
Intolerance; Tendon Injury;					
Vein Rupture; Vertigo;					
Vision Blurred; Visual					
Impairment; Vomiting;					
Weight Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15877889	EXPEDITED (15-DAY)		OT	US-SA-2019SA020253		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Body	Arava			S		Unk		Sanofi
Height Decreased;	Methotrexate			S		Unk		Not Reported
Diabetes Mellitus; Drug	Azithromycin			S		Unk		Not Reported
Ineffective;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastrointestinal Disorder; Hip Arthroplasty; Intervertebral Disc Protrusion; Lip Squamous Cell Carcinoma; Psoriasis; Skin Cancer	Sulfasalazine Humira Enbrel Otezla Xeljanz Xr Xeljanz Xr Rituxan	S S S S S S C		Unk Subcutaneous Unk Unk Oral 11 Mg, Qid Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15878191	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-002976		28 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia	Azithromycin			S	Oral	250 Dosage Form, Unk			Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15878194	NON-EXPEDITED			US-PFIZER INC- 2019038007		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin Erythromycin			S S		Unk Unk			Pfizer Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15878284	NON-EXPEDITED		OT	US-PFIZER INC- 2019029594		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15878338	NON-EXPEDITED			US-PFIZER INC- 2019031463		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15878623	NON-EXPEDITED			US-PFIZER INC-2019038136		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15879242	EXPEDITED (15-DAY)		OT	FR-ZYDUS-032922		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Aripiprazole			S	Oral			Not Reported	
	Paracetamol			S	Intravenous (not otherwise specified)			Not Reported	
	Acetorphan			S	Oral	100 Mg Capsule		Not Reported	
	Potassium			S	Oral	Lp 1000 Mg Prolonged-Release Tablet		Not Reported	
	Azithromycin			S	Oral			Zydus Pharm	
	Xeplion			S	Intramuscular			Not Reported	
	Smectite			S	Oral			Not Reported	
	Levothyroxine			S	Oral	50 Micrograms, Scored Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880334	DIRECT	Y	HO			56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cholelithiasis; Hepatic Steatosis; Hepatitis Acute; Hepatocellular Injury;	Azithromycin			S	Oral			Teva	
	Atorvastatin 40mg			C				Not Reported	
	Tamsulosin 0.4mg			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nausea; Vomiting	Hyzaar 100/12.5mg	C	Not Reported
	Carvedilol 25mg	C	Not Reported
	Aspirin 325mg	C	Not Reported
	Tramadol 50mg	C	Not Reported
	Spironolactone 50mg	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880441	DIRECT		HO			64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Balance Disorder; Drug Ineffective; Nystagmus; Vertigo; Vomiting; Wheezing	Azithromycin Tablets, Usp			S	Oral	Quantity:6 Tablet(S);		Sandoz
	Cardura			C				Not Reported
	Metoprolol			C				Not Reported
	Protonix			C				Not Reported
	Norvasc			C				Not Reported
	Proscar			C				Not Reported
	Lipitor			C				Not Reported
	Valium			C				Not Reported
	Prednisone			C				Not Reported
	Meclizine			C				Not Reported
	Baby Asa			C				Not Reported
	Claritin			C				Not Reported
	Mvi			C				Not Reported
	Mega Reds			C				Not Reported
	Vit D3			C				Not Reported
	Zantac			C				Not Reported
	Cold Calm			C				Not Reported
	Mucinex			C				Not Reported
	Cherry Tart Tablets			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880541	NON-EXPEDITED			US-TEVA-2019-US-999535		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Dyspnoea	Azithromycin Tablet			S	Unknown			Not Reported
	Azithromycin Tablet			S				Not Reported
	Azithromycin Tablet			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unknown Green Vitamin	C	Unknown	Not Reported
Fenofibrate	C	Unknown	Not Reported
Magnesium	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880549	DIRECT		HO, LT, OT			30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Conjunctivitis; Drug Hypersensitivity; Herpes Virus Infection	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2019	15880972	NON-EXPEDITED			US-PFIZER INC- 2019034103			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash Macular; Urticaria	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	11544419	NON-EXPEDITED			US-PFIZER INC- 2015314431			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Ceclor			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	12681565	EXPEDITED (15-DAY)		HO, OT	US-DSJP-DSU-2016- 115190			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Biliary Dyskinesia; Coeliac	Benicar			S	Oral	20 Mg, Qd		Daiichi
	Z-Pak			S	Oral	250 Mg, Qd		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Disease; Dizziness;
Gastroesophageal Reflux
Disease; Sprue-Like
Enteropathy

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15750133	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2018517992		79 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Lower Respiratory Tract Infection	Azithromycin			S	Unknown	Unk		Pfizer	
	Abatacept			S	Subcutaneous	125 Mg, Weekly		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Carbocisteine			C	Unknown	Unk		Not Reported	
	Rivaroxaban			C	Unknown	Unk		Not Reported	
	Dexamethasone			C	Oral	500 Mg, Unk		Not Reported	
	Furosemide			C	Unknown	Unk		Not Reported	
	Atorvastatin			C	Unknown	Unk		Not Reported	
	Digoxin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15839586	EXPEDITED (15-DAY)		HO	AU-TEVA-2019-AU-997703			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Toxicity To Various Agents	Azithromycin			S	Unknown			Not Reported	
	Pravastatin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15882629	EXPEDITED (15-DAY)		OT	FR-ROCHE-2251292		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Nodule	Roactemra			S	Subcutaneous	Most Recent Dose On		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novatrex		S		Oral		05/Dec/2018.		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15884207	NON-EXPEDITED			US-PFIZER INC-2019038520		34 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15884249	NON-EXPEDITED			US-PFIZER INC-2019041604		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15884537	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1007406		182 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Erythema	Azithromycin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2019	15884876	NON-EXPEDITED			US-PFIZER INC-2019041871		15 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	12922557	EXPEDITED (15-DAY)		HO, OT	US-DSJP-DSU-2016-125963			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diverticulum; Dyspepsia; Haemorrhoids; Helicobacter Test Positive; Irritable Bowel Syndrome; Leukocytosis; Liver Function Test Increased; Sinusitis; Syncope; Vitamin D Decreased	Benicar			S	Oral	20 Mg, Unk		Daiichi	
	Benicar Hct			S	Oral	20/12.5 Mg, Qd		Daiichi	
	Azithromycin /00944303/			S		Unk		Not Reported	
	Prilosec /00661201/			C	Oral	20 Mg, Qd		Not Reported	
	Aspirin /00002701/			C	Oral	81 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15887231	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1003928		79 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis; Lower Respiratory Tract Infection	Azithromycin			S	Unknown			Not Reported	
	Abatacept			S	Subcutaneous	125 Mg, Qwk		Not Reported	
	Dexamethasone			C	Oral	500 Mg, Unk		Not Reported	
	Atorvastatin			C	Unknown			Not Reported	
	Carbocisteine			C	Unknown			Not Reported	
	Furosemide			C	Unknown			Not Reported	
	Amlodipine			C	Unknown			Not Reported	
	Digoxin			C	Unknown			Not Reported	
	Rivaroxaban			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15888003	NON-EXPEDITED			US-PFIZER INC-2019042218			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Aztreonam			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	
	Lasix			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ofloxacin		S			Unk			Not Reported
	Prednisone		S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15888277	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1004367		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycine Monohydratée			S	Oral			Not Reported	
	Flagyl			S	Oral			Not Reported	
	Deroxat			S	Unknown			Not Reported	
	Candesartan Cilexetil			C		8 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15890953	NON-EXPEDITED			US-PFIZER INC-2019033218			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Cefdinir			S		Unk		Pfizer	
	Neosporin			S		Unk		Pfizer	
	Methylparaben			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2019	15891138	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1008063		65 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	13076987	NON-EXPEDITED			US-PFIZER INC-2016594250			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	14289168	NON-EXPEDITED			US-PFIZER INC-2017535469		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15839599	EXPEDITED (15-DAY)		HO	AU-TEVA-2019-AU-997706			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Toxicity To Various Agents	Atorvastatin Calcium			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15849352	EXPEDITED (15-DAY)			HU-PFIZER INC-2019020609		26 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Pfizer	
	Azithromycin			S				Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Levofloxacin		S	Unknown	Unk			Not Reported	
	Levofloxacin		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15893842	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-197526		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Paracetamol		Y	S	Intravenous (not otherwise specified)	4 Gram, Daily		Ohm Lab	
	Abilify 5 Mg, Comprime			S	Oral	5 Milligram, Daily		Not Reported	
	Tiorfan 100 Mg, Gelule			S	Oral	3 Dosage Form, Daily		Not Reported	
	Kaleorid Lp 1000 Mg, Comprime			S	Oral	6 Gram, Daily		Not Reported	
	A Liberation Prolongee								
	Azithromycine Anhydre			S	Oral	500 Milligram, Daily		Not Reported	
	Paliperidone Palmitate			S	Intramuscular	1 Dosage Form, Monthly		Not Reported	
	Smecta			S	Oral	3 Dosage Form, Daily		Not Reported	
	Levothyrox 50 Microgrammes, Comprime Secable			S	Oral	87.5 Microgram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15895739	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC- 2019038941		84 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Asthma; Ventricular Tachycardia	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896228	EXPEDITED (15-DAY)		DS	FR-TEVA-2019-FR- 1005418		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Izilox		S	Oral	400 Milligram Daily;		Not Reported		
	Myambutol		S	Oral	800 Milligram Daily;		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896473	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019038635		4 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Zithromax			S	Oral	150 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2019	15896507	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019035097		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rheumatoid Nodule; Therapeutic Product Effect Decreased	Novatrex			S	Oral	8 Df, Weekly		Pfizer	
	Roactemra			S	Subcutaneous	162 Mg, Weekly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15760834	NON-EXPEDITED			US-PFIZER INC-2018527335			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15858439	NON-EXPEDITED			US-PFIZER INC-2019029999		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898105	EXPEDITED (15-DAY)		DS	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-197911		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Azithromycine			S	Oral	Total Daily Dose: 250 Mg Unit Dose: 250 Mg		Sun	
	Izilox			S	Oral	Total Daily Dose: 400 Mg Unit Dose: 400 Mg		Not Reported	
	Myambutol			S	Oral	Total Daily Dose: 800 Mg Unit Dose: 800 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898398	EXPEDITED (15-DAY)		DE, OT	PT-AUROBINDO-AUR- APL-2019-004305			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Failure; Multiple Organ Dysfunction Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15898955	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-004299			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin			S	Oral	Unk		Aurobindo	
	Flagyl			S	Oral	Unk		Not Reported	
	Deroxat			S				Not Reported	
	Candesartan			C	Unknown	8 Milligram, Once A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15899581	NON-EXPEDITED			US-PFIZER INC-2019047214		67 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15899967	NON-EXPEDITED			US-VERTEX PHARMACEUTICALS-2018-008704			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Insurance Issue; Nausea; Product Dose Omission	Symdeko			S	Oral	100mg Tezacaftor/150mg Ivacaftor Am; 150mg Ivacaftor Pm		Vertex	
	Azithromycine			S	Unknown	In Every 2 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15900519	EXPEDITED (15-DAY)		HO, OT	UA-TEVA-2019-UA-1005885			Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia	Sumamed 500 Mg Tablets			S	Unknown	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15900717	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019048990		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease;	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Infection; Therapeutic
Product Effect Incomplete;
White Blood Cell Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15901592	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT020456		47 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Gonorrhoea; Rash Maculo-Papular	Ceftriaxone			S	Intravenous (not otherwise specified)			Novartis
	Azithromycin			S		Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2019	15902215	NON-EXPEDITED			US-PFIZER INC- 2019047248			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Cipro [Ciprofloxacin]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2019	15903095	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB- 1006853		6 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematochezia	Azithromycin			S	Oral			Not Reported
	Docusate			C				Not Reported
	Hydrocortisone			C				Not Reported
	Domperidone			C				Not Reported
	Hyoscine Hydrobromide			C				Not Reported
	Lansoprazole			C				Not Reported
	Vigabatrin			C				Not Reported
	Sodium Chloride			C		Twice A Day		Not Reported
	Movicol			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cetirizine	C	Not Reported
Brufen	C	Not Reported
Buscopan	C	Not Reported
Baclofen	C	Not Reported
Sodium Chloride Solution 0.9%	C	Not Reported
Sodium Valproate	C	Not Reported
Zoladex La	C	Not Reported
Subcutaneous		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2019	15903139	NON-EXPEDITED			US-TEVA-2019-US-996016			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Migraine; Product Substitution Issue	Azithromycin			S				Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2019	15701812	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2018-CA-984100		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diltiazem			S	Unknown	1 Dosage Forms Daily;		Teva
Alopecia; Asthenia;	Prednisone			S	Unknown	50 Milligram Daily;		Actavis
Asthma; Balance Disorder;	Prednisone			S	Unknown			Actavis
Bladder Disorder; Blood	Prednisone			S	Unknown			Actavis
Glucose Abnormal; Blood	Prednisone			S	Unknown			Actavis
Pressure Systolic	Prednisone			S	Unknown			Actavis
Increased; Body	Prednisone			S	Unknown			Actavis
Temperature Decreased;	Prednisone			S	Unknown			Actavis
Brain Hypoxia; Breath	Prednisone			S	Unknown			Actavis
Odour; Breath Sounds	Prednisone			S	Unknown			Actavis
Abnormal; Bronchitis;	Prednisone			S	Unknown			Actavis
Carbon Dioxide Increased;	Prednisone			S	Unknown			Actavis
Chest Discomfort; Chest	Prednisone			S	Unknown			Actavis
Pain; Cough; Crepitations;	Prednisone			S	Unknown			Actavis
Diarrhoea; Dizziness;	Prednisone			S	Unknown			Actavis
Dizziness; Drug	Prednisone			S	Unknown			Actavis
Ineffective; Dyspepsia;	Prednisone			S	Unknown	50 Milligram Daily;		Actavis
Dyspnoea; Dyspnoea	Prednisone			S	Unknown			Actavis
Exertional; Fall; Fatigue;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Feeling Abnormal; Forced Expiratory Volume	Prednisone	S	Unknown	50 Milligram Daily;	Actavis
Decreased; Frustration	Prednisone	S	Unknown		Actavis
Tolerance Decreased;	Prednisone	S	Unknown		Actavis
Gait Disturbance;	Prednisone	S	Unknown		Actavis
Gastrooesophageal Reflux Disease; General Physical Health Deterioration;	Prednisone	S	Unknown		Actavis
Haemarthrosis; Headache;	Prednisone	S	Unknown		Actavis
Headache; Heart Rate Increased; Humidity Intolerance;	Prednisone	S	Unknown	50 Milligram Daily;	Actavis
Hypersensitivity;	Ventolin	S	Unknown		Not Reported
Hypoventilation; Infection;	Ventolin	S	Unknown	40 Dosage Forms Daily;	Not Reported
Injury; Insomnia; Joint Swelling; Lung Disorder;	Ventolin	S	Unknown		Not Reported
Malaise; Memory Impairment; Muscle Disorder; Muscle Spasms;	Ventolin	S	Unknown	8 Dosage Forms Daily;	Not Reported
Musculoskeletal Discomfort;	Ventolin	S	Unknown		Not Reported
Nasopharyngitis;	Ventolin	S	Unknown		Not Reported
Odynophagia; Oral Candidiasis;	Ventolin	S	Unknown		Not Reported
Oropharyngeal Pain; Pain In Extremity; Palpitations;	Xolair	S	Subcutaneous		Not Reported
Paraesthesia; Peak Expiratory Flow Rate	Xolair	S	Subcutaneous		Not Reported
Abnormal; Peak Expiratory Flow Rate Decreased;	Xolair	S	Subcutaneous		Not Reported
Peripheral Swelling;	Xolair	S	Subcutaneous		Not Reported
Pneumonia; Pollakiuria;	Xolair	S	Subcutaneous		Not Reported
Poor Quality Sleep;	Xolair	S	Subcutaneous		Not Reported
Productive Cough;	Xolair	S	Subcutaneous		Not Reported
Pulmonary Function Test Decreased; Pyrexia;	Xolair	S	Subcutaneous		Not Reported
Respiratory Rate Increased; Respiratory Tract Congestion;	Xolair	S	Subcutaneous		Not Reported
Rhinorrhoea; Seasonal Allergy; Sputum Discoloured; Stress;	Xolair	S	Subcutaneous		Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Tendonitis; Tremor; Viral Infection; Vomiting; Weight Decreased; Wheezing	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Xolair	S	Subcutaneous		Not Reported
Zithromax	S	Unknown		Not Reported
Zithromax	S			Not Reported
Advair	C		2 Dosage Forms Daily;	Not Reported
Advair	C			Not Reported
Alvesco	C	Unknown		Not Reported
Atrovent	C	Unknown		Not Reported
Calcium Carbonate/Sodium Alginate	C	Oral	2 Dosage Forms Daily;	Not Reported
Calcium Carbonate/Sodium Alginate	C	Oral	4 Dosage Forms Daily;	Not Reported
Dexilant	C	Unknown	1 Dosage Forms Daily;	Not Reported
Ipratropium Bromide/Salbutamol Sulfate	C	Unknown		Not Reported
Spiriva	C	Unknown	2 Dosage Forms Daily;	Not Reported
Tums	C	Unknown		Not Reported
Zenhale	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	9990520	NON-EXPEDITED			US-PFIZER INC-2014063699			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	13234526	NON-EXPEDITED			US-PFIZER INC-2017057242		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Percocet			S		Unk		Not Reported	
	Theraflu			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	14037730	NON-EXPEDITED			US-PFIZER INC-2017426160			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Demerol			S		Unk		Pfizer	
	Zithromax Z-Pack			S		Unk		Not Reported	
	Imitrex			S		Unk		Not Reported	
	Hydrocodone Bitartrate			S		Unk		Not Reported	
	Topamax			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	14744955	NON-EXPEDITED			US-PFIZER INC-2018144813		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Zithromax			S	Oral	750 Mg, Weekly [250 Mg Three Times Weekly]		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15531741	NON-EXPEDITED			US-PFIZER INC-2018422132			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15681551	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2018M1089671		10 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Therapeutic Product Effect Incomplete	Azithromycin			S		Unk		Not Reported	
	Clindamycin			S		Unk		Not Reported	
	Ibuprofen			S		Unk		Not Reported	
	Metronidazole			S		Unk		Not Reported	
	Penicillin /00000901/			S		Unk		Mylan	
	Vitamin D3			C		Unk		Mylan	
	Vitamin B6			C		Unk		Mylan	
	Sulfasalazine			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15756154	EXPEDITED (15-DAY)		OT	PHHY2018HU189802		26 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macule; Pharyngeal Enanthema; Pharyngeal Oedema; Product Use In Unapproved Indication; Skin Plaque; Syphilis	Levofloxacin			S	Unknown			Novartis	
	Levofloxacin			S				Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15868546	EXPEDITED (15-DAY)		OT	FR-JNJFOC-20190125103		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Campylobacter Gastroenteritis;	Xeplion			S	Intramuscular			Not Reported	
	Smecta			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypokalaemia	Levothyrox	S	Oral	Not Reported
	Abilify	S	Oral	Not Reported
	Tiorfan	S	Oral	Not Reported
	Kaleorid Lp	S	Oral	Not Reported
	Azithromycine	S	Oral	Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15884175	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019030234			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Dysphagia	Zithromac Sr 2g			S	Oral	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15905744	EXPEDITED (15-DAY)		DE, OT	US-CROSSMEDIKA SA-2062114		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Decreased Appetite; Diarrhoea; Nausea; Optic Neuritis; Visual Impairment; Weight Decreased	Moxifloxacin Hydrochloride			S				Crossmedika	
	Azithromycin Anhydrous			S				Not Reported	
	Filgrastim			C	Subcutaneous			Not Reported	
	Tacrolimus			C				Not Reported	
	Ethambutol			C				Not Reported	
	Prednisone			C				Not Reported	
	Acetylcysteine			C				Not Reported	
	Rifampin			C				Not Reported	
	Insulin Aspart			C	Subcutaneous			Not Reported	
	Pentamidine			C	Respiratory (inhalation)			Not Reported	
	Atorvastatin			C				Not Reported	
	Levemir			C	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15906967	NON-EXPEDITED			US-PFIZER INC-2019051313		78 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Macrobid [Clarithromycin]			S		Unk		Not Reported	
	Percocet [Oxycodone Hydrochloride;Paracetamol]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15906969	NON-EXPEDITED			US-PFIZER INC-2019051443		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	E-Mycin [Erythromycin]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15909624	EXPEDITED (15-DAY)		DS	FR-PFIZER INC-2019043212		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Visual Impairment	Azithromycine			S	Oral	250 Mg, 1x/Day		Pfizer	
	Izilox			S	Oral	400 Mg, 1x/Day		Not Reported	
	Myambutol			S	Oral	800 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	15913286	NON-EXPEDITED			US-PFIZER INC-2019043879			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nystagmus; Vomiting	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	16017855	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Wrong Product Stored	Azithromycin			S				Not Reported	
	Vancomycin Hcl			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2019	16017949	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Packaging Confusion	Protonix			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	13286637	NON-EXPEDITED			US-PFIZER INC-2017081694			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Arthrotec			S		Unk (75)		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Extendryl			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Colchicine			S		Unk		Not Reported	
	Meclizine			S		Unk		Not Reported	
	Methylscopolamine			S		Unk		Not Reported	
	Sulfanilamide			S		Unk		Not Reported	
	Vioxx			S		Unk		Not Reported	
	Dexchlorpheniramine Maleate			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	14352153	NON-EXPEDITED			US-PFIZER INC-2017551686		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash; Urticaria; Vomiting	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Amoxicillin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15609108	EXPEDITED (15-DAY)		CA, OT	UG-MYLANLABS-2018M1084907			Female	UGA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Birth Mark; Congenital Umbilical Hernia; Foetal Exposure During Pregnancy; Sepsis Neonatal; Umbilical Granuloma	Tenofovir Df/Lamivudine/Efavirenz Tablets 300/300/600mg			S	Transplacental	1 Df, Qd		Mylan	
	Azithromycin			S	Transplacental	Unk		Mylan	
	Coartem			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15784859	EXPEDITED (15-DAY)		OT	JP-ROCHE-2237939		21 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction	Xofluza			S	Oral			Not Reported	
	Zithromac			S	Unknown			Not Reported	
	Flomox (Japan)			C				Not Reported	
	Calonal			C	Oral			Not Reported	
	Resplen			C	Oral			Not Reported	
	Polaramine			C	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15917333	NON-EXPEDITED			US-CELGENEUS-USA-20190110110			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Arthralgia	Revlimid			S	Oral	25 Milligram		Celgene	
	Revlimid			S	Oral	10 Milligram		Celgene	
	Revlimid			S	Oral	10 Milligram		Celgene	
	Z-Pak			S	Unknown			Not Reported	
	Kyprolis			C	Unknown			Not Reported	
	Neupogen			C	Unknown			Not Reported	
	Tylenol			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15918046	EXPEDITED (15-DAY)		HO	UA-TEVA-2019-UA-1008348		152 DAY	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Sumamed Suspension 100 Mg/5 MI			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15918437	NON-EXPEDITED			PHEH2019US004561			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Gastrointestinal Disorder	Azithromycin			S	Oral	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15920233	NON-EXPEDITED			US-PFIZER INC-2019052130		71 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Disorder; Drug Interaction	Zithromax	S	Unk	Pfizer
	Warfarin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15921194	EXPEDITED (15-DAY)		HO	PHEH2019US004506		64 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysstasia; Eye Disorder; Tremor; Vomiting	Azithromycin			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	15922989	DIRECT						Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxil			S				Not Reported
	Zithromax			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2019	16034881	DIRECT		DE, DS			73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia; Rash; Rash Pruritic	Azithromycin	Y		S	Oral	Quantity:250 Mg Milligram(S)		Wockhardt
	Hyzaar			C				Not Reported
	Amlopidine			C				Not Reported
	Latanoprost			C				Not Reported
	B-Complex			C				Not Reported
	Vitamin C			C				Not Reported
	Cod Liver Oil			C				Not Reported
	Asa			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	13257488	NON-EXPEDITED			US-PFIZER INC-2017070457		62 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15409093	EXPEDITED (15-DAY)		DE, HO, OT	GB-PFIZER INC-2017513728			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain Upper; Alopecia; Anxiety; Asthenia; Asthenia; Breast Pain; Cataract; Cataract; Cellulitis; Chest Pain; Chest Pain; Condition Aggravated; Cough; Death; Depressed Mood; Depression; Drug Ineffective; Dyspnoea; Dyspnoea; Erythema; Fatigue; Fatigue; Flushing; Frequent Bowel Movements; Gastrointestinal Disorder; Gastrointestinal Pain; Gastrooesophageal Reflux Disease; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Haemoptysis; Headache; Heart Rate Increased; Hiatus Hernia; Hypotension; Increased Upper Airway Secretion; Inguinal Hernia; Insomnia; Jaw Cyst; Lethargy; Lower Respiratory Tract	Azithromycin			S		Unk		Pfizer
	Pirfenidone			S	Oral	801 Mg, Daily		Not Reported
	Pirfenidone			S	Oral	801 Mg, Daily		Not Reported
	Pirfenidone			S	Oral	Full Dose		Not Reported
	Pirfenidone			S	Oral	2403 Mg, Unk		Not Reported
	Pirfenidone			S	Oral	2403 Mg, Unk		Not Reported

Infection; Lower
Respiratory Tract
Infection; Malaise;
Musculoskeletal Stiffness;
Musculoskeletal Stiffness;
Nasopharyngitis;
Osteomyelitis;
Osteomyelitis; Oxygen
Saturation Decreased;
Panic Attack; Pneumonia;
Pneumonia; Productive
Cough; Pruritus; Pruritus;
Pulmonary Function Test
Decreased; Pulmonary
Oedema; Pulmonary Pain;
Rash; Seasonal Allergy;
Seborrhoea; Skin Irritation;
Skin Ulcer; Sunburn;
Swelling; Tearfulness;
Therapeutic Product Effect
Decreased; Tinnitus;
Tooth Injury; Total Lung
Capacity Decreased;
Tremor; Ulcer; Upper-
Airway Cough Syndrome;
Vertigo; Viral Infection;
Weight Decreased; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15668353	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR- APL-2018-057439			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Intentional Self-Injury; Substance Abuse	Amoxicillin+Clavulanic Acid			S	Oral	1 Gram, In Total		Aurobindo	
	Paracetamol			S	Oral	1000 Milligram Total		Aurobindo	
	Azithromycin			S	Oral	1500 Milligram Total		Aurobindo	
	Nimesulide			S	Oral	1500 Milligram, In Total		Not Reported	
	Oki			S	Unknown	120 Milligram, In Total		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15692394	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-192815		16 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Intentional Self-Injury; Substance Abuse	Nimesulide			S	Oral	In Total		Not Reported	
	Azithromycin			S	Oral	In Total		Sun	
	Amoxicillin/Clavulanic Acid			S	Oral	In Total		Ranbaxy	
	Paracetamol			S	Oral	In Total		Not Reported	
	Oki 80 Mg Granulato Per Soluzione Orale			S	Unknown	In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15804036	EXPEDITED (15-DAY)		OT	PHHY2019IT002284		40 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hyperaemia; Periorbital Swelling	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Gentalyn			S	Topical	1 Mg/L, Unk		Not Reported	
	Brufen			S	Oral	600 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15807194	EXPEDITED (15-DAY)		HO, LT	GB-MYLANLABS- 2019M1001394			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Angina Pectoris; Arrhythmia; Blood Iron Decreased; Dizziness; Electrocardiogram Qt Prolonged; Loss Of Consciousness; Nausea; Pain; Pulmonary Congestion; Syncope;	Azithromycin			S	Unknown			Not Reported	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Cefotaxime			C	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Torsade De Pointes;
Transferrin Saturation
Decreased; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15923164	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019051583		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Ineffective; Product Use Issue	Zithromax			S	Oral	250 Mg, Three Times Per Week On Monday, Wednesday And Friday As Directed		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15923448	EXPEDITED (15-DAY)		OT	BE-ACCORD-105795			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Interaction; Renal Failure	Itraconazole Azithromycin Crestor Tildiem			S S S S				Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15925112	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA- 1008319			Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia	Sumamed			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15925578	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-005014			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Azithromycin			S	Oral	120 Milligram		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Docusate	C	Unknown	Unk	Not Reported
	Hydrocortisone	C	Unknown	Unk	Not Reported
	Domperidone	C	Unknown	Unk	Not Reported
	Hyoscine Hydrobromide	C	Unknown	Unk	Not Reported
	Lansoprazole	C	Unknown	Unk	Not Reported
	Vigabatrin	C	Unknown	Unk	Not Reported
	Sodium Chloride	C	Unknown	Unk, Twice A Day	Not Reported
	Movicol	C	Unknown	Unk	Not Reported
	Cetirizine	C	Unknown	Unk	Not Reported
	Brufen	C	Unknown	Unk, As Necessary	Not Reported
	Buscopan	C	Unknown	Unk	Not Reported
	Baclofen	C	Unknown	Unk	Not Reported
	Sodium Chloride 0.9%	C	Unknown	Unk	Not Reported
	Sodium Valproate	C	Unknown	Unk	Not Reported
	Zoladex La	C	Subcutaneous	1 Dosage Form, 10 Weeks	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15925851	EXPEDITED (15-DAY)		OT	US-BION-007775			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bruxism; Seizure; Tremor	Benzonatate			S				Not Reported
	Naproxen Sodium			S				Not Reported
	Gabapentin			S				Not Reported
	Cyclobenzaprine			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15925857	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-005711			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Gonorrhoea; Rash Maculo-Papular	Ceftriaxone			S	Intravenous (not	Unk		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin		S		otherwise specified) Unknown		Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15926317	EXPEDITED (15-DAY)		OT	PHHY2019FR027253			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Thrombocytopenia	Azithromycin			S	Unknown	Unk		Novartis	
	Abatacept			S	Unknown	125 Mg, Q3w		Not Reported	
	Cymbalta			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2019	15929347	NON-EXPEDITED			PHEH2019US004970			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Eye; Lymphadenopathy; Odynophagia	Azithromycin			S	Unknown	250 Mg, Unk		Novartis	
	Tums			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	10031689	NON-EXPEDITED			US-PFIZER INC- 2014082352			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	10644214	NON-EXPEDITED			US-PFIZER INC- 2014335589		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Sulfamethoxazole			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	14436364	EXPEDITED (15-DAY)		HO, OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2018-006621		90 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage; Haematemesis	Eliquis			S	Oral	5 Meq, Every 1 Day		Bristol Myers Squibb	
	Azithromycin			S	Unknown			Not Reported	
	Acetaminophen			C	Unknown			Not Reported	
	Calcium			C	Unknown			Not Reported	
	Finasteride			C	Unknown			Not Reported	
	Metoprolol			C	Unknown			Not Reported	
	Pregabalin			C	Unknown			Not Reported	
	Vitamin D /00107901/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	14739902	NON-EXPEDITED			US-PFIZER INC- 2018146256		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15065660	NON-EXPEDITED			US-PFIZER INC- 2018257053		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15793494	NON-EXPEDITED			US-PFIZER INC- 2019005549		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Dyspnoea	Zithromax	S	Oral	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15838474	EXPEDITED (15-DAY)		HO, OT	PHHY2019ES009716		63 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15864433	EXPEDITED (15-DAY)		OT	PHHY2019FR012808		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Aripiprazole			S	Oral	5 Mg, Qd		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	4 G, Qd		Not Reported
	Azithromycin Monohydrate			S	Oral	500 Mg, Qd		Not Reported
	Abilify			S	Oral	5 Mg, Qd		Not Reported
	Tiorfan			S	Oral	3 Df, Qd (3 Ug/Litre)		Not Reported
	Tiorfan			S	Oral	3 Df, Qd (3 Ug/Litre)		Not Reported
	Kaleorid Lp			S	Oral	6 G, Qd		Not Reported
	Xeplion			S	Intramuscular	1 Df, Qmo (1 Ug/Litre)		Not Reported
	Smecta			S	Oral	3 Df, Qd (3 Sachet/ Day)		Not Reported
	Levothyroxine Sodium			S	Oral	87.5 Ug, Qd		Not Reported
	Racecadotril			S	Oral	3 Df, Qd (3 Dosage Form Every 1 Day)		Not Reported
	Potassium Chloride			S	Oral	6 G, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15916083	EXPEDITED (15-DAY)		HO, OT	PHHY2019BG021413		72 YR	Female	BGR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Azithromycin			S	Unknown	Unk		Novartis	
	Azithromycin			S			Novartis		
	Azithromycin			S			Novartis		
	Azithromycin			S			Novartis		
	Azithromycin			S			Novartis		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932197	NON-EXPEDITED			US-PFIZER INC-2019056788		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Rash; Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932212	NON-EXPEDITED			US-PFIZER INC-2019056329		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932246	NON-EXPEDITED			US-PFIZER INC-2019046016		87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Meperidine Hcl			S		Unk		Unknown	
	Demerol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cephalexin [Cefalexin]			S		Unk		Not Reported	
	Percocet [Oxycodone]			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrochloride;Oxycodone
Terephthalate;Paracetamol]
Cipro [Ciprofloxacin]
Tylenol W/Codeine

S
S

Unk
Unk

Not Reported
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932314	NON-EXPEDITED			US-PFIZER INC- 2019053854		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Palpitations	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932427	EXPEDITED (15-DAY)		HO, OT	US-AMGEN- USASP2019017327		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Colitis; Haematuria; Lung Infiltration; White Blood Cell Count Increased	Neulasta			S	Unknown	6 Mg, Unk		Amgen
	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Vancomycin			S	Oral	Unk		Not Reported
	Aztreonam			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Gemcitabine			C		Unk		Not Reported
	Paclitaxel Albumin			C		Unk		Not Reported
	Darunavir			C		Unk		Not Reported
	Cobicistat			C		Unk		Not Reported
	Truvada			C		Unk		Not Reported
	Raltegravir			C		Unk		Not Reported
	Metronidazole			C		Unk		Not Reported
	Tamiflu			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932463	NON-EXPEDITED			US-PFIZER INC-2019056598		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932481	NON-EXPEDITED			US-PFIZER INC-2019056716		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Aspirin (E.C.)			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15932560	EXPEDITED (15-DAY)		HO, OT	IT-APOTEX-2019AP007226		67 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia Bacterial; Rhodococcus Infection; Treatment Noncompliance	Mycophenolate			S	Unknown	500 Mg, Bid		Apotex	
	Azithromycin			S	Oral	250 Mg, Qd		Apotex	
	Levofloxacin			S	Oral	750 Mg, Qd		Apotex	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Tacrolimus			S		1.5 Mg, Unk		Not Reported	
	Methylprednisolone			S	Unknown	6 Mg, Qd		Not Reported	
	Meropenem			S	Unknown	1 G, Bid		Not Reported	
	Moxifloxacin			S	Oral	400 Mg, Qd		Not Reported	
	Pentamidine Isethionate			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15933610	EXPEDITED (15-DAY)		DS	GB-MYLANLABS-2019M1010873		73 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Ear Discomfort	Azithromycin			S	Oral	750 Milligram, Qw		Not Reported	
	Anoro			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15934250	NON-EXPEDITED			US-PFIZER INC-2019054313		70 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Pregabalin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15934318	NON-EXPEDITED			US-PFIZER INC-2019054181			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15934846	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2062317		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Tachycardia	Azithromycin			S	Oral			Wockhardt	
	Multivitamin			C				Not Reported	
	Calcium Supplements			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2019	15935029	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1010639		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Clostridium Difficile Colitis; Diarrhoea	Azithromycin			S	Unknown	Received The Week Before Anal Sphincterotomy And Haemorrhoidectomy, Performed In August 2015		Not Reported	
	Ciprofloxacin			S	Oral	Started A Week After Anal Sphincterotomy And Haemorrhoidectomy		Not Reported	
	Ciprofloxacin			S	Unknown	Received Multiple Courses On And Off		Not Reported	
	Ciprofloxacin			S	Unknown	Unk		Not Reported	
	Ciprofloxacin			S	Oral	Received Additional 2-Week Course In September 2015		Not Reported	
	Clindamycin			S	Unknown	Single Dose Prior To Perianal Abscess Incision		Not Reported	
	Clindamycin			S	Unknown	For An Episode Of Group C Streptococcal-Positive Pharyngitis		Not Reported	
	Clindamycin			S	Unknown	Two Weeks After Tonsillectomy		Not Reported	
	Fluconazole			S	Oral			Not Reported	
	Rifaximin			S	Unknown			Mylan	
	Metronidazole			C	Unknown	Started Prior To Perianal Abscess Incision		Mylan	
	Metronidazole			C	Unknown	Received Multiple Courses On And Off		Mylan	
	Metronidazole			C	Oral	Unk		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	14162336	NON-EXPEDITED			US-PFIZER INC-2017477954			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15120304	EXPEDITED (15-DAY)		HO, OT	PT-009507513-1807PRT002765		65 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Therapeutic Response Decreased	Lisinopril			S	Oral	Unk		Merck	
	Amoxicillin (+) Clavulanate Potassium			S	Unknown	Unk		Not Reported	
	Indapamide (+) Perindopril			S	Unknown	Dose Had Been Doubled		Not Reported	
	Alendronate Sodium (+) Cholecalciferol			S	Unknown	Unk		Not Reported	
	Alendronate Sodium (+) Cholecalciferol			S				Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15749672	NON-EXPEDITED			US-PFIZER INC-2018525829		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Vancomycin Hcl			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Achromycin	S	Unk	Not Reported
Achromycin	S		Not Reported
Tequin	S	Took Once	Not Reported
Nitrofurantoin	S	0.4 Mg, As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15935578	EXPEDITED (15-DAY)		LT	IT-ACCORD-106024		62 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Toxic Epidermal Necrolysis	Azithromycin			S	Oral			Not Reported	
	Quetiapine			S	Oral			Not Reported	
	Diazepam			S	Oral			Not Reported	
	Rocefin			S	Parenteral	1g/10 MI Powder And Solvent For Solution For Injection For Use		Not Reported	
	Zolpidem			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936116	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR- APL-2019-006473			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoglobin Decreased; Lung Infiltration	Ceftriaxone			S	Unknown	2 Gram,Unk		Aurobindo	
	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936440	EXPEDITED (15-DAY)		OT	HU-MACLEODS PHARMACEUTICALS US LTD- MAC2019019998			Unknown	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication; Syphilis	Levofloxacin			S	Unknown	Unk		Macleods	
	Levofloxacin			S				Macleods	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azithromycin		S	Unknown	Unk			Not Reported	
	Azithromycin		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15936474	NON-EXPEDITED		HO, OT	US-APOTEX-2019AP007339		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Clostridium Difficile Infection; Diarrhoea	Azithromycin			S	Unknown	Unk		Apotex	
	Ciprofloxacin			S	Oral	Unk		Apotex	
	Clindamycin			C	Unknown	Unk, Single		Not Reported	
	Metronidazole			C	Unknown	Unk For Two Weeks		Not Reported	
	Metronidazole			C	Unknown	Unk		Not Reported	
	Metronidazole			C	Oral	Unk		Not Reported	
	Fluconazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15937609	EXPEDITED (15-DAY)		DE	PT-MYLANLABS-2019M1011719		92 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Drug Ineffective; Enterococcal Infection; Multiple Organ Dysfunction Syndrome; Nocardiosis	Voriconazole			S		Unk		Not Reported	
	Piperacillin/Tazobactam			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Sulphamethoxazole/Trimethoprim			S		Unk		Not Reported	
	Imipenem			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15939052	NON-EXPEDITED			US-PFIZER INC-2019056311			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gabapentin			S			Unk			Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
08-Feb-2019	15939055	NON-EXPEDITED			US-PFIZER INC-2019056662		90 YR	Male	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Drug Ineffective	Zithromax			S		500 Mg, (On Day 1)		Pfizer			
	Zithromax			S		250 Mg, (Daily On Days 2-5)		Pfizer			
	Zithromax			S				Pfizer			
	Zithromax			S				Pfizer			
	Zithromax			S				Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>		
08-Feb-2019	15939092	NON-EXPEDITED			US-PFIZER INC-2019048760		74 YR	Female	USA		
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>			
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer			
	Morphine Sulfate			S		Unk		Unknown			
	Metformin Hcl			S		Unk		Pfizer			
	Piroxicam			S		Unk		Pfizer			
	Lorazepam			S		Unk		Pfizer			
	Azithromycin			S		Unk		Pfizer			
	Doxycycline Hyclate			S		Unk		Pfizer			
	Erythromycin			S		Unk		Pfizer			
	Inderal			S		Unk		Pfizer			
	Remeron			S		Unk		Not Reported			
	Duloxetine Hcl			S		Unk		Not Reported			
	Macrobid (Nitrofurantoin)			S		Unk		Not Reported			
	Prochlorperazine			S		Unk		Not Reported			
	[Prochlorperazine Edisylate]										

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sulfamethoxazole	S	Unk	Not Reported
Iodine	S	Unk	Not Reported
Lovastatin	S	Unk	Not Reported
Trazodone Hcl	S	Unk	Not Reported
Prednisolone Sodium Phosphate	S	Unk	Not Reported
Oxycodone Hcl	S	Unk	Not Reported
Methadone Hcl	S	Unk	Not Reported
Nystatin	S	Unk	Not Reported
Hyoscyamine	S	Unk	Not Reported
Pseudoephedrine Hcl	S	Unk	Not Reported
Tetanus Toxoid	S	Unk	Not Reported
Cipro [Ciprofloxacin]	S	Unk	Not Reported
Penicillin V Potassium	S	Unk	Not Reported
Magnesium Aluminum Silicate	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2019	15939125	NON-EXPEDITED			US-PFIZER INC-2019056507		87 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Tetracycline Hcl			S		Unk		Pfizer
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer
	Cefuroxime Axetil			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Nitrofurantoin Monohydrate/Macrocrystals			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2019	15941644	DIRECT		DS, HO, LT, OT			48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Fatigue; Gait Disturbance; Lymphadenopathy; Multi-Organ Disorder; Pain; Pyrexia; Rash; Seizure; Soft Tissue Swelling; Swelling	Z Pack			S	Oral	Quantity:1 Tablet(S);	5 DAY	Not Reported	
	Zolpidem Er			C				Not Reported	
	Diazepam			C				Not Reported	
	Estazolam			C				Not Reported	
	Imitrex			C				Not Reported	
	Sudafed			C				Not Reported	
	Aspirin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2019	15942268	EXPEDITED (15-DAY)		LT, OT	CZ-TEVA-2019-CZ-1008708		77 DAY	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking; Cyanosis; Tongue Oedema; Vomiting	Sumamed 20mg/ML Prasek Pro Perorální Suspenzi			S	Oral	20 Milligram Daily;		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2019	15942591	NON-EXPEDITED			US-TEVA-2019-US-1001141			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hyperaesthesia; Sensitive Skin	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2019	15942437	EXPEDITED (15-DAY)		HO, OT	PHHY2019SE027927		67 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain;	Azithromycin	S	Unknown	Unk	Novartis
Confusional State;	Azithromycin	S	Unknown	250 Mg, Unk	Novartis
Constipation; Dizziness;	Azithromycin	S			Novartis
Fatigue; Hypoaesthesia;	Xalatan	C	Unknown	Unk	Not Reported
Insomnia; Mental	Symbicort Forte	C	Unknown	Unk	Not Reported
Disorder; Muscle Spasms;					
Polyneuropathy; Syncope					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	12133580	NON-EXPEDITED			US-PFIZER INC-2016076256			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer	
Urticaria	Ampicillin Sodium			S		Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	14445070	NON-EXPEDITED			US-PFIZER INC-2018031373		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug	Zithromax			S		500 Mg, Unk (2 Pak- 250 Mg)		Pfizer	
Hypersensitivity; Nausea;	Iodine			S		Unk		Not Reported	
Rash Macular; Vomiting	Bactrim Ds			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	14452973	NON-EXPEDITED			US-PFIZER INC-2018035216			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug	Zithromax			S		Unk		Pfizer	
Hypersensitivity; Malaise									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	14543874	NON-EXPEDITED			US-PFIZER INC-2018065972			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Midazolam Hydrochloride			S		Unk		Pfizer	
	Nortriptyline			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15201329	EXPEDITED (15-DAY)		HO	PT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-179596		65 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Therapeutic Response Decreased	Amoxicillin/Clavulanic Acid			S	Unknown	()		Ranbaxy	
	Lisinopril			S	Unknown	()		Sun	
	Alendronate+Cholecalciferol			S	Unknown	()		Not Reported	
	Perindopril+Indapamide			S	Unknown	()		Not Reported	
	Azithromycin			S	Unknown	()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15478673	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2018397655		85 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium; Feeling Abnormal	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
	Carbocisteine			S		1 G, 3x/Day		Not Reported	
	Bakumondoto			S		3 G, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15894821	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2019-004221			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrial Fibrillation	Paracetamol	S	Intravenous (not otherwise specified)	4 Gram, Once A Day	Aurobindo
	Abilify	S	Oral	5 Milligram, Once A Day	Not Reported
	Tiorfan	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Kaleorid Lp	S	Oral	6 Gram, Once A Day	Not Reported
	Azithromycine	S	Oral	500 Milligram, Once A Day	Not Reported
	Xeplion	S	Intramuscular	1 Dosage Form, Every Month	Not Reported
	Smecta	S	Oral	3 Dosage Form, Once A Day	Not Reported
	Levothyrox	S	Oral	87.5 Microgram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15932330	NON-EXPEDITED			US-PFIZER INC-2019050798		33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15944713	NON-EXPEDITED			US-PFIZER INC-2019055309		21 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15947001	NON-EXPEDITED			US-PFIZER INC-2019060716		69 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Clarithromycin			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15947321	NON-EXPEDITED			US-PFIZER INC-2019062566		65 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15947352	NON-EXPEDITED			US-PFIZER INC-2019055775		42 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15947512	NON-EXPEDITED			US-PFIZER INC-2019059730		79 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Nausea; Rash	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Feb-2019	15948992	EXPEDITED (15-DAY)		HO, OT	US-BAXTER-2019BAX002029		21 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Tubulointerstitial Nephritis	Ceftriaxone Injection, Usp (In			S	Unknown			Baxter	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Dextrose)
Azithromycin

S

Unknown

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15953168	NON-EXPEDITED			US-PFIZER INC- 2019051326		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Bacitracin			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Neomycin Sulfate			S		Unk		Pfizer
	Neosporin			S		Unk		Pfizer
	Polymyxin B Sulfate			S		Unk		Unknown
	Prozac			S		Unk		Not Reported
	Ceclor			S		Unk		Not Reported
	Ciloxan			S		Unk		Not Reported
	Fluoxetine Hydrochloride			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Cefaclor			S		Unk		Not Reported
	Bacitracin Zinc			S		Unk		Not Reported
	Bacitracin			S		Unk		Not Reported
	W/Neomycin/Polymyxin B							

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2019	15953225	NON-EXPEDITED			US-PFIZER INC- 2019059514		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Azithromycin			S		Unk		Pfizer
Rash	Levofloxacin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ciprofloxacin	S	Unk	Unknown
Clarithromycin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	13832886	NON-EXPEDITED			US-PFIZER INC-2017336335			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Trumenba			S		Single Dose		Pfizer
	Zithromax			S		Unk		Pfizer
	Allopurinol			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Colchicine			S		Unk		Not Reported
	Tresiba			S		Unk		Not Reported
	Humalog			S		Unk		Not Reported
	Humalog			S		Unk (75/25)		Not Reported
	Mobic			S		Unk		Not Reported
	Mobic			S		15 Mg, Unk		Not Reported
	Z-Pak			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	14446888	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2018036047		90 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Gastrointestinal Haemorrhage; Haematemesis	Eliquis			S	Oral	5 Meq, Every 1 Day		Not Reported
	Azithromycin			S	Unknown	Unk		Pfizer
	Acetaminophen			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Finasteride			C	Unknown	Unk		Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Pregabalin			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D /00107901/

C

Unknown

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15673306	NON-EXPEDITED			US-PFIZER INC-2018480161		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		250 Mg, Daily		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15770527	EXPEDITED (15-DAY)		DE	IT-TEVA-2018-IT-992543		90 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Azithromycin Dihydrate			S	Oral	500 Milligram Daily;		Not Reported
	Lercanidipine			C	Oral			Not Reported
	Valsartan			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15797297	NON-EXPEDITED			US-PFIZER INC-2019009314		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15949850	NON-EXPEDITED			PHEH2019US006020			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort	Azithromycin			S	Unknown	250 Mg, Unk		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15949961	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1011634		14 YR	Male	UKR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Angina Pectoris	Sumamed			S	Unknown	10 Mg/Kg Daily;		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15952488	NON-EXPEDITED			US-PFIZER INC-2019062232		52 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15952529	NON-EXPEDITED			US-PFIZER INC-2019062924			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Insomnia; Product Use In Unapproved Indication	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15952714	NON-EXPEDITED			US-PFIZER INC-2019064486			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Feb-2019	15952726	NON-EXPEDITED			US-PFIZER INC-2019058346		67 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Bupropion			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15952809	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019054855			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Road Traffic Accident	Zithromac Sr 2g			S	Oral	2 G, Single		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15953145	EXPEDITED (15-DAY)		OT	PHHY2019GB030931			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Colitis	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2019	15954406	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019057829		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Haematochezia; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S				Not Reported	
	Xeljanz			C	Oral	10 Mg, 2x/Day		Not Reported	
	Eliquis			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	13906938	EXPEDITED (15-DAY)		OT	AU-PFIZER INC- 2017359166		4 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bradycardia; Hypothermia	Azithromycin	S	Intravenous (not otherwise specified)	170 Mg, Daily (10 Mg/Kg)	Pfizer
	Azithromycin	S	Intravenous (not otherwise specified)	85 Mg, Daily (5 Mg/Kg)	Pfizer
	Piperacillin W/Tazobactam /01606301/	C	Intravenous (not otherwise specified)	1.7 G, 4x/Day (100 Mg/Kg Piperacillin)	Not Reported
	Piperacillin W/Tazobactam /01606301/	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	850 Mg, Daily	Not Reported
	Ceftriaxone	C			Not Reported
	Ceftriaxone	C			Not Reported
	Amikacin	C	Intravenous (not otherwise specified)	380 Mg, Daily	Not Reported
	Amphotericin B	C	Intravenous (not otherwise specified)	60 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15877652	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2019-003287			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15885742	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1004202		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation	Azithromycine Anhydre			S	Oral	500 Milligram Daily;		Not Reported
	Abilify 5 Mg, Comprimé			S	Oral	5 Milligram Daily;		Not Reported
	Paracetamol			S	Intravenous (not otherwise specified)	4 Gram Daily;		Not Reported
	Tiorfan 100 Mg, Gélule			S	Oral	3 Dosage Forms Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Kaleorid Lp 1000 Mg, Comprimé À Libération Prolongée	S	Oral	6 Gram Daily;	Not Reported
Xeplion 25 Mg, Suspension Injectable À Libération Prolongée	S	Intramuscular		Not Reported
Smecta	S	Oral	3 Dosage Forms Daily;	Not Reported
Levothyrox 50 Microgrammes, Comprimé Sécable	S	Oral	87.5 Microgram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15956695	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1011999		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Myopathy	Azithromycin			S	Oral	250 Milligram, Q2d (Tous Les 2 Jours)		Not Reported	
	Sporanox			S		200 Milligram, Qd		Mylan	
	Seretide			S	Respiratory (inhalation)	Unk Unk, Qd (2 Bouffées Par Jour)		Mylan	
	Mysoline			C		Unk		Mylan	
	Ramipril			C		Unk		Mylan	
	Lansoprazole			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2019	15957847	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019057726		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Squamous Cell Carcinoma Of Skin	Novatrex			S	Oral	2.5 Mg, Weekly		Pfizer	
	Cotriatec			S	Oral	5/12.5 Mg		Not Reported	
	Omeprazole			C	Oral	Unk		Not Reported	
	Crestor			C	Oral	Unk		Not Reported	
	Aceclofenac			C	Oral	Unk		Not Reported	
	Zolmitriptan			C	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid			C		Oral		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
13-Feb-2019	15960393	DIRECT		DS			59 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Burning Sensation; Rash Erythematous; Rash Papular	Azithromycin 250 Mg Tab; Generic For Zithromax Z-Pack 250 Mg			S	Oral	2 Tablet(S);Other Frequency:2 Tabs, Then 1 Tab;		Lupin		
	Progesterone			C				Not Reported		
	Lorazepam			C				Not Reported		
	Hormonal Cream (E3/E2/Dhea/Testosterone)			C				Not Reported		
	Thyroid Tab			C				Not Reported		
	Probiotic			C				Not Reported		
	Glucosamine Sulfate			C				Not Reported		
	Pregnenolone			C				Not Reported		
	Multi-Vitamin			C				Not Reported		
	Vitamin D3			C				Not Reported		
Colostrum Powder			C					Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Feb-2019	14611802	NON-EXPEDITED			US-PFIZER INC- 2018094563		75 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Swelling	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
14-Feb-2019	15027823	NON-EXPEDITED			US-PFIZER INC- 2018248952			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Gastrointestinal Disorder	Zithromax			S		Unk		Pfizer		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15960557	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-007173			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Thrombocytopenia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Abatacept			S	Unknown	125 Milligram, For Every 2 Weeks		Not Reported	
	Cymbalta			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15961049	NON-EXPEDITED			US-PFIZER INC-2019058526		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Pseudoephedrine			S		Unk		Not Reported	
	Claritin [Loratadine]			S		Unk		Not Reported	
	Allegra			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15961566	EXPEDITED (15-DAY)		CA	US-JNJFOC-20190210781			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cleft Lip And Palate; Congenital Central Nervous System Anomaly; Congenital Musculoskeletal Anomaly; Foetal Exposure During Pregnancy; Heart Disease Congenital; Holoprosencephaly; Kidney Malformation; Microcephaly	Cetirizine Hydrochloride		Y	S	Transplacental			Not Reported	
	Cetirizine Hydrochloride			S	Transplacental			Not Reported	
	Fluconazole		Y	S	Transplacental			Not Reported	
	Diphenhydramine Hydrochloride		Y	S	Transplacental			Not Reported	
	Oxymetazoline Hydrochloride		Y	S	Transplacental			Not Reported	
	Pseudoephedrine Hydrochloride		Y	S	Transplacental			Not Reported	
	Pseudoephedrine Hydrochloride			S	Transplacental			Not Reported	

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Phenylephrine Hydrochloride	Y	S	Transplacental	Not Reported
Ibuprofen	Y	S	Transplacental	Not Reported
Ibuprofen		S	Transplacental	Not Reported
Paracetamol	Y	S	Transplacental	Not Reported
Paracetamol		S	Transplacental	Not Reported
Loratadine		S	Transplacental	Not Reported
Miconazole		S	Transplacental	Not Reported
Doxylamine		S	Transplacental	Not Reported
Chlorpheniramine		S	Transplacental	Not Reported
Fexofenadine		S	Transplacental	Not Reported
Ranitidine		S	Transplacental	Not Reported
Sertraline		S	Transplacental	Not Reported
Paroxetine		S	Unknown	Not Reported
Codeine		S	Transplacental	Not Reported
Oxycodone		S	Transplacental	Not Reported
Hydrocodone		S	Transplacental	Not Reported
Amoxicillin		S	Transplacental	Not Reported
Azithromycin		S	Transplacental	Not Reported
Nitrofurantoin		S	Transplacental	Not Reported
Sulfamethoxazole		S	Transplacental	Not Reported
Trimethoprim		S	Transplacental	Not Reported
Cefalexin		S	Transplacental	Not Reported
Ampicillin		S	Transplacental	Not Reported
Psyllium		S	Transplacental	Not Reported
Docusate		S	Transplacental	Not Reported
Bismuth		S	Transplacental	Not Reported
Levothyroxine		S	Transplacental	Not Reported
Phenothiazine		S	Transplacental	Not Reported
Metoclopramide		S	Transplacental	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Guaifenesin		S	Transplacental	Not Reported
Ondansetron		S	Transplacental	Not Reported
Insulin		S	Transplacental	Not Reported
Influenza Vaccine		S	Transplacental	Not Reported
Tdap Ipv		S	Transplacental	Not Reported
Albuterol		S	Transplacental	Not Reported
Montelukast		S	Transplacental	Not Reported
Fluticasone		S	Transplacental	Not Reported
Simethicone		S	Transplacental	Not Reported
Dextromethorphan	Y	S	Transplacental	Not Reported
Omeprazole		S	Transplacental	Not Reported
Naproxen		S	Transplacental	Not Reported
Aspirin		S	Transplacental	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15962228	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circumstance Or Information Capable Of Leading To Medication Error; Packaging Design Issue	Azithromycin			S				Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15962778	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2019061662		24 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Language Disorder; Migraine	Zithromax			S	Oral	1 G, Single		Pfizer	
	Diane			S	Oral	35 Ug, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15962900	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1011633		11 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris	Sumamed			S		10 Mg/Kg Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15963134	NON-EXPEDITED			US-ALLERGAN-1826508US		21 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Rash	Tazarotene - Bp			S	Topical	Unk Unk, Qd		Stiefel	
	Azithromycin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15963673	EXPEDITED (15-DAY)		HO	PHHY2019HR032972		60 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Oedema;	Quetiapine			S	Oral	1 Df, Qd		Novartis	
Haematoma; Periorbital	Pregabalin			S	Oral	100 Mg, Qd		Not Reported	
Oedema; Pruritus;	Detralex			S	Oral	2x1		Not Reported	
Pyrexia; Rash; Skin	Sumamed			S	Oral	500 Mg, Qd		Not Reported	
Lesion; Skin Plaque;	Andol			S	Oral	600 Mg, Qd		Not Reported	
Urticaria	Spasmomen			S	Oral	Unk		Not Reported	
	Normabel			S	Oral	5 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15963811	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS-2018AMN00803			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin	S	Unknown	Unknown	Amneal				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2019	15963909	EXPEDITED (15-DAY)	HO		US-TEVA-2019-US-1010345		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Clostridium Difficile Colitis; Clostridium Difficile Infection; Diarrhoea	Azithromycin			S	Unknown	Received The Week Before Anal Sphincterotomy And Haemorrhoidectomy, Performed In -Aug-2015.		Not Reported	
	Ciprofloxacin			S	Oral	Started A Week After Anal Sphincterotomy And Haemorrhoidectomy		Not Reported	
	Ciprofloxacin			S	Unknown	Received Multiple Courses On And Off		Not Reported	
	Ciprofloxacin			S	Unknown	Received Additional 2-Week Course In September 2015		Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Clindamycin			S	Unknown	Single Dose Prior To Perianal Abscess Incision		Teva	
	Clindamycin			S	Unknown	For An Episode Of Group C Streptococcal-Positive Pharyngitis		Teva	
	Clindamycin			S	Unknown	Two Weeks After Tonsillectomy		Teva	
	Fluconazole			S	Oral			Not Reported	
	Rifaximin			S	Unknown			Not Reported	
	Metronidazole			C	Unknown	Started Prior To Perianal Abscess Incision		Not Reported	
	Metronidazole			C	Unknown	Received Multiple Courses On And Off		Not Reported	
	Metronidazole			C	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	14391020	NON-EXPEDITED			US-PFIZER INC-2018016135			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Zithromax			S		Unk		Pfizer	
	Wellbutrin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15535834	NON-EXPEDITED			US-PFIZER INC-2018427507		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pharyngeal Swelling	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15557957	EXPEDITED (15-DAY)		HO	US-009507513-1810USA010477		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cat Scratch Disease; Treatment Noncompliance	Isentress			S	Oral	Unk		Merck	
	Azithromycin			S		Unk, Weekly		Not Reported	
	Emtricitabine (+) Rilpivirine Hydrochloride (+) Tenofovir Disoproxil F Sulfamethoxazole (+) Trimethoprim			S		Unk		Not Reported	
				C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15833706	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2018M1095157		17 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Conjunctival Hyperaemia;	Nimesulide			S	Unknown	Unk		Not Reported	
	Nimesulide			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enanthema; Eye	Azithromycin	S	Unknown	Unk	Not Reported
Discharge; Genital	Azithromycin	S			Not Reported
Ulceration; Lip Erythema;	Clarithromycin	S	Unknown	Unk	Not Reported
Lip Oedema; Lung	Clarithromycin	S			Not Reported
Infiltration; Nasal Mucosal	Bilastina	S	Unknown	Unk	Mylan
Disorder; Oral Mucosa	Bilastina	S			Mylan
Erosion; Pyrexia; Rash	Brivudine	S		Unk	Mylan
Maculovesicular; Rash					
Papular; Stevens-Johnson Syndrome					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15838164	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019022511		40 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperaemia; Periorbital Swelling; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Gentalyn			S	Topical	1 Df, As Needed		Not Reported	
	Brufen			S	Oral	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15889313	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019034880		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Abilify			S	Oral	5 Mg, 1x/Day		Not Reported	
	Paracetamol			S	Intravenous (not otherwise specified)	4 G, 1x/Day		Not Reported	
	Tiorfan			S	Oral	3 Df, 1x/Day		Not Reported	
	Kaleorid Lp			S	Oral	6 G, 1x/Day		Not Reported	
	Xeplion			S	Intramuscular	1 Df, Monthly		Not Reported	
	Smecta [Diosmectite]			S	Oral	3 Df, 1x/Day		Not Reported	
	Levothyrox			S	Oral	87.5 Ug, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15964356	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR-APL-2019-008227			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extradural Haematoma; International Normalised Ratio Increased	Ciprofloxacin Hydrochloride Arrow Film-Coated Tablet 500mg			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Ceftazidime Arrow (Ceftazidime)			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported	
	Zithromax			S	Oral	250 Milligram, Once A Day		Not Reported	
	Previscan (Pentoxifylline)			S	Oral	30 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15965241	EXPEDITED (15-DAY)		HO, OT	SE-TEVA-2019-SE-1011443		67 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Confusional State; Constipation; Dizziness; Fatigue; Hypoaesthesia; Insomnia; Mental Disorder; Muscle Spasms; Polyneuropathy; Syncope	Azithromycin (Azithromycin)			S	Unknown			Not Reported	
	Azithromycin (Azithromycin)			S	Unknown			Not Reported	
	Xalatan			C				Not Reported	
	Symbicort Forte Turbuhaler			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15965255	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-008307			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukocytosis; Pleural Effusion; Pneumonia	Methylprednisolone			S	Unknown	Unk, Every 6 Hours		Aurobindo	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
	Ibuprofen			S	Unknown	Unk		Aurobindo	
	Vancomycin			S	Intravenous (not	Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vancomycin	S	otherwise specified)	Unk	Aurobindo
Azithromycin	S	Intravenous (not otherwise specified)	Unk	Aurobindo
Piperacillin+Tazobactam	S	Intravenous (not otherwise specified)	Unk	Aurobindo
Piperacillin+Tazobactam	S	Intravenous (not otherwise specified)	Unk	Aurobindo
Ceftriaxone	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15965971	NON-EXPEDITED			US-PFIZER INC-2019061723		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer
	Amoxicillin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15969292	EXPEDITED (15-DAY)		HO	HR-ASTRAZENECA-2019SE23126		60 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eyelid Oedema; Haematoma; Periorbital Oedema; Pruritus; Pyrexia; Rash; Skin Lesion; Skin Plaque; Urticaria	Quetiapine			S	Oral			Zeneca
	Andol			S	Oral			Not Reported
	Detralex			S	Oral			Not Reported
	Sumamed			S	Oral			Not Reported
	Pregabalin			S	Oral			Not Reported
	Spasmomen			S	Oral			Not Reported
	Normabel			S	Oral	5 Mg: Pp		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15969481	NON-EXPEDITED			US-PFIZER INC-2019070335			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2019	15969504	NON-EXPEDITED			US-PFIZER INC-2019068851		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nasal Congestion; Pain; Rash; Rash Pruritic; Rhinorrhoea	Azithromycin			S		Unk		Pfizer	
	Symbicort			C		Unk		Not Reported	
	Albuterol [Salbutamol]			C		Unk		Not Reported	
	Oxygen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2019	12286766	EXPEDITED (15-DAY)		HO	CN-JNJFOC-20160406394		50 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption; Pruritus; Rash	Tylenol		Y	S	Oral			Not Reported	
	Tylenol			S	Oral			Not Reported	
	Cefotiam Hydrochloride			S	Intravenous (not otherwise specified)	For 2 Days		Not Reported	
	Cefotiam Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2019	15582996	EXPEDITED (15-DAY)		HO	ES-ACCORD-090917		67 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Eosinophilic Pleural Effusion	Allopurinol			S	Oral	Strength: 300 Mg		Accord	
	Levofloxacin/Levofloxacin Mesylate			S	Oral			Not Reported	
	Amoxicillin/Clavulanic Acid			S	Oral	1.1.1, Strength: 875 Mg/125 Mg		Not Reported	
	Azithromycin			S	Oral	1 Cp		Not Reported	
	Hidroferol			C	Oral	1 Amp, Strength: 266		Not Reported	
	Hydrochlorothiazide/Valsartan			C	Oral	1-0-0, Strength:32 / 12.5		Not Reported	
	Tamsulosin/Tamsulosin Hydrochloride			C	Oral	1 Cp		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2019	15935585	EXPEDITED (15-DAY)		HO	IT-ACCORD-106317		21 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Intentional Self-Injury; Sopor	Aripiprazole			S	Oral			Not Reported	
	Escitalopram			S	Oral			Not Reported	
	Zitromax			S	Oral	Strength: 500 Mg		Not Reported	
	Prozin (Chlorpromazine Hydrochloride)			S	Oral	Strength: 25 Mg		Not Reported	
	Alprazolam			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	14653986	NON-EXPEDITED			US-PFIZER INC- 2018114277			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15334377	NON-EXPEDITED			US-PFIZER INC- 2018348871			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Gabapentin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Duloxetine			S		Unk		Not Reported
	Compazine [Prochlorperazine Edisylate]			S		Unk		Not Reported
	Sumatriptan			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15855949	EXPEDITED (15-DAY)		DE, HO, LT, OT	GB-CELLTRION INC.- 2019US018021			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Drug Ineffective; Lung Opacity; Lymphopenia; Off Label Use; Pneumocystis Jirovecii Pneumonia; Pneumomediastinum; Respiratory Failure; Sepsis; Syncope	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	On Days 3, 10, 17, 24		Not Reported
	Rituximab (Unknown)			S	Intravenous (not otherwise specified)	On Days 3, 10, 17, 24		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Dexamethasone Salt Not Specified			S	Unknown	Tapered Dose		Not Reported
	Dexamethasone Salt Not Specified			S	Unknown	Tapered Dose		Not Reported
	Dexamethasone Salt Not Specified			S	Oral	4 Mg, Qd		Not Reported
	Dexamethasone Salt Not Specified			S	Oral	4 Mg, Qd		Not Reported
	Dexamethasone Salt Not Specified			S	Oral	4 Mg, Qd		Not Reported
	Dexamethasone Salt Not Specified			S	Unknown	Tapered Dose		Not Reported
	Bactrim			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Leucovorin /00566701/			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decadron /00016001/	S	Unknown	4 Mg, Qd	Not Reported
Decadron /00016001/	S	Unknown	4 Mg, Qd	Not Reported
Azithromycin	S	Unknown		Not Reported
Piperacillin/ Tazobactam	S	Unknown		Not Reported
Temozolomide	S	Oral	On Days 7-11	Not Reported
Temozolomide	S	Oral	On Days 7-11	Not Reported
Furosemide	S	Unknown	Unk	Not Reported
Methotrexate	S	Intravenous (not otherwise specified)	On Day 1 And 15	Not Reported
Coumadin	C	Unknown		Not Reported
Levetiracetam	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15887882	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-197536		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Acyclovir			S	Transplacental	Unk		Sun
	Azithromycin			S	Transplacental	Unk		Sun
	Bactrim			S	Transplacental	Unk		Sun
	Lamivudine			S	Transplacental	150 Milligram, Daily		Ranbaxy
	Zidovudine			S	Transplacental	300 Milligram, Daily		Ranbaxy
	Viread			S	Transdermal	300 Milligram, Daily		Not Reported
	Intelence			S	Unknown	200 Milligram, Qd		Not Reported
	Prezista			S	Transplacental	600 Milligram, Daily		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Milligram, Daily		Not Reported
	Ritonavir			S	Transplacental	100 Milligram, Daily		Not Reported
	Multi Vitamin And Mineral			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Iron			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Magnesium Gluconate	C	Unknown	Unk	Not Reported
Abacavir	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15975107	NON-EXPEDITED			US-PFIZER INC-2019060290		52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Doxycycline Hyclate			S		Unk		Pfizer
	Hydromorphone Hydrochloride			S		Unk		Unknown
	Morphine Sulfate			S		Unk		Unknown
	Ciprofloxacin Hcl			S		Unk		Unknown
	Ami-Tex (Guaifenesin\Phenylephrine\Phe nylpropanolamine)			S		Unk		Not Reported
	Azithromycin Dihydrate			S		Unk		Not Reported
	Carbamazepine			S		Unk		Not Reported
	Cefaclor			S		Unk		Not Reported
	Ceftin [Ceftriaxone]			S		Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported
	Nefazodone Hydrochloride			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15976168	NON-EXPEDITED			US-PFIZER INC-2019064208		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15976269	NON-EXPEDITED			US-PFIZER INC-2019061786		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Rash		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15976320	NON-EXPEDITED			US-PFIZER INC- 2019071587		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Ceclor			S		Unk		Not Reported	
	Cephalexin [Cefalexin]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15976331	NON-EXPEDITED		OT	US-PFIZER INC- 2019071855			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Stevens-Johnson Syndrome	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15976364	EXPEDITED (15-DAY)		OT	CA-009507513- 1902CAN006473		56 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Raltegravir Potassium			S	Transplacental	400.0 Milligram		Merck	
	Acyclovir			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental			Not Reported	
	Bactrim			S	Transplacental			Not Reported	
	Intelence			S	Transplacental	200.0 Milligram		Not Reported	
	Lamivudine			S	Transplacental	150.0 Milligram		Not Reported	
	Prezista			S	Transplacental	600.0 Milligram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ritonavir	S	Transplacental	100.0 Milligram	Not Reported
Tenofovir	S	Transdermal	300 Milligram	Not Reported
Zidovudine	S	Transplacental	300.0 Milligram	Not Reported
Abacavir	C	Transplacental	300.0 Milligram	Not Reported
Vitamins (Unspecified)	C			Not Reported
Folic Acid	C			Not Reported
Iron (Unspecified)	C			Not Reported
Magnesium Gluconate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2019	15977080	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1012648		39 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral			Not Reported	
	Oki 80 Mg Granulato Per Soluzione Orale			C	Oral			Not Reported	
	Amoxicillina/Acido Clavulanico			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15858469	NON-EXPEDITED			US-PFIZER INC-2019025076		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Secretion Discharge	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15981584	EXPEDITED (15-DAY)		HO	PHHY2019US038324		42 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Disorder	Azithromycin			S	Unknown	Unk		Novartis	
	Levofloxacin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15982179	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2062885		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic	Azithromycin			S	Oral			Wockhardt	
	Amlodipine			C				Not Reported	
	Hyzaar			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15982203	EXPEDITED (15-DAY)		HO, OT	SE-PFIZER INC- 2019070097		67 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin			S		Unk		Pfizer	
Confusional State;	Xalatan			C				Not Reported	
Constipation; Dizziness;	Symbicort Forte Turbohaler			C				Not Reported	
Fatigue; Hypoaesthesia;									
Insomnia; Mental									
Disorder; Muscle Spasms;									
Polyneuropathy; Product									
Use In Unapproved									
Indication; Syncope									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2019	15982633	EXPEDITED (15-DAY)		OT	AT-PFIZER INC- 2019067969		8 YR	Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour;	Zithromax			S				Pfizer	
Amnesia; Hallucination;									
Somnambulism									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15840421	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018RR-196245		40 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hyperaemia; Periorbital Swelling	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Gentalyn			S	Topical	As Necessary		Not Reported	
	Brufen 600 Mg Granulato Effervescente			S	Oral	600 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15984675	NON-EXPEDITED			PHEH2019US007096			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15986120	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019067695		55 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder	Azithromycin			S	Intravenous drip	Unk		Pfizer	
	Olumiant			C		Unk		Not Reported	
	Celecox Tablets 200mg			C	Oral	Unk		Not Reported	
	Nexium [Esomeprazole Magnesium]			C	Oral	Unk		Not Reported	
	Fructlact			C		200 MI, Unk		Not Reported	
	Rinderon [Betamethasone Sodium Phosphate]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15986604	DIRECT	Y	HO, LT, OT			37 YR	Female	SAU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Cardiac Arrest; Electrocardiogram Qt Prolonged	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15986764	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2019023194		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Electrocardiogram Abnormal; Heart Rate Increased; Palpitations	Ventolin Hfa Inhalation Powder			S	Respiratory (inhalation)			Glaxosmithkline	
	Ventolin Hfa Inhalation Powder			S				Glaxosmithkline	
	Azithromycin			S				Glaxosmithkline	
	Azithromycin			S				Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15987246	EXPEDITED (15-DAY)		HO, LT	PHHY2019ES039382		50 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Hepatitis Cholestatic	Azitromicina			S	Intravenous (not otherwise specified)	500 Mg, Qd		Novartis	
	Linezolid			S	Intravenous (not otherwise specified)	600 Mg, Q12h		Not Reported	
	Voriconazole			S	Oral	500 Mg, Qd		Not Reported	
	Amoxicillin+Clavulanic Acid			S	Intravenous (not otherwise specified)	1 Df, Q8h		Not Reported	
	Tamiflu			S	Oral	75 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15987839	NON-EXPEDITED			US-PFIZER INC- 2019066595			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Talwin			S		Unk		Pfizer	
	Accupril			S		Unk		Pfizer	
	Codeine Sulfate			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxazosin	S	Unk	Not Reported
Thorazine [Chlorpromazine Hydrochloride]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2019	15987984	EXPEDITED (15-DAY)		HO	HR-TEVA-2019-HR-1013601		60 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Oedema; Haematoma; Periorbital Oedema; Pruritus; Pyrexia; Rash; Skin Lesion; Skin Plaque; Urticaria	Sumamed			S	Oral	500 Milligram Daily; 500 Mg; 1x1 3 Dana		Not Reported	
	Andol			S	Oral	600 Milligram Daily; 300 Mg; 2x1		Not Reported	
	Quetiapine			S	Oral	1x1		Teva	
	Pregabalin			S	Oral	100 Milligram Daily; 50 Mg; 2x1		Not Reported	
	Detralex			S	Oral	1000 Milligram Daily; 2x1		Not Reported	
	Spasmomen			S	Oral			Not Reported	
	Normabel			S	Oral	5 Mg; Pp		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	11595924	NON-EXPEDITED			US-PFIZER INC-2015319871			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15310762	EXPEDITED (15-DAY)		DE	CN-PFIZER INC-2018339290		1 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Intravenous (not otherwise specified)	Unk (Infusion)		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Meropenem		S		Unk		Pfizer		
	Vancomycin		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15798599	NON-EXPEDITED		OT	US-PFIZER INC-2019010536			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity; Rash; Seizure	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15884306	NON-EXPEDITED			US-PFIZER INC-2019040051			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Ciprofloxacin			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15980974	NON-EXPEDITED			US-PFIZER INC-2019064343			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988668	EXPEDITED (15-DAY)		OT	CA-009507513-1902CAN006453		56 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Raltegravir Potassium			S	Transplacental	400 Milligram		Merck	
	Abacavir			S	Transplacental	300 Milligram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acyclovir	S	Transplacental		Not Reported
Azithromycin	S	Transplacental	Dosage Form: Not Specified	Not Reported
Bactrim	S	Transplacental	Dosage Form: Not Specified	Not Reported
Intelence	S	Transplacental	200 Milligram	Not Reported
Lamivudine	S	Transplacental	150 Milligram, Dosage Form: Not Specified	Not Reported
Prezista	S	Transplacental	600 Milligram	Not Reported
Ritonavir	S	Transplacental	100 Milligram, Dosage Form: Not Specified	Not Reported
Tenofovir	S	Transdermal	300 Milligram	Not Reported
Zidovudine	S	Transplacental	300 Milligram, Dosage Form: Not Specified	Not Reported
Folic Acid	C			Not Reported
Iron (Unspecified)	C			Not Reported
Magnesium Gluconate	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15988713	EXPEDITED (15-DAY)		HO, OT	ES-ZYDUS-033660		63 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Product Use In Unapproved Indication	Azithromycin			S				Zydus Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15989479	NON-EXPEDITED			US-PFIZER INC-2019071132		68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Drug Ineffective; Infection; Nasal Congestion; Wheezing	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15989581	NON-EXPEDITED			US-PFIZER INC-2019068928			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Cefuroxime			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15990135	EXPEDITED (15-DAY)		HO, OT	ES-APOTEX-2019AP007981			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15991395	EXPEDITED (15-DAY)		HO	HR-PFIZER INC-2019075125		60 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Oedema; Haematoma; Periorbital Oedema; Pruritus; Pyrexia; Rash; Skin Lesion; Skin Plaque; Urticaria	Pregabalin			S	Oral	50 Mg, 2x/Day		Pfizer	
	Detralex			S	Oral	1000 Mg, 1x/Day		Not Reported	
	Sumamed			S	Oral	500 Mg, 1x/Day, 3 Days		Not Reported	
	Andol [Acetylsalicylic Acid]			S	Oral	300 Mg, 2x/Day		Not Reported	
	Quetiapine			S	Oral	1x1		Not Reported	
	Spasmomen			S	Oral			Not Reported	
	Normabel			S	Oral	5 Mg, As Needed		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2019	15991543	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019074706		13 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arrhythmia; Leukocytosis; Palpitations		Zitromax	S	Oral	300 Mg, 1x/Day		Pfizer		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15991683	EXPEDITED (15-DAY)		DE, OT	JP-PFIZER INC- 2019072388		94 YR	Male	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Disease Progression; Pneumonia	Zithromac			S	Oral	Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Feb-2019	15991698	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019074244		4 YR	Female	JPN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eosinophilia; Pulmonary Arterial Hypertension	Zithromac 10%			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15832451	NON-EXPEDITED			US-TEVA-2019-US- 995081			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cough; Diarrhoea; Dyspepsia; Dysphonia; Hyperchlorhydria; Nasopharyngitis	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Feb-2019	15843803	EXPEDITED (15-DAY)		OT	CA-NAPPMUNDI-CAN- 2019-0009532		53 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Theophylline			S	Oral	450 Mg, Daily		Purdue	
	Atrovent			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Oral	250 Mg, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ipratropium Bromide W/Salbutamol Sulfate Omalizumab	S	Unknown	Unk		Not Reported
		S	Intravenous (not otherwise specified)	Unk		Not Reported
	Prednisone	S	Oral	45 Mg, Daily		Not Reported
	Salbutamol Sulfate	S	Unknown	Unk		Not Reported
	Glycopyrronium Bromide	S	Unknown	1 Df, Daily		Not Reported
	Singulair	S	Oral	10 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15993623	EXPEDITED (15-DAY)		HO, OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-199811		63 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	()		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15996594	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2019075132		19 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Urine Present; Drug Ineffective; Infectious Mononucleosis; Ocular Icterus; Yellow Skin	Zitromax Zitromax			S S				Pfizer Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15997615	NON-EXPEDITED			US-TEVA-2019-US- 1005218		7 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Infection	Azithromycin Oral Suspension			S	Oral	10 Mg/Kg For The First Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin Oral Suspension

S

Oral

5 Mg/Kg For T Days Two
Through Five

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2019	15997618	EXPEDITED (15-DAY)		HO	PHHY2019ZA041612			Female	ZAF

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hip Fracture	Coxleone			S	Oral	200 Mg, Unk		Not Reported
	Azithromycin Sandoz			S	Unknown	500 Mg, Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2019	15800812	EXPEDITED (15-DAY)		OT	FR-ACCORD-100622		60 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Montelukast			S	Unknown	10 Mg, Daily		Not Reported
	Azithromycin			S	Unknown	250 Milligram,Every Other Day For 3 Months		Not Reported
	Albuterol			S	Unknown	6 Puffs/Day		Not Reported
	Levocetirizine/Levocetirizine Dihydrochloride			S	Unknown	5 Mg, Daily		Not Reported
	Fluticasone			S	Unknown	1000 Ug,Qd		Not Reported
	Salmeterol			S	Unknown	6 Puffs/Day 100 ?G/Day		Not Reported
	Fluticasone			S	Nasal	Dose: 55g/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	13841520	NON-EXPEDITED			US-PFIZER INC- 2017338379			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Amoxicillin			S		Unk		Pfizer
	Aspirin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Polysporin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	15314244	NON-EXPEDITED			US-PFIZER INC-2018338488			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Rash; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	15453879	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018GB109325		9 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Leukocytosis; Myalgia; Off Label Use; Product Use In Unapproved Indication; Purpura; Pyrexia; Rash Erythematous; Rash Maculo-Papular; Thrombocytopenia; Transaminases Increased	Teicoplanin			S	Oral	Unk		Not Reported	
	Teicoplanin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Moxifloxacin			S	Oral	Unk		Novartis	
	Co-Trimoxazole			S	Oral			Not Reported	
	Meropenem			C	Unknown	Unk		Not Reported	
	Cefoxitin			C	Unknown	Unk		Not Reported	
	Amikacin			C	Unknown			Not Reported	
	Chlorpheniramine C			C	Oral			Not Reported	
	Prednisolone			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	15880748	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2019034512		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Product Use In	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16001538	EXPEDITED (15-DAY)		OT	PHEH2019US007762		43 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Muscular Weakness; Oesophageal Disorder; Pulmonary Mass	Clarithromycin			S	Unknown	Unk		Novartis
	Doxycycline			S	Unknown	Unk		Not Reported
	Linezolid			S	Unknown	Unk		Not Reported
	Minocycline Hydrochloride			S	Unknown	Unk		Not Reported
	Tigecycline			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Cefox [Cefuroxime Axetil]			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Moxifloxacin			S	Unknown	Unk		Not Reported
	Amikacin			S	Unknown	Unk		Not Reported
	Imepenum Cilastatine			S	Unknown	Unk		Not Reported
	Panpharma Sulfamethoxazole And Trimethoprim			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16001920	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019076865		56 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vascular Purpura	Zithromax			S	Oral	2 Df, 1x/Day		Pfizer
	Polery (Aconite Tincture\Belladonna Leaf\Codeine\Ethylmorphine Hydrochloride\Polygala Tenuifolia Root\Sodium Benzoate\Sodium Bromide)			S	Oral	As Needed		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16008409	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2647277-00		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Memory Impairment; Pneumonia; Renal Failure	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Humira 40mg/0.8ml			S	Subcutaneous			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Testosterone Pump			C				Not Reported	
	Bupropion XI			C				Not Reported	
	Carvedilol			C				Not Reported	
	Citalopram Hydrobromide			C				Not Reported	
	Folic Acid			C				Not Reported	
	Furosemide			C				Not Reported	
	Methotrexate			C				Not Reported	
	Spironolactone			C				Not Reported	
	Doxazosin Mesylate			C				Not Reported	
	Amlodipine Besylate			C				Not Reported	
	Rosuvastatin Calcium			C				Not Reported	
	Finasteride			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16009068	EXPEDITED (15-DAY)		OT	PHHY2019FR041235		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrasystoles; Tachycardia	Azithromycin			S	Oral	Unk		Novartis	
	Nozinan			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2019	16009382	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-200020		28 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vision Blurred; Visual Impairment		Azithromycin		S	Oral	()		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16004150	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2019-009125			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Hepatitis Cholestatic	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo	
	Amoxicillin+Clavulanic Acid			S	Intravenous (not otherwise specified)	1 Dosage Form, 3 Times A Day		Aurobindo	
	Voriconazole			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Linezolid			S	Intravenous (not otherwise specified)	600 Milligram, Two Times A Day		Aurobindo	
	Tamiflu			S	Oral	75 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16004716	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2019-BI-00		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Spiriva			S	Unknown			Boehringer Ingelheim	
	Alvesco			S	Unknown	Dosage Form: Aerosol, Metered Dose		Not Reported	
	Salbutamol Sulfate			S	Unknown			Not Reported	
	Zenhale			S	Unknown	Dosage Form: Aerosol,Metered Dose		Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16004881	EXPEDITED (15-DAY)		HO, LT, OT	US-TEVA-2019-US-1016918		52 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Cough; Drug Interaction; Heart Rate Increased; Inappropriate Schedule Of Product Administration; Pain; Product Label Confusion	Teva Azithromycin			S	Oral	300 Milligram Daily;		Not Reported	
	Teva Azithromycin			S				Not Reported	
	Camber Levofloxacin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16005181	NON-EXPEDITED			US-PFIZER INC- 2019079708		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16006088	NON-EXPEDITED		OT	CA-STI PHARMA LLC- 2063208		11 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Ethambutol Hydrochloride			S	Oral			Sti Pharma	
	Brincidofovir			S	Oral			Not Reported	
	Linezolid			S				Not Reported	
	Azithromycin Monohydrate			S	Intravenous (not otherwise specified)			Not Reported	
	Rifabutin			S				Not Reported	
	Levofloxacin			S				Not Reported	
	Acetaminophen			C				Not Reported	
	Chlorhexidine Gluconate			C				Not Reported	
	Dimenhydrinate			C				Not Reported	
	Diphenhydramine Hydrochloride			C				Not Reported	
	Hydrocortisone			C				Not Reported	
	Lansoprazole			C				Not Reported	
	Nicotinamine, Pyridoxine Hcl,			C				Not Reported	
	Tyrosine								
	Smoflipid			S				Not Reported	
	Voriconazole			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Vancomycin Hydrochloride		C					Not Reported
		Meropenem		C					Not Reported
		Clarithromycin		C					Not Reported
		Granisetron Hydrochloride		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16007685	NON-EXPEDITED		OT	US-PFIZER INC-2019084903		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16007843	EXPEDITED (15-DAY)		HO, OT	BG-PFIZER INC-2019079571		72 YR	Female	BGR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Azithromycin			S	Unknown	Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16007857	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019075071			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematoma; Thrombocytopenia	Azithromycin			S				Pfizer	
	Abatacept			S		125 Mg, Q2wk		Not Reported	
	Cymbalta			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16008327	NON-EXPEDITED			US-BAYER-2019-038816			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Cipro	S	Unk	Bayer
	Doxycycline	S		Not Reported
	Azithromycin	S	Unk	Not Reported
	Effexor	S	Unk	Not Reported
	Zoloft	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16008377	EXPEDITED (15-DAY)		OT	PHHY2019AU038378		33 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Headache; Immune Reconstitution Inflammatory Syndrome; Lung Consolidation; Lymphadenopathy; Mycobacterium Avium Complex Infection; Pleural Effusion; Pulmonary Cavitation; Pulmonary Mass; Pyrexia; Vomiting	Emtricitabine+Tenofovir			S	Unknown	300/200 Mg Daily		Not Reported
	Ciprofloxacin			S	Oral	750 Mg, Bid		Not Reported
	Azithromycin			S	Unknown	1 G, Qw		Novartis
	Sulfamethoxazole And Trimethoprim			S	Unknown	80/400 Mg Daily		Not Reported
	Atazanavir			S	Unknown	300 Mg, Qd		Not Reported
	Ritonavir			S	Unknown	100 Mg, Qd		Not Reported
	Ertapenem			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Meropenem			C	Intravenous (not otherwise specified)	1 G, Tid		Not Reported
	Vancomycin			C	Unknown	1.25 G, Bid		Not Reported
	Granulocyte Colony Stimulating Factor			C	Unknown	300 Ug, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2019	16012477	DIRECT		OT			14 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lip Pruritus; Lip Swelling; Oral Pain	Azithromycin Generic For Zithroma X			S	Oral	Quantity:1 Tablet(S);Other Frequency:2 First Day, 1/Day;		Vivimed Labs

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	9997879	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2014064137		22 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury; Pancytopenia; Rash	Zithromax			S	Oral	Unk		Pfizer	
	Malocide (Pyrimethamine)			S	Oral	Unk		Not Reported	
	Doliprane			C		Unk		Not Reported	
	Indocollyre			C		Unk		Not Reported	
	Lederfolin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	14708561	EXPEDITED (15-DAY)		DE, HO, OT	CA-GLAXOSMITHKLINE-CA2018GSK055269			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Decreased Activity; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Therapeutic Product Effect Incomplete; Wheezing	Salbutamol Sulphate			S		100 ?G, Prn		Glaxosmithkline	
	Zithromax			S		Unk		Not Reported	
	Alvesco			S		2 Puff(S), Qd		Not Reported	
	Spiriva			S		2 Puff(S), Bid		Not Reported	
	Zenhale			S		2 Puff(S), Bid		Not Reported	
	Prednisone			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16010281	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2019-ES-1015854		50 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Hepatitis Cholestatic	Linezolid (1279a)			S	Intravenous (not otherwise specified)			Teva	
	Voriconazol (2878a)			S	Oral	500 Milligram Daily;		Teva	
	Tamiflu 75 Mg Capsulas Duras, 10 Cápsulas			S	Oral	75 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azitromicina (7019a)	S	Intravenous (not otherwise specified)	500 Milligram Daily;	Not Reported
Amoxicilina + Ácido Clavulánico	S	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16010862	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010546			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoglycaemia	Cefuroxime			S	Oral	5 Milligram, 2 Every One Day		Aurobindo
	Azithromycin			S	Oral	5 Milligram, 2 Every One Day		Not Reported
	Glyburide			C				Not Reported
	Metformin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16011425	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1016043		54 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pharyngeal Oedema;	Azithromycin			S	Oral			Not Reported
Scrotal Oedema	Velamox			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16012625	EXPEDITED (15-DAY)		HO, LT	ES-FRESENIUS KABI-FK201902021		50 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy; Hepatitis Cholestatic	Linezolid (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Oseltamivir Phosphate			S	Oral			Not Reported
	Voriconazole			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clavulanate
Potassium/Amoxicillin Trihydrate

S

Intravenous (not
otherwise specified)

Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16012935	NON-EXPEDITED			US-PFIZER INC- 2019084593			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16013528	NON-EXPEDITED			US-PFIZER INC- 2019075993			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16013768	EXPEDITED (15-DAY)		OT	PHHY2019NL042142		62 YR	Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Basal Cell Carcinoma; Keratoacanthoma; Photosensitivity Reaction	Azithromycin			S	Unknown	500 Mg, Bid (3x Week 500mg)		Novartis
	Calcium			C	Unknown	Unk		Not Reported
	Ascal			C	Unknown	Unk		Not Reported
	D-3			C	Unknown	Unk		Not Reported
	Persantin			C	Unknown	Unk		Not Reported
	Multi Vitamin			C	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2019	16014104	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019083073		16 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Kidney Injury;	Azithromycin	S	Unknown	Unk	Pfizer
Cerebrovascular Disorder;	Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	Unk	Pfizer
Chest X-Ray Abnormal;	Heparin Sodium	S	Intravenous (not otherwise specified)	Unk	Unknown
Gastrointestinal	Levofloxacin	S	Unknown	Unk	Pfizer
Haemorrhage; Hypoxia;	Vancomycin Hcl	S	Intravenous (not otherwise specified)	1 G, Twice Daily	Pfizer
Infection; Influenza Like Illness; Neuropathy	Amoxicillin	S	Unknown	Unk	Not Reported
Peripheral; Pancreatitis;	Betamethasone	S	Unknown	Unk	Not Reported
Polynuropathy;	Oseltamivir Phosphate	S	Oral	75 Mg, Twice Daily	Not Reported
Premature Labour;					
Respiratory Acidosis;					
Respiratory Distress;					
Respiratory Failure;					
Tachypnoea					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2019	16016356	DIRECT		DS, LT			47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Fear;	Azithromycin			S	Oral	Quantity:5 Capsule(S);		Pfizer
Intentional Self-Injury;	Loratadine			C				Not Reported
Suicidal Ideation								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	10230067	NON-EXPEDITED			US-PFIZER INC-2014153325			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	15166093	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018283925		82 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Zithromac 250mg			S	Oral	500 Mg, Daily		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bakumondoto			S	Oral	9 G, Daily			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	15613374	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2018462178		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Levofloxacin			S	Oral	500 Mg, 1x/Day		Not Reported	
	Clenil [Beclometasone Dipropionate]			C		Unk		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 G, Unk		Not Reported	
	Breva			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16015265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2014-12674			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Chills; Colitis; Diarrhoea; Nausea	Azithromycin Arrow Film-Coated Tablets 250mg			S	Oral	Unk, 2 Tablets On Evening		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16015475	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1016631		64 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Extrasystoles; Tachycardia	Azithromycine Anhydre			S	Oral			Not Reported	
	Nozinan			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16018723	EXPEDITED (15-DAY)		HO, LT, OT	ES-PFIZER INC-2019091108		50 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coagulopathy; Hepatitis Cholestatic	Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, 1x/Day	Pfizer
	Voriconazole	S	Oral	500 Mg, 1x/Day	Pfizer
	Linezolid	S	Intravenous (not otherwise specified)	600 Mg, 2x/Day (12h)	Pfizer
	Tamiflu	S	Oral	75 Mg, 1x/Day	Not Reported
	Amoxicillin Sodium/Clavulanic Acid	S	Intravenous (not otherwise specified)	1 Df, 3x/Day (8h)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16019041	NON-EXPEDITED			US-PFIZER INC- 2019085445			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16019044	NON-EXPEDITED			US-PFIZER INC- 2019080363			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Benzylpenicillin Sodium			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Tetracycline Hcl			S		Unk		Pfizer
	Prednisone			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2019	16019718	EXPEDITED (15-DAY)		OT	US-JNJFOC- 20190230392			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rhabdomyolysis	Topamax			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	15496799	EXPEDITED (15-DAY)		HO	BR-BIOGEN-2018BI00644328		54 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Headache; Sinusitis	Avonex			S	Intramuscular			Biogen	
	Azithromycin			S	Unknown			Not Reported	
	Clavulin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16020430	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-009775			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Extrasystoles; Tachycardia	Azithromycin			S	Oral	Unk		Aurobindo	
	Nozinan			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16021013	NON-EXPEDITED			US-PFIZER INC-2019085741		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16022012	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010557			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Pneumonia; Vomiting	Cefprozil			S	Oral	500 Milligram, Two Times A Day		Aurobindo	
	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	Unk	Not Reported
Doxycycline Hyclate	S	Unknown	100 Milligram, Two Times A Day	Not Reported
Remicade	S	Intravenous (not otherwise specified)	672 Milligram (1 Every 8 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	672 Milligram (1 Every 8 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram (1 Every 8 Weeks)	Not Reported
Remicade	S	Intravenous (not otherwise specified)	672 Milligram (1 Every 8 Weeks)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16022330	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-010441			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Headache	Cefixime			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram 1 Every 8 Week		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16023045	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019087143		38 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Rovamycin [Spiramycin Adepace]			S		Unk		Not Reported	
	Levofloxacin Kabi			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16023078	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP008419		71 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malacoplakia; Rhodococcus Infection; Treatment Failure	Mycophenolate			S	Unknown	500 Mg, Bid		Apotex
	Mycophenolate			S				Apotex
	Azithromycin			S	Oral	250 Mg, Qd		Apotex
	Basiliximab			S	Intravenous (not otherwise specified)	20 Mg, Unk		Not Reported
	Tacrolimus			S	Unknown	1 Mg, Q.Am		Not Reported
	Tacrolimus			S	Unknown	2 Mg, Q. Af		Not Reported
	Tacrolimus			S	Unknown	0.5 Mg, Bid		Not Reported
	Tacrolimus			S	Unknown	1 Mg, Q.Am		Not Reported
	Tacrolimus			S	Unknown	0.5 Mg, Q. Af		Not Reported
	Prednisone			S	Unknown	5 Mg, Daily		Not Reported
	Moxifloxacin			C	Oral	400 Mg, Qd		Not Reported
	Itraconazole			C	Oral	200?300 Mg , Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2019	16028793	DIRECT					1 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption	Azithromycin	Y		S	Oral	Quantity:15 Ml;		Greenstone

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16025628	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1019041			Female	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pathogen Resistance; Pneumonia	Sumamed			S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16026011	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-009275			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Confusional State; Diarrhoea; Dizziness; Malaise; Somnolence	Azithromycin			S	Oral	2000 Milligram, 1 Total, Single Dose (8x250mg)		Aurobindo	
	Truvada			C		Unk		Not Reported	
	Imodium Ibs Relief			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16026050	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2019-010854			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea	Azithromycin			S	Unknown	Unk		Aurobindo	
	Septotele Duo			S	Oral	1.5 Df, Single Dose		Not Reported	
	Sinutab li			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16029156	DIRECT		OT			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Weight Decreased	Zithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2019	16029217	DIRECT		OT			59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Flushing; Swelling; Urticaria	Azithromycin			S	Oral	Quantity:1 Tablet(S);	5 DAY	Wockhardt	
	Vitamin C			C				Not Reported	
	Fish Oil With Dha			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	8320059	EXPEDITED (15-DAY)		HO, OT	FR-SANOFI-AVENTIS-2011SA083234		14 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Drug Level Increased	Rifadine			S	Oral	600 Mg,Qd		Sanofi	
	Voriconazole			S	Oral	200 Mg,Bid		Not Reported	
	Voriconazole			S	Unknown	Unk Unk,Unk		Not Reported	
	Caspofungin Acetate			S	Intravenous (not otherwise specified)	1 Df,Qd		Not Reported	
	Azithromycin			S	Oral	500 Mg,Qod		Not Reported	
	Azithromycin			S	Oral	250 Mg,Tiw		Not Reported	
	Tacrolimus			S		Unk		Not Reported	
	Tacrolimus			S	Oral	.5 Mg,Bid		Not Reported	
	Tacrolimus			S	Oral	.2 Mg,Bid		Not Reported	
	Tacrolimus			S	Oral	.5 Mg,Bid		Not Reported	
	Tacrolimus			S		Unk		Not Reported	
	Mycophenolate Mofetil			C		1 G,Qd		Not Reported	
	Mycophenolate Mofetil			C		500 Mg,Qd		Not Reported	
	Rimifon			C		300 Mg,Qd		Not Reported	
	Pirilene			C		Unk		Not Reported	
	Ethambutol			C		Unk		Not Reported	
	Creon			C		Unk		Not Reported	
	Insulin			C		Unk		Not Reported	
	Retinol			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	11630619	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2015338548		35 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Reaction With Eosinophilia And Systemic Symptoms	Azadosé	S	Oral	Unk	Pfizer
	Eupantol	S	Oral	Unk	Pfizer
	Bactrim	S	Oral	Unk	Not Reported
	Truvada	S	Oral	Unk	Not Reported
	Isentress	S	Oral	Unk	Not Reported
	Ceftriaxone Kabi	C		Unk	Not Reported
	Rovamyciné /00074401/	C		Unk	Not Reported
	Lovenox	C		Unk	Not Reported
	Cymévan	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	12569406	NON-EXPEDITED			US-PFIZER INC-2016317826		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Glossodynia	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	14267507	NON-EXPEDITED			US-PFIZER INC-2017528199		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Arthrotec			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Vioxx			S		Unk		Not Reported	
	Risperdal			S		Unk		Not Reported	
	Serzone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	14307387	NON-EXPEDITED			US-PFIZER INC-2017536501		65 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Diflucan			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Nitroglycerin			S		Unk		Pfizer
	Solu-Medrol			S		Unk		Pfizer
	Skelaxin			S		Unk		Pfizer
	Talwin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Ambien			S		Unk		Not Reported
	Advair			S		Unk		Not Reported
	Albuterol			S		Unk		Not Reported
	Allegra			S		Unk		Not Reported
	Allegra D			S		Unk		Not Reported
	Amerge			S		Unk		Not Reported
	Bentyl			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Betadine			S		Unk		Not Reported
	Benadryl			S		Unk		Not Reported
	Buspar			S		Unk		Not Reported
	Chloraseptic			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Decadron			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Imitrex			S		Unk		Not Reported
	Luvox			S		Unk		Not Reported
	Methazone			S		Unk		Not Reported
	Macrochantin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prozac	S	Unk	Not Reported
Parafon Forte	S	Unk	Not Reported
Soma	S	Unk	Not Reported
Serzone	S	Unk	Not Reported
Uni-Dur	S	Unk	Not Reported
Unna Boot Bandage	S	Unk	Not Reported
Ultram	S	Unk	Not Reported
Versed	S	Unk	Not Reported
Wygesic	S	Unk	Not Reported
Zyflo	S	Unk	Not Reported
Zomig	S	Unk	Not Reported
Zoto Hc	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	14347171	NON-EXPEDITED			US-PFIZER INC-2017555300		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Cephalexin			S		Unk		Not Reported
	Naproxen			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15587338	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1082269		74 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anaemia; Mycobacterium Chelonae Infection; Neuropathy Peripheral; Pancreatitis Acute;	Azithromycin			S		Unk		Not Reported
	Moxifloxacin			S	Oral			Not Reported
	Tigecycline			S		Unk		Mylan
	Tigecycline			S		Unk		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Use In Unapproved Indication; Pulmonary Embolism	Tigecycline	S		Unk	Mylan
	Tigecycline	S		Unk	Mylan
	Tobramycin	S		Unk	Mylan
	Sivextro	S	Oral	Unk	Mylan
	Acenocoumarol	C		Unk	Mylan
	Amoxicillin And Clavulanate	C			Mylan
	Potassium				
	Amikacin /00391002/	C		Unk	Mylan
	Rifabutin	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15721776	NON-EXPEDITED			US-PFIZER INC-2018512895			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15798446	EXPEDITED (15-DAY)		OT	HU-PFIZER INC-2019005916		16 YR	Male	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Dysphagia; Hyperaemia; Leukocytosis; Lymph Node Palpable; Oropharyngeal Pain; Pyrexia; Streptococcal Infection; Tonsillar Hypertrophy	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15798775	EXPEDITED (15-DAY)		OT	HU-PFIZER INC-2019005931		17 YR	Female	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Epstein-Barr Virus Infection; Fatigue; Leukocytosis; Liver Function Test Increased; Lymphadenitis; Lymphocytosis; Malaise; Product Use In Unapproved Indication; Pyrexia	Azithromycin	S	Unknown	Unk				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15825044	NON-EXPEDITED			US-PFIZER INC-2019017861		77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	15833964	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1003345		21 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Arthropathy; Blood Creatinine Increased; Blood Urea Increased; Drug Interaction; Dyspepsia; Hypophagia; Influenza Like Illness; Vomiting; Weight Decreased	Azithromycin			S	Unknown	Unk		Not Reported	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Tobramycin			S	Intravenous (not otherwise specified)	120 Milligram, Tid		Not Reported	
	Tobramycin			S	Intravenous (not otherwise specified)	8 Milligram/Kilogram, Qd		Not Reported	
	Colomycin /00013203/			S	Intravenous (not otherwise specified)	2 Megaunits, Tid		Mylan	
	Colomycin /00013203/			S	Intravenous (not otherwise specified)	6 Dosage Form, Qd		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	15901000	NON-EXPEDITED			US-PFIZER INC-2019048417		64 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16028023	NON-EXPEDITED			US-TEVA-2019-US-1009080			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Pruritus; Rash; Skin Discolouration; Urticaria	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16030827	NON-EXPEDITED			US-PFIZER INC-2019091572			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16030906	NON-EXPEDITED			US-PFIZER INC-2019087908		71 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash; Urticaria	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2019	16030962	NON-EXPEDITED			US-PFIZER INC-2019094310		43 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16031071	EXPEDITED (15-DAY)		OT	NL-PFIZER INC- 2019091249		62 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma; Keratoacanthoma; Photosensitivity Reaction	Azithromycin			S	Oral	500 Mg, 3x/Week		Pfizer	
	Calcium			C	Oral	Unk		Not Reported	
	Ascal Cardio			C		Unk		Not Reported	
	D3			C		Unk		Not Reported	
	Persantin			C		Unk		Not Reported	
	Multivitamin [Vitamins Nos]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16031500	NON-EXPEDITED			US-PFIZER INC- 2017469739			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Simponi			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16031508	NON-EXPEDITED			US-PFIZER INC- 2019092310			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Augmentin [Amoxicillin			S		Unk		Not Reported	
	Sodium;Clavulanate Potassium]								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2019	16032027	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019089988			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage	Zithromac			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	13877159	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2017RR-147678		78 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vestibular Disorder	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Ranbaxy	
	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	15916514	EXPEDITED (15-DAY)		HO	CA-MYLANLABS-2019M1002594		24 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Malaise; Nausea; Upper Respiratory Tract Infection	Tobramycin			S	Respiratory (inhalation)	1 Df, Bid		Not Reported	
	Xolair			S	Subcutaneous	150 Mg, Every 4 Weeks		Mylan	
	Xolair			S	Subcutaneous	150 Mg, Every 4 Weeks		Mylan	
	Xolair			S	Subcutaneous	150 Mg, Every 4 Weeks		Mylan	
	Xolair			S	Subcutaneous	150 Mg, Every 4 Weeks		Mylan	
	Azithromycin			S	Oral	1 Df, Qd		Mylan	
	Ventolin /00139501/			C	Respiratory (inhalation)	2 Df, Prn (4-6 Times A Day)		Mylan	
	Pulmicort			C	Respiratory (inhalation)	2 Df, Bid		Mylan	
	Symbicort			C	Respiratory	2 Df, Bid		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmozyme	C	(inhalation) Respiratory (inhalation)	1 Df, Qd	Mylan
Gabapentin	C	Oral	1 Df, Tid	Mylan
Creon 10	C	Nasal	1 Df, Unk	Mylan
Ibuprofen	C	Oral	1 Df, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16033782	EXPEDITED (15-DAY)		HO, LT	ES-ROCHE-2270428		50 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy; Hepatitis Cholestatic	Tamiflu			S	Oral			Not Reported
	Azitromicina			S	Intravenous (not otherwise specified)			Not Reported
	Amoxicillin/Clavulanic Acid			S	Intravenous (not otherwise specified)			Not Reported
	Voriconazol			S	Oral			Not Reported
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16034411	NON-EXPEDITED			US-PFIZER INC-2019080287			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Parosmia; Taste Disorder; Vomiting	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16035306	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1020885		80 YR	Male	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity;	Sumamed			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Laryngeal Oedema

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16035634	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1018699		69 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Pemphigoid; Pruritus; Pustule	Azithromycin			S	Oral	Unk		Not Reported	
	Amoxicillin Sodium W/Clavulanic Acid			S	Oral	Unk		Mylan	
	Momenxsin			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2019	16169200	DIRECT	N	HO			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Surgery	Xeljanz 5 Mg			S	Oral			Not Reported	
	Prednisone			C				Not Reported	
	Atorvastatin			C				Not Reported	
	Aspirin			C				Not Reported	
	Zithromax			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	15426472	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2018383652		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Diplopia; Hyperhidrosis; Injection Site Pain	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Single		Pfizer	
	Losartan Pensa			C	Oral	25 Mg, 1x/Day		Not Reported	
	Pantoprazol Bexal			C	Oral	20 Mg, 1x/Day		Not Reported	
	Ceftriaxona Normon			C	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	15645250	NON-EXPEDITED			US-PFIZER INC-2018478699			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	15853990	NON-EXPEDITED			US-PFIZER INC-2019027673		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16018080	NON-EXPEDITED			US-PFIZER INC-2019082544			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Fluconazole			S		Unk		Pfizer	
	Methylprednisolone Acetate			S		Unk		Pfizer	
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported	
	Erythromycin Base			S		Unk		Not Reported	
	Rofecoxib			S		Unk		Not Reported	
	Influenza Virus Vaccine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16039260	EXPEDITED (15-DAY)		OT	NL-TEVA-2019-NL-1018531		62 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma;	Azithromycine			S		3x Week 500mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Keratoacanthoma; Photosensitivity Reaction		500mgazitromycine Tablet							
		500mg							
		Calcium		C					Not Reported
		Ascal 80 Mg		C					Not Reported
		D3		C					Not Reported
		Persantin		C					Not Reported
		Multi Vitamine		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16040039	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1020580		40 YR	Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Azithromycin 500 Mg			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16040040	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1020585		45 YR	Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Azithromycin 500 Mg			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16041224	EXPEDITED (15-DAY)		OT	CH-TEVA-2019-CH-1021219		86 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Co-Amoxi			S	Intravenous drip				Teva
	Zithromax			S	Oral				Not Reported
	Symfona (Ginkgo Biloba)			C	Oral				Not Reported
	Xgeva			C	Intravenous drip				Not Reported
	Faslodex			C	Intramuscular				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16041603	NON-EXPEDITED			US-PFIZER INC-2019096252			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Lyrica			S		Unk		Pfizer
	Medrol			S		Unk		Pfizer
	Norvasc			S		Unk		Pfizer
	Avelox			S		Unk		Not Reported
	Biaxin			S		Unk		Not Reported
	Clonidine			S		Unk		Not Reported
	Hydrocodone Bitartrate			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Valacyclovir Hcl			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16041695	NON-EXPEDITED			US-PFIZER INC-2019094490		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16041964	NON-EXPEDITED			US-PFIZER INC-2019098379		57 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Trazodone Hcl			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16042030	EXPEDITED (15-DAY)		HO, OT	JP-GLAXOSMITHKLINE-JP2019038547		60 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Haemorrhage	Voltaren (Diclofenac Sodium)			S	Oral	50 Mg, Unk		Glaxosmithkline	
	Zithromac			S	Oral	500 Mg, Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16042671	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1019706		58 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Ventolin /00139501/			C	Respiratory (inhalation)	Unk (Asnecessary)		Mylan	
	Zaditen			C	Ophthalmic	Unk (Asnecessary)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2019	16044492	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1020883		67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Ototoxicity	Azithromycin			S	Oral	On A Monday, Wednesday And Friday		Not Reported	
	Amitriptyline Hydrochloride			C				Mylan	
	Fostair			C				Mylan	
	Paracetamol			C				Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Montelukast Sodium		C					Mylan
		Co-Codamol		C					Mylan
		Esomeprazole /01479302/		C					Mylan
		Salbutamol		C					Mylan
		Fluoxetine Hydrochloride		C					Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	9571510	NON-EXPEDITED			US-PFIZER INC-2013276776			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	14282055	NON-EXPEDITED		HO	US-PFIZER INC-2017528486		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Eating Disorder; Flatulence; Nausea; Retching	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16046847	NON-EXPEDITED			US-PFIZER INC-2019096828		71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16046859	NON-EXPEDITED			US-PFIZER INC-2019097765			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Oxycodone			S		Unk		Not Reported	
	Methadone			S		Unk		Not Reported	
	Topiramate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16048031	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019097717		81 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Single		Pfizer	
	Tenoretic			C		Unk		Not Reported	
	Tenoretic			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2019	16048935	EXPEDITED (15-DAY)		HO, OT	FR-009507513-1202USA00571		14 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Drug Level Increased; Hepatocellular Injury; Renal Failure	Cancidas			S	Intravenous drip	70 Mg, Qd		Merck	
	Zithromax			S	Oral	250 Mg, 3 Times Per Week		Not Reported	
	Zithromax			S	Oral	500 Mg, Alternate Day		Not Reported	
	Tacrolimus			S		Unk		Not Reported	
	Modigraf			S	Oral	Unk		Not Reported	
	Modigraf			S	Oral	0.5 Mg, Bid		Not Reported	
	Modigraf			S	Oral	0.2 Mg, Bid		Not Reported	
	Modigraf			S	Oral	0.5 Mg, Bid		Not Reported	
	Modigraf			S	Oral	0.5 Mg, 2x/Day		Not Reported	
	Rifadin			S	Oral	600 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Vfend	S	Oral	200 Milligram, Bid	Not Reported
	Vfend	S		Unk	Not Reported
	Rimifon	C		Unk	Not Reported
	Cellcept	C		Unk	Not Reported
	A 313	C		Unk	Not Reported
	Insulin	C		Unk	Not Reported
	Creon (Pancreatin)	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	11767321	NON-EXPEDITED			US-PFIZER INC-2015391685			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
	E-Mycin [Erythromycin]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	14187886	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2017488670			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Polymyositis	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	15849708	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1004204		19 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Oral	1 Gram, Total (Stat Dose)		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051214	NON-EXPEDITED			US-TEVA-2019-US-1012146		1 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Expired Product Administered; Product Dispensing Error; Rash	Azithromycin For Oral Suspension, Usp			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051275	NON-EXPEDITED			US-TEVA-2019-US-1012166			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Product Storage Error; Pyrexia	Azithromycin For Oral Suspension, Usp			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051432	EXPEDITED (15-DAY)		OT	HU-TEVA-2019-HU-1021230		45 YR	Male	HUN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Toxic Skin Eruption; Viral Rash	Sumamed 500 Mg			S	Oral	500 Milligram Daily;		Teva	
	Sumamed 500 Mg			S				Teva	
	Bisoprolol			C				Not Reported	
	Revix Axahaler			C		240 Micrograms/20 Micrograms Dry-Powder Inhaler		Not Reported	
	Ventolin Evohaler			C		Pressurized Inhalation Suspension		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Mar-2019	16051828	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1021351			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Heart Rate Increased; Product Substitution Issue	Azithromycin-Generic Zithromax	S				500 Mg Two Tablets On The First Day And 250 Mg For Four Consecutive Days By Mouth			Not Reported
	Azithromycin-Generic Zithromax	S				500 Mg Two Tablets On The First Day And 250 Mg For Four Consecutive Days By Mouth			Not Reported
	Crestor	C		Oral		5 Milligram Daily;			Not Reported
	Amoxicillin	C							Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16051967	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019099367			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rectal Haemorrhage	Enzalutamide			S	Oral	120 Mg, Once Daily		Pfizer	
	Azithromycin			S				Pfizer	
	Warfarin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16053475	NON-EXPEDITED			US-PFIZER INC-2019094789		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16054090	NON-EXPEDITED			US-PFIZER INC-2019099720			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Lip Swelling; Mouth Swelling	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Prednisone			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2019	16056340	DIRECT		OT			41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Dizziness; Heart Rate Abnormal; Pollakiuria; Thirst	Azithromycin			S	Oral			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	12141288	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2016128297		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Pantoprazole			S	Oral	Unk		Pfizer	
	Lansoprazole			S	Oral	Unk		Unknown	
	Azithromycin			S	Oral	Unk		Pfizer	
	Atorvastatin Calcium			S	Oral	Unk		Pfizer	
	Voriconazole			S	Oral	Unk		Pfizer	
	Voriconazole			S	Oral	Unk		Pfizer	
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported	
	Prednisone			S	Oral	Unk		Not Reported	
	Tacrolimus			S	Oral	Unk		Not Reported	
	Sulfamethoxazole And Trimethoprim			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2019	14482776	EXPEDITED (15-DAY)		OT	FR-BRISTOL-MYERS SQUIBB COMPANY-BMS-2018-007763		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase	Eliquis			S	Oral	Unk		Bristol Myers Squibb	
	Zithromax			S	Oral	1 Df, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Hepatocellular Injury	Methotrexate	S	Oral	0.5 Dosage Form	Not Reported
	Hemigoxine Nativelle	S	Oral	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16050276	EXPEDITED (15-DAY)		OT	PT-TEVA-2019-PT-1020234		34 YR	Female	PRT

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Face Oedema; Periorbital Oedema; Pruritus	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16055342	EXPEDITED (15-DAY)		OT	ES-TEVA-2019-ES-1021682		71 YR	Male	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hepatitis Acute	Amoxicilina / Acido Clavulanico			S	Oral	1750 Milligram Daily; 1-0-1		Teva
	Teva 500 Mg/125 Mg			S	Oral	500 Milligram Daily; 500		Not Reported
	Azitromicina (7019a)					Mg Dia		

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16056350	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-01375		55 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Confusional State; Homicidal Ideation; Product Colour Issue; Product Quality Issue; Psychotic Disorder	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057211	NON-EXPEDITED			US-PFIZER INC-2019100636		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypersensitivity	Bosulif	S	Oral	Unk	Pfizer
	Bosulif	S	Oral	100 Mg, 2x/Day	Pfizer
	Azithromycin	S	Oral	Unk Unk, Daily [500 By Mouth Daily For 5 Days]	Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16057875	NON-EXPEDITED			US-TEVA-2019-US-1014341			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Product Substitution Issue	Azithromycin Dihydrate Teva			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16058931	NON-EXPEDITED			US-PFIZER INC-2019101518			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer
	Hydrocodone			S		Unk		Not Reported
	Compazine [Prochlorperazine Edisylate]			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Vioxy			S		Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16196932	DIRECT	Y	HO			72 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholestatic Liver Injury	Azithromycin			S				Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Mar-2019	16197407	DIRECT		RI, OT			65 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin (Zithromax 250mg Y Oral 1 Tab)			S	Oral	Quantity:250 Mg Milligram(S);Other Frequency:2 -1st Day/1 Pill ;		Teva	
	Hydrochlorothiazide (Esidrix/Hydrodiuril)			C				Not Reported	
	Vitamin C			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	9513067	NON-EXPEDITED			US-PFIZER INC-2013256178			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Palpitations	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	12578866	NON-EXPEDITED			US-PFIZER INC-2016345255			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	15043720	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2018M1041448		63 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Pleural Effusion; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxone			S	Unknown	Unk		Mylan	
	Ceftriaxone			S				Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16060111	EXPEDITED (15-DAY)		HO, OT	US-HETERO CORPORATE- HET2019US00288		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apparent Death; Atrial Fibrillation; Cardiac Discomfort	Levofloxacin			S	Oral	500 Mg, Qd		Hetero	
	Azithromycin			S	Oral	150 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16060758	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT- 1022118		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Anaemia	Prednisone			S	Oral	25 Milligram Daily;		Actavis	
	Zitromax 500 Mg Compresse			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Rivestite Con Film								
	Coumadin 5 Mg Compresse			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Augmentin			S	Oral	2 Dosage Forms Daily;		Not Reported	
	Zyloric 300 Mg Compresse			C	Oral			Not Reported	
	Bisoprolol Hemifumarate			C	Oral			Not Reported	
	Triatec			C	Oral			Not Reported	
	Lasix 25 Mg Compresse			C	Oral			Not Reported	
	Spiriva Respimat 2,5 Microgrammi, Soluzione Per Inalazione			C	Respiratory (inhalation)			Not Reported	
	Amiodarone Hydrochloride			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16061214	EXPEDITED (15-DAY)		OT	BR-LUPIN PHARMACEUTICALS INC.-2019-01368		34 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised	Azithromycin			S	Unknown	Unk		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exanthematous Pustulosis	Cephalexin	S	Unknown	Unk	Lupin
	Azathioprine	S	Unknown	Unk	Not Reported
	Oxacillin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16061617	NON-EXPEDITED			US-PFIZER INC-2019103468		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Fosamax			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16061808	NON-EXPEDITED			US-PFIZER INC-2019103561		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ceftin			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16062590	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1021124		14 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Drug Level Increased	Tacrolimus			S	Oral	.5 Milligram Daily;		Actavis	
	Zithromax			S	Unknown	250 Mg, 3 Times Per Week		Not Reported	
	Candidas			S	Intravenous (not otherwise specified)	1 Dosage Forms Daily;		Not Reported	
	Vfend			S	Oral	200 Milligram Daily; 2x/Day		Not Reported	
	Tacrolimus			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Zithromax	S	Oral	, Alternate Day	Not Reported
	Vfend	S	Unknown	Unk	Not Reported
	Rifadine	S	Oral	600 Milligram Daily; 600 Mg, 1x/Day	Not Reported
	A 313	C		Unk	Not Reported
	Rimifon	C		Unk	Not Reported
	Cellcept	C		Unk	Not Reported
	Insulin	C		Unk	Not Reported
	Creon	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16062868	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2019M1022701		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disseminated Mycobacterium Avium Complex Infection; Hepatotoxicity; Large Intestine Infection	Tacrolimus			S	Unknown	2 Milligram		Not Reported
	Mycophenolate Mofetil			S	Unknown	1000 Milligram		Not Reported
	Rifampicin			S	Oral	600 Milligram, Qd		Not Reported
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported
	Ethambutol			C	Oral	Three Times A Week		Mylan
	Meropenem			C	Unknown			Mylan
	Vancomycin			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2019	16064624	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC-2019105139		84 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Decreased Appetite; Drug Ineffective; Fatigue; Malignant Neoplasm Progression; Pancreatic Neuroendocrine Tumour;	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin Hcl			S	Unknown	Unk		Unknown
	Afinitor			S	Oral	5 Mg, 1x/Day		Not Reported
	Octreotide			S	Subcutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Platelet Count Decreased; Rash; Somnolence; Weight Decreased	Sandostatin	S	Unknown	60 Mg, Unk	Not Reported
	Trimethoprim	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16041372	EXPEDITED (15-DAY)		OT	NL-APOTEX- 2019AP009083		47 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Level Below Therapeutic; Neuropathy Peripheral	Isoniazid			S	Unknown	300 Mg, Unk		Not Reported
	Azithromycin			S	Unknown	500 Mg, Unk (Loading Dose)		Apotex
	Azithromycin			S	Unknown	250 Mg, Qd		Apotex
	Azithromycin			S	Unknown	250 Mg, Unk (Rechallenged)		Apotex
	Rifampin			S	Unknown	600 Mg, Unk		Not Reported
	Rifampin			S	Unknown	900 Mg, Unk		Not Reported
	Rifampin			S	Unknown	1800 Mg, Unk		Not Reported
	Pyrazinamide			S	Unknown	1500 Mg, Unk		Not Reported
	Ethambutol			S	Unknown	1000 Mg, Unk		Not Reported
	Moxifloxacin			S	Unknown	400 Mg, Unk		Not Reported
	Moxifloxacin			S	Unknown	600 Mg, Unk		Not Reported
	Vitamins /00067501/			C	Unknown	Unk		Not Reported
	Insulin			C	Unknown	4 To 30 Units , Tid, Short- Acting Insulin		Not Reported
	Insulin			C	Unknown	22 Units, Qd, Long-Acting Insulin		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16065832	NON-EXPEDITED			PHEH2019US009536			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Irritable	Azithromycin			S	Unknown	Unk		Novartis

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Bowel Syndrome; Pain

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16067921	NON-EXPEDITED			US-PFIZER INC-2019109311		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16068078	NON-EXPEDITED			US-PFIZER INC-2019108942		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Ear Swelling; Erythema	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2019	16206728	DIRECT	Y	HO			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infective Pulmonary Exacerbation Of Cystic Fibrosis	Azithromycin 500mg Tablet			S	Oral				Teva
	Dekas Plus			C					Not Reported
	Cayston			C					Not Reported
	Acetylcysteine			C					Not Reported
	Scandishake			C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	11899021	NON-EXPEDITED			US-PFIZER INC-2016004022		53 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Saravanta			S		Unk		Not Reported	
	Serevent			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	12322752	NON-EXPEDITED			US-PFIZER INC-2016234267		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Skin Burning Sensation	Zithromax			S		Unk		Pfizer	
	Primidone			S		Unk		Not Reported	
	Tegretol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	13017624	NON-EXPEDITED			US-PFIZER INC-2016574899			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	15878179	NON-EXPEDITED			US-PFIZER INC-2019036629			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16069856	NON-EXPEDITED			US-TEVA-2019-US-1016310			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Irregular; Myalgia	Azithromycin Teva			S		Tablets The First Day And 1 Tablet Daily For 4 More Days		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16071186	NON-EXPEDITED			US-PFIZER INC-2019102878		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Robitussin Honey Maximum Strength Cough + Chest Congestion Dm		Y	S	Oral	Unk, 2x/Day [Maximum Strength Liquid, 1 Teaspoon By Mouth Twice A Day]		Pfizer	
	Robitussin Honey Maximum Strength Cough + Chest Congestion Dm		Y	S				Pfizer	
	Robitussin Honey Maximum Strength Cough + Chest Congestion Dm		Y	S				Pfizer	
	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
	Lumigan			C	Ophthalmic	2 Gtt, 1x/Day [1 Drop In Both Eyes Once A Day At Night]		Not Reported	
	Timolol Maleate			C	Ophthalmic	2 Gtt, 1x/Day [1 Drop In Each Eye Once A Day In The Morning]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16071332	DIRECT		OT			30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Chest Pain; Crying; Dyspepsia; Ear Discomfort; Ear Pain; Epistaxis; Feeling Abnormal; Feeling Hot; Gastroesophageal Reflux Disease; Headache; Hypoaesthesia Oral; Insomnia; Muscle	Azithromycin Monohydrate			S	Oral	Quantity:6 Tablet(S);		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Twitching; Musculoskeletal
Pain; Neck Pain; Panic
Reaction; Paraesthesia
Oral; Tinnitus

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16071469	NON-EXPEDITED			US-PFIZER INC- 2019110198			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Phenergan [Promethazine]			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16072735	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2019108539		71 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hepatitis Acute	Azithromycin			S	Oral	500 Mg, 1x/Day (Every 24 Hours)		Pfizer	
	Amoxicillin Clavulanic Acid			S	Oral	875 Mg, 2x/Day (Every 12 Hours)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16073219	NON-EXPEDITED			US-PFIZER INC- 2019111465			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Mar-2019	16074457	NON-EXPEDITED		OT	US-PFIZER INC- 2019111191		53 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain;	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Angioedema; Diarrhoea;
Drug Hypersensitivity;
Nausea; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Mar-2019	16074571	EXPEDITED (15-DAY)		DE	ES-TEVA-2019-ES-1023286		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rhabdomyolysis	Simvastatina (1023a)			S	Oral			Ivax	
	Azitromicina Cinfa 500 Mg Polvo Para Suspension Oral Efg , 3 Sobres			S	Oral	1 On The Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	12967864	NON-EXPEDITED			US-PFIZER INC-2016537972			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Macrodantin			S		Unk		Not Reported	
	Aspirin			S		Unk		Not Reported	
	Docusate			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	15596212	EXPEDITED (15-DAY)		OT	PHHY2018PL143756			Female	POL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Leukopenia; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
	Encorton			S	Oral	40 Mg In The Morning		Not Reported	
	Pyrimethamine			S	Unknown	25 Mg, ((Twice Daily For The First Two Days, Followed By Once Daily On Days 3–21))		Not Reported	
	Sulfadoxine			S	Unknown	500 Mg, Unk (Twice Daily For The First Two Days, Followed By Once Daily On Days 3-21)		Not Reported	
	Spiramycin			S	Unknown	3 M, Tid		Not Reported	
	Ranitidine			C	Oral	Unk		Not Reported	
	Omeprazole			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	15766482	NON-EXPEDITED			US-PFIZER INC-2018527350		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	15902828	EXPEDITED (15-DAY)		HO	CZ-AUROBINDO-AUR-APL-2019-002022			Unknown	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Drug Ineffective; Leukocytosis; Nausea; Oropharyngeal Discomfort; Polycythaemia; Prescribed Overdose	Desloratadine Film-Coated Tablet			S	Unknown	5 Milligram, Once A Day		Not Reported	
	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Bilastine			S	Unknown	60 Milligram		Not Reported	
	Bilastine			S	Unknown	20 Milligram, Once A Day		Not Reported	
	Bilastine			S	Oral	40 Milligram, Once A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Bilastine	S	Unknown	60 Milligram, Unk	Not Reported
	Prednisone	S	Unknown	60 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	10 Milligram, Once A Day	Not Reported
	Prednisone	S	Oral	40 Milligram, Once A Day	Not Reported
	Amoxicillin	S	Oral	1 Gram, Two Times A Day	Not Reported
	Amoxicillin	S			Not Reported
	Omalizumab	S	Oral	1 Gram For 1 Hour	Not Reported
	Diprophos	C	Intramuscular	1 Milliliter	Not Reported
	Diprophos	C			Not Reported
	Bisulepin Hydrochloride	C	Unknown	Unk	Not Reported
	Betamethasone	C	Topical	Unk	Not Reported
	Betamethasone	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16076250	NON-EXPEDITED			US-PFIZER INC-2019108363		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16076308	NON-EXPEDITED			US-PFIZER INC-2019108100		88 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Malaise; Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
	Mucinex			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16076335	NON-EXPEDITED			US-PFIZER INC-2019108203			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Malaise	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16076409	NON-EXPEDITED			US-PFIZER INC-2019108188		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Malaise	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16076425	NON-EXPEDITED			US-PFIZER INC-2019107331		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Glipizide			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Codeine			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16078136	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2019092204			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder; Renal Disorder	Zithromac			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16078373	DIRECT		HO, OT			69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Diarrhoea; Dizziness; Dyspnoea; Fatigue; Nausea	Azithromycin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Mar-2019	16078998	NON-EXPEDITED			US-PFIZER INC-2019100578		11 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2019	16081360	NON-EXPEDITED			PHEH2019US011718			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Vomiting	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	15575959	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2018M1081656		21 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Pantoprazole			S	Oral	Non Communiquee		Not Reported	
	Alprazolam			S	Oral	Non Communiquee		Not Reported	
	Azithromycin			S	Oral	Non Communiquee		Not Reported	
	Terbutaline			S	Respiratory (inhalation)	Non Communiquee		Not Reported	
	Neoral			S	Oral	Non Communiquee		Mylan	
	Hydrocortisone			S	Oral	Non Communiquee		Mylan	
	Hizentra			S	Subcutaneous	Non Communiquee		Mylan	
	Bactrim			S	Oral	Non Communiquee		Mylan	
	Oracilline /00001805/			S	Oral	Non Communiquee		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vfend	C	Oral	Non Communiquee	Mylan
Ventoline /00139501/	C	Respiratory (inhalation)	Non Communiquee	Mylan
Folinoral	C	Oral	Non Communiquee	Mylan
Seresta	C	Oral	Non Communiquee	Mylan
Pulmicort	C	Respiratory (inhalation)	Non Communiquee	Mylan
Zelitrex	C	Oral	Non Communiquee	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16082692	EXPEDITED (15-DAY)		HO, OT	US-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-023642			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased; Rectal Haemorrhage	Warfarin Sodium			S	Unknown			Bristol Myers Squibb	
	Enzalutamide			S	Oral	120 Mg (Titer), Qd		Not Reported	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16082734	NON-EXPEDITED		HO	US-APOTEX-2019AP009453		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Resistance	Ciprofloxacin			S	Unknown	500 Mg, Bid		Apotex	
	Ciprofloxacin			S	Unknown	750 Mg, Unk		Apotex	
	Ciprofloxacin			S				Apotex	
	Azithromycin			S	Oral	500 Mg, Qd		Apotex	
	Azithromycin			S	Oral	250 Mg, Qd		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16083451	NON-EXPEDITED			US-TEVA-2019-US-1016843			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Rash		Azithromycin		S	Unknown		Not Reported		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16084048	NON-EXPEDITED			US-PFIZER INC- 2019106134		17 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16084119	NON-EXPEDITED			US-PFIZER INC- 2019112989		61 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16084370	EXPEDITED (15-DAY)		HO, LT, OT	PT- GLAXOSMITHKLINE- PT2019048031		41 YR	Male	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Stevens-Johnson Syndrome	Amoxicillin + Clavulanic Acid			S	Unknown	Unk		Glaxosmithkline	
	Cefuroxime			S	Unknown	Unk		Glaxosmithkline	
	Azithromycin			S	Unknown	Unk		Glaxosmithkline	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Mar-2019	16084472	EXPEDITED (15-DAY)		HO	PHHY2019US052842		70 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Decreased Appetite; General Physical Health Deterioration; Liver	Azithromycin			S	Oral	250 Mg, Qd		Novartis	
	Ethambutol			S	Oral	800 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Function Test Increased; Nausea; Treatment Failure	Rifabutin	S	Oral	300 Mg, Qd	Not Reported
	Amikacin	S	Intravenous (not otherwise specified)	500 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16085270	NON-EXPEDITED			US-PFIZER INC- 2019111026			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16085307	EXPEDITED (15-DAY)		DE, OT	PHHY2019CA060086		81 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Acute	Aclasta			S	Intravenous drip			Novartis	
Kidney Injury; Adjustment	Codeine			S	Unknown			Not Reported	
Disorder; Anaemia;	Actonel			S	Unknown			Not Reported	
Angina Pectoris; Atrophy;	Amoxil			S	Unknown			Not Reported	
Back Pain; Bundle Branch	Zithromax			S	Unknown			Not Reported	
Block Left; Death; Drug	Dilaudid			C	Unknown	1 Mg, Unk		Not Reported	
Hypersensitivity; Drug	Esomeprazole Sodium			C	Unknown	1 Df, Qd		Not Reported	
Intolerance; Hepatic	Propranolol Hydrochloride			C	Unknown	1 Df, Qd		Not Reported	
Steatosis;									
Hypercalcaemia;									
Hypertension; Monoclonal									
Gammopathy;									
Musculoskeletal Pain;									
Osteoarthritis; Palmar									
Erythema; Plasma Cell									
Myeloma; Sacroiliitis;									
Spinal Disorder; Toxicity									
To Various Agents									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16085602	NON-EXPEDITED			US-PFIZER INC- 2019117675		52 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16085958	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2018GSK204988			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Cough; Dyspnoea; Gastrooesophageal Reflux Disease; Therapeutic Product Effect Incomplete	Salbutamol Sulphate			S		2 Puff(S), Prn		Glaxosmithkline	
	Erythromycin			C		250 Mg, Qd		Glaxosmithkline	
	Montelukast			S		10 Mg, Qd		Glaxosmithkline	
	Singulair			S		Unk		Glaxosmithkline	
	Azithromycin			S		250 Mg, Qd		Glaxosmithkline	
	Spiriva			S		2 Puff(S), Qd		Not Reported	
	Pulmicort			S		Unk		Not Reported	
	Symbicort			S		2 Puff(S), Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2019	16086163	NON-EXPEDITED			PHEH2019US011555			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Azithromycin 250 Mg			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	13010821	NON-EXPEDITED			US-PFIZER INC-2016561453			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	14262699	NON-EXPEDITED			US-PFIZER INC-2017522970		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Acetaminophen			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	14647423	NON-EXPEDITED			US-PFIZER INC-2018108522			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
	Phenergan			S		Unk		Not Reported	
	Indocin [Indometacin]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	14999351	NON-EXPEDITED			US-PFIZER INC-2018235624		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	15276914	EXPEDITED (15-DAY)		HO, OT	PHHY2018IT072242		57 YR	Male	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Levofloxacin			S	Oral	1 Df, Qd		Novartis	
	Azithromycin			S	Oral	1 Df, Qd		Not Reported	
	Olmotec Comp			C	Unknown	20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	15571810	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2018M1081083		64 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cell Death; Cholestasis; Liver Disorder	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	15712885	EXPEDITED (15-DAY)		OT	PHHY2018HU175345		16 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dysphagia; Hyperaemia; Leukocytosis; Lymph Node Palpable; Oropharyngeal Pain; Pyrexia; Streptococcal Infection; Tonsillar Hypertrophy	Azithromycin			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Novartis	
	Clindamycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16087065	NON-EXPEDITED			PHEH2019US011307			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Oxaprozin			S	Unknown	Unk		Novartis	
	Z-Pak			S	Unknown	Unk		Not Reported	
	Lipitor			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levaquin	S	Unknown	Unk	Not Reported
Splenda	S	Unknown	Unk	Not Reported
Turmeric	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16087643	EXPEDITED (15-DAY)		OT	NL-APOTEX-2019AP009440		62 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma; Keratoacanthoma; Photosensitivity Reaction	Azithromycin			S	Unknown	500 Mg, Once Every 2 Days (3x Week 500mg)		Apotex	
	Calcium			C	Unknown	Unk		Not Reported	
	Ascal Cardio			C	Unknown	Unk		Not Reported	
	D3			C	Unknown	Unk		Not Reported	
	Persantin			C	Unknown	Unk		Not Reported	
	Multivitamin /00097801/			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16088607	NON-EXPEDITED			US-PFIZER INC-2019109823		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16088619	NON-EXPEDITED			US-PFIZER INC-2019109619			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Hydromorphone Hydrochloride			S		Unk		Unknown	
	Methotrexate Sodium			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Morphine Sulfate			S		Unk			Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16088828	EXPEDITED (15-DAY)		DE	AU-ACTELION-A-CH2019-187261		10 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Epoprostenol Sodium			S	Intravenous (not otherwise specified)			Not Reported	
	Oseltamivir			S	Unknown			Not Reported	
	Lincomycin Hydrochloride			S	Unknown			Not Reported	
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Vancomycin Hydrochloride			S	Unknown			Not Reported	
	Meropenem			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16089492	NON-EXPEDITED		DE, OT	US-SA-2019SA068696			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Plavix			S		Unk, Unk		Sanofi	
	Azithromycin			S		Unk Unk, Unk		Not Reported	
	Fish Oil			S		Unk Unk, Unk		Not Reported	
	Acetylsalicylic Acid			S				Not Reported	
	Tiotropium Bromide			S				Not Reported	
	Moxifloxacin Hydrochloride			S				Not Reported	
	Paracetamol			S				Not Reported	
	Hydrocodone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2019	16090780	EXPEDITED (15-DAY)		DS	PT-MYLANLABS-2019M1024189		46 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Generalised Exanthematous Pustulosis	Azithromycin	S	Oral	500 Milligram, Qd	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	15306073	NON-EXPEDITED			US-PFIZER INC-2018337956		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	15859191	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019029555		37 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anuria; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16092902	NON-EXPEDITED			US-TEVA-2019-US-1018075			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Cough; Nasopharyngitis	Z Pack Teva (Azithromycin)			S					Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Mar-2019	16093742	EXPEDITED (15-DAY)		HO, OT	FR-ACCORD-114242		17 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise; Mydriasis; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral				Not Reported
	Paracetamol			S	Oral				Accord
	Hepatoum			S	Oral				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azithromycin	S	Oral			Not Reported
	Arestal	S	Oral	Strength: 1 Mg		Not Reported
	Seresta	S	Oral	Strength: 10 Mg		Not Reported
	Prednisolone	S	Oral			Not Reported
	Inorial	S	Oral	Strength: 20 Mg		Not Reported
	Augmentin	S	Oral			Not Reported
	Cefpodoxime/Cefpodoxime	S	Oral			Not Reported
	Proxetil					
	Trimebutine	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094502	NON-EXPEDITED			US-PFIZER INC-2019119595		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094523	NON-EXPEDITED			US-PFIZER INC-2019118143		34 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094527	NON-EXPEDITED			US-PFIZER INC-2019114064		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Dilaudid			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeine	S	Unk	Not Reported
Darvocet	S	Unk	Not Reported
Percocet [Oxycodone Hydrochloride;Paracetamol]	S	Unk	Not Reported
Percodan Compuesto	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094551	NON-EXPEDITED			US-PFIZER INC-2019118949		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094707	NON-EXPEDITED			US-TEVA-2019-US-1019129			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Constipation	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16094964	NON-EXPEDITED			US-PFIZER INC-2019113787		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ceftriaxone Sodium			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Tetanus Toxoid			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2019	16096686	NON-EXPEDITED			US-PFIZER INC-			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2019120651

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cyclobenzaprine			S		Unk		Not Reported
	Sumatriptan			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	14517907	NON-EXPEDITED			US-PFIZER INC-2018057516		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Methotrexate Sodium			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Rocephin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16098714	NON-EXPEDITED			US-TEVA-2019-US-1017740			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Inappropriate Schedule Of Product Administration; Palpitations; Thirst	Azithromycin Tablets			S	Unknown	1 Dosage Forms Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16099018	NON-EXPEDITED			US-PFIZER INC-2019122777		12 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101286	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2019-US-1027097		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Disseminated Mycobacterium Avium Complex Infection; Hepatotoxicity	Mycophenolate Mofetil			S	Unknown	2000 Milligram Daily;		Teva	
	Rifampin			S	Oral	600 Milligram Daily;		Actavis	
	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	
	Tacrolimus			S	Unknown	4 Milligram Daily;		Not Reported	
	Ethambutol			C	Oral	Three Times A Week		Not Reported	
	Meropenem			C	Unknown			Not Reported	
	Vancomycin			C	Unknown			Not Reported	
	Moxifloxacin			C	Unknown			Not Reported	
	Amikacin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101307	EXPEDITED (15-DAY)		OT	PHHY2019DE061974		80 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Product Size Issue	Azithromycin - 1 A Pharma			S	Unknown	1 Df, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2019	16101416	EXPEDITED (15-DAY)		DS, OT	GB-ACCORD-113033		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acoustic Neuroma; Balance Disorder; Deafness Neurosensory;	Tigecycline			S	Intravenous (not otherwise specified)	50 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deafness Unilateral; Facial Paralysis; Fatigue; Insomnia; Nausea; Ototoxicity; Vestibular Disorder	Azithromycin	S	Oral	500 Mg, Qd	Not Reported
	Moxifloxacin	S	Oral	400 Mg, Qd	Not Reported
	Amikacin	S	Unknown	500 Mg, Bid	Not Reported
	Clofazimine	S	Oral	100 Mg, Qd	Not Reported
	Minocycline	S	Oral	100 Mg, Bid	Not Reported
	Meropenem	S	Intravenous (not otherwise specified)	2 G, Tid	Not Reported
	Imipenem	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Azithromycin	S	Oral	250 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	15815469	EXPEDITED (15-DAY)		DE	PHEH2019US001576		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Pneumonia	Clofazimine			S	Oral	50 Mg, Qd		Novartis
	Azithromycin 250 Mg			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	15979007	EXPEDITED (15-DAY)		OT	AT-SA-2019SA042709			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; C-Reactive Protein Increased; Candida Infection; Drug Ineffective; Infection	Rifoldin			S	Intravenous (not otherwise specified)			Sanofi
	Azithromycin			S				Not Reported
	Colistin Sulfate			S				Not Reported
	Tigecycline			S				Not Reported
	Sulbactam			S				Not Reported
	Cubicin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16103834	NON-EXPEDITED			US-PFIZER INC- 2019123109			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Vioxx			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104647	EXPEDITED (15-DAY)		DE, HO, OT	CA-BAYER-2019-050926		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptococcosis; Drug Ineffective; Drug Intolerance; Drug Resistance; Enterocolitis; Multiple Organ Dysfunction Syndrome; Mycobacterium Avium Complex Infection; Nosocomial Infection	Moxifloxacin Oral			S	Unknown	Unk		Bayer
	Amikacin			S	Parenteral			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Clarithromycin			S	Oral	Unk		Not Reported
	Ethambutol			S	Oral	Unk		Not Reported
	Fluconazole			S	Oral	Unk		Not Reported
	Mycophenolate Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rifabutin			S	Oral	Unk		Not Reported
	Rifampin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16104778	NON-EXPEDITED			US-PFIZER INC-2019120493			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2019	16107600	EXPEDITED (15-DAY)		HO, LT, OT	US-009507513-		53 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

1903USA008035

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Drug Hypersensitivity; Dry Skin; Fear; Stevens-Johnson Syndrome	Invanz			S				Merck
	Zithromax			S				Not Reported
	Vancomycin			S	Intravenous (not otherwise specified)	1000 Mg, Qd		Not Reported
	Vancomycin			S		Unk		Not Reported
	Keflex			S				Not Reported
	Biaxin			S				Not Reported
	Azactam			S		Unk		Not Reported
	Meropenem			C		Unk		Not Reported
	Ergocalciferol			C	Oral	50000 Iu, Qw		Not Reported
	Activa			C		Unk		Not Reported
	Tramadol Hydrochloride			C	Oral	100 Mg (Er), Bid		Not Reported
	Sensipar			C	Oral	30 Mg, Qd		Not Reported
	Ranitidine			C		150 Mg, Qd		Not Reported
	Norvasc			C	Oral	5 Mg, Qd		Not Reported
	Metoprolol Tartrate			C	Oral	50 Mg, Bid		Not Reported
	Lyrica			C		150 Mg, Qd		Not Reported
	Lasix (Furosemide)			C	Oral	40 Mg, Qod		Not Reported
	Klor-Con			C	Oral	20 Meq, Qd		Not Reported
	Flexeril			C	Oral	10 Mg, Qd		Not Reported
	Amitriptyline Hydrochloride			C	Oral	100 Mg, Hs		Not Reported
	Magnesium Oxide			C	Oral	400 Mg, Qd		Not Reported
	Ferrous Sulfate			C	Oral	325 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2019	16108848	EXPEDITED (15-DAY)		OT	US-BAXTER-2019BAX006044			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Central Nervous System Infection; Infection; Infection Protozoal	Fluconazole Injection, Usp			S	Unknown	Administered In One Dose		Baxter
	Pentamidine			S	Unknown			Not Reported
	Sulfadiazine			S	Unknown			Not Reported
	Flucytosine			S	Unknown			Not Reported
	Azithromycin			S	Unknown	Administered In One Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	14763268	EXPEDITED (15-DAY)		OT	PHHY2016CA097923		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthropathy; Blister; Burning Sensation; Chest Pain; Cough; Cystitis; Dizziness; Drug Ineffective; Erythema; Fall; Fatigue; Feeling Abnormal; Gait	Xolair			S	Subcutaneous	150 Mg, Biw		Not Reported
Disturbance; Headache; Heart Rate Increased; Histamine Level	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported
Increased; Hypertension; Incorrect Dose	Xolair			S	Subcutaneous	150 Mg, Once In 4 Weeks		Not Reported
Administered; Influenza Like Illness; Injection Site	Xolair			S	Subcutaneous	200 Mg, Biw		Not Reported
Rash; Insomnia; Lip Swelling; Mobility	Xolair			S	Subcutaneous	Unk		Not Reported
Decreased; Muscular Weakness; Myalgia; Nasopharyngitis; Pain; Pain In Extremity; Painful Respiration; Peripheral Swelling; Peripheral Swelling; Product Storage	Xolair			S	Subcutaneous	Unk		Not Reported
Error; Pruritus; Rash; Respiratory Tract Congestion; Scratch;	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair							

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sensation Of Foreign Body; Stress; Swelling; Thyroid Hormones	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
Increased; Thyroid Mass; Tooth Fracture; Urticaria; Urticaria; Urticaria	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	225 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 3 Weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Azithromycin	S	Unknown	250 Mg, Unk	Not Reported
	Azithromycin	S			Not Reported
	Azithromycin	S			Not Reported
	Azithromycin	S			Not Reported
	Pantoprazole	C	Unknown	40 Mg, Qd	Not Reported
	Hydroxyzine	C	Unknown		Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	2 Df, Qd	Not Reported
	Prednisone	C	Unknown	1 Df, Unk	Not Reported
	Cetirizine	C	Unknown	Unk	Not Reported
	Nystatin	C	Unknown	Unk	Not Reported
	Pepcid	C	Unknown	Unk	Not Reported
	Ventolin	C	Unknown	Unk	Not Reported
	Metronidazole	C	Unknown	Unk	Not Reported
	Fucidin	C	Unknown	Unk	Not Reported
	Demulen	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Singulair		C	Unknown	2 Df, Unk				Not Reported
	Zoloft		C	Unknown	Unk				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	15824943	NON-EXPEDITED			US-PFIZER INC-2019017786			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Ocular Hyperaemia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16110314	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2019049869		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancytopenia	Zelitrex			S	Oral	2 Df, Qd		Glaxosmithkline	
	Oracilline			S	Oral	2 Df, Qd		Glaxosmithkline	
	Pantoprazole			S	Oral	40 Mg, Qd		Glaxosmithkline	
	Pentacarinat			S	Unknown	Unk		Not Reported	
	Quizartinib			S	Unknown	Unk		Not Reported	
	Zithromax			S	Oral	3 Df, We		Not Reported	
	Folinoral			C	Unknown	Unk		Glaxosmithkline	
	Celluvisc			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16111039	EXPEDITED (15-DAY)		HO	FR-ACCORD-115509		17 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intentional Overdose; Malaise; Mydriasis; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Escitalopram			S	Oral	Overdose: 140 Mg, 1 Day		Not Reported	
	Paracetamol			S	Oral	79 G, Total		Accord	
	Trimebutine			S	Oral	14000 Mg, Total		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inorial	S	Oral	120 Mg, Total	Not Reported
Azithromycin	S	Oral	1500 Mg, Total	Not Reported
Hepatoum	S	Oral	Unspecified	Not Reported
Arestal	S	Oral	30 Mg, Total	Not Reported
Seresta	S	Oral	310 Mg, Total	Not Reported
Cefpodoxime/Cefpodoxime Proxetil	S	Oral	2000 Mg, Total	Not Reported
Augmentin	S	Oral	6 G, 1 Day	Not Reported
Prednisolone	S	Oral	200 Mg, Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16111065	EXPEDITED (15-DAY)		HO, OT	KR-BAYER-2019-054248		70 YR	Male	KOR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use; Pathogen Resistance	Ciprofloxacin			S		Unk		Bayer
	Ceftriaxone			S		2 G, Qd		Not Reported
	Cefazolin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113314	NON-EXPEDITED			US-PFIZER INC-2019121882		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported
	Omnicef [Cefdinir]			S		Unk		Not Reported
	Darvocet-N			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Paracetamol]			S		Unk		Not Reported
	Theo-Dur			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ultram [Tramadol Hydrochloride]	S		Unk		Not Reported			
	Vicodin	S		Unk		Not Reported			
	Zelnorm	S		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113320	NON-EXPEDITED			US-PFIZER INC-2019122028			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Meloxicam			S		Unk		Not Reported	
	Ultram [Tramadol Hydrochloride]			S		Unk		Not Reported	
	Ambien			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113404	NON-EXPEDITED			US-PFIZER INC-2019123328			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16113740	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2019127822		39 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis	Azithromycin			S		Unk		Pfizer	
	Risperidone			S		Unk		Not Reported	
	Chlorpromazine			S		Unk		Not Reported	
	Fluvoxamine			S		Unk		Not Reported	
	Amlodipine/Perindopril			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16114920	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2019051592			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Bronchitis; Drug Ineffective; Dyspnoea; Feeling Jittery; Hallucination; Insomnia; Respiratory Tract Congestion	Ventolin Hfa Inhalation Powder			S	Respiratory (inhalation)	2 Puff(S), Prn		Glaxosmithkline	
	Bupropion Hydrochloride Xl Tablet			S		300 Mg, Qd		Glaxosmithkline	
	Bupropion Hydrochloride Xl Tablet			S				Glaxosmithkline	
	Z-Pak Tablet			S		Unk		Glaxosmithkline	
	Mucinex			S		Unk		Not Reported	
	Bupropion Hcl Tablet			C		100 Mg, Bid		Glaxosmithkline	
	Spiriva			C				Not Reported	
	Symbicort			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16114977	EXPEDITED (15-DAY)		HO	BR-MYLANLABS- 2019M1026387		34 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Oxacillin			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Mylan	
	Cefalexin			S	Unknown			Mylan	
	Azithromycin			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2019	16115354	NON-EXPEDITED			US-PFIZER INC- 2019124890			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	15827140	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019PT003141		41 YR	Male	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Conjunctival Hyperaemia; Leukocytosis; Odynophagia; Off Label Use; Oral Disorder; Oral Mucosal Exfoliation; Pyrexia; Rash; Rash Pustular; Stevens- Johnson Syndrome	Azithromycin			S	Oral	Unk		Novartis	
	Azithromycin			S				Novartis	
	Amoxicillin + Clavulanate			S	Unknown			Not Reported	
	Potassium								
	Amoxicillin + Clavulanate			S				Not Reported	
	Potassium								
	Cefuroxime			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16112565	NON-EXPEDITED			US-PFIZER INC- 2019120504			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16116998	NON-EXPEDITED			US-PFIZER INC- 2019125183			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Discomfort; Drug Hypersensitivity; Drug Intolerance	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16117080	NON-EXPEDITED			US-PFIZER INC- 2019128557		18 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16117917	NON-EXPEDITED			US-PFIZER INC-2019123353			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Demerol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16118803	NON-EXPEDITED			US-TEVA-2019-US-1020455			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16119425	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019128806		17 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Eye Disorder; Syncope	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Vitamin B6			S	Intravenous drip	0.2 G, 1x/Day		Not Reported	
	Glucose			C	Intravenous drip	500 MI, 1x/Day		Not Reported	
	Glucose			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2019	16119555	EXPEDITED (15-DAY)		DE	DK-AMNEAL PHARMACEUTICALS-2019AMN00363			Unknown	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event	Prednisolone Sodium Phosphate			S	Oral	Unk		Amneal	
	Azathioprine			S	Unknown	Unk		Amneal	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	Unk	Amneal
Methylprednisolone	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Mar-2019	16119557	EXPEDITED (15-DAY)		DE	DK-AMNEAL PHARMACEUTICALS COMPANY GMBH- 2019AGH0003			Unknown	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Adverse Event	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)			Amneal
	Prednisolone			S	Oral	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	13466009	NON-EXPEDITED			US-PFIZER INC- 2017169689		62 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity; Dyspnoea	Azithromycin			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	15932269	NON-EXPEDITED			US-PFIZER INC- 2019054334		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Azithromycin			S	Oral	500 Mg, 1x/Day [500mg Or Cc ; No: 5 ; Sig: 1 Po Qd (Once A Day) X 5d]		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Mar-2019	16112559	NON-EXPEDITED			US-PFIZER INC- 2019117620		62 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Etanercept			S		Unk		Pfizer
	Adalimumab			S		Unk		Not Reported
	Ees			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported
	Percocet [Oxycodone Hydrochloride;Oxycodone Terephthalate;Paracetamol]			S		Unk		Not Reported
	Pseudoephedrine			S		Unk		Not Reported
	Triprolidine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16120800	EXPEDITED (15-DAY)		HO, OT	UA-TEVA-2019-UA-1030629		34 YR	Male	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Diarrhoea; Drug Ineffective; Dysbiosis; Irritable Bowel Syndrome; Pneumonia; Product Use Issue	Sumamed			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16122772	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2717062-00			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Disorder; Diabetes Mellitus; Drug Ineffective; Gastrointestinal Disorder; General Physical Condition Abnormal; Hip Arthroplasty; Intervertebral Disc Protrusion; Lip	Humira			S	Subcutaneous			Not Reported
	Arava			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Squamous Cell Carcinoma; Psoriasis; Skin Cancer	Enbrel	S	Unknown	Not Reported
	Otezla	S	Unknown	Not Reported
	Xeljanz Xr	S	Oral	Not Reported
	Xeljanz Xr	S		Not Reported
	Rituxan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2019	16124956	NON-EXPEDITED			US-PFIZER INC-2019127343			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Desipramine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	15545965	EXPEDITED (15-DAY)		HO	FR-NAPPMUNDI-GBR-2018-0060667			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Pulmonary Oedema; Atrial Fibrillation; Autoimmune Hepatitis; Cerebrovascular Accident; Coma; Death; Fall; Hepatic Failure; Nausea; Osteoporosis; Pleurisy; Renal Failure; Respiratory Distress; Respiratory Failure; Vomiting	Oxycodone Hydrochloride			S	Oral	5 Mg, Daily		Purdue	
	Neurontin			S	Oral	3 Df, Daily (Strength 100mg)		Not Reported	
	Durogesic			S	Transdermal	12 Mcg, Q3d		Not Reported	
	Durogesic			S	Transdermal	25 Mcg, Q3d		Not Reported	
	Instanyl			S	Nasal	Unk		Not Reported	
	Zithromax			S	Oral	500 Mg, Daily (Strength 250 Mg)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16084364	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2019M1023944		3 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Azithromycin	S	Unk	Not Reported
	Cefuroxime Axetil	S	Unk	Mylan
	Cefotaxime	C	Unk	Mylan
	Vancomycin	C	Unk	Mylan
	Acetylsalicylic Acid	C	4 Mg/Kg/Qd	Mylan
	Acetylsalicylic Acid	C	3 Mg/Kg/Qd	Mylan
	Immunoglobulins Nos	C	2 Gram Per Kilogram	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16125640	NON-EXPEDITED			US-TEVA-2019-US-1031055			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tooth Discolouration	Azithromycin Teva			S	Oral	5 MI Daily; Strength: 200 Mg/5 MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126124	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1030634			Unknown	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pathogen Resistance; Therapeutic Product Effect Decreased	Sumamed			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16126351	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1031661		60 YR	Unknown	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia; Cardiotoxicity	Sumamed 500 Mg			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16127456	NON-EXPEDITED			US-PFIZER INC-2019132196		44 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Pneumovax			S		Unk		Not Reported	
	Bromhexine			S		Unk		Not Reported	
	Pseudoephedrine			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16127612	NON-EXPEDITED			US-PFIZER INC-2019129021		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Sinusitis; Ear Pain; Oropharyngeal Pain; Purulent Discharge	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16128079	EXPEDITED (15-DAY)		DE, DS, HO	CA-PURDUE PHARMA-CAN-2019-0009840		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Purdue	
	Morphine Sulfate			S	Intravenous (not otherwise specified)	Unk, 1 Every 10 Minutes		Purdue	
	Amiodarone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily [1 Every 1 Day]		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Daily [1 Every 1 Day]		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	10 Mg, Q1h		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Mg, Q4h		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diltiazem Cd	S	Oral	180 Mg, Unk	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Q4h	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg, 1 Every 14 Days	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, Daily	Not Reported
Furosemide	S	Oral	40 Mg, Daily	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q4h	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Q6h	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Mg, Q6h	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Mg, Q6h	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, 1 Every 14 Days	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Q1h	Not Reported
Procytox	S	Unknown	1060 Mg, 1 Every 14 Days	Not Reported
Trastuzumab	S	Unknown		Not Reported
Aprepitant	C	Oral	125 Mg, Unk	Not Reported
Dexamethasone	C	Oral	20 Mg, Daily	Not Reported
Filgrastim	C	Subcutaneous	300 Mcg, Daily	Not Reported
Gabapentin	C	Oral	100 Mg, Tid [3 Every 1 Day]	Not Reported
Metoclopramide	C	Oral	10 Mg, Qid	Not Reported
Ondansetron	C	Oral	8 G, Bid [2 Every 1 Day]	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16128684	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019128893		2 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Diarrhoea; Gastrointestinal Disorder; Mental Impairment; Vomiting		Zithromax	S	Oral	1.5 Df, 1x/Day		Pfizer		
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16128722	NON-EXPEDITED			US-PFIZER INC-2019129408			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16129476	EXPEDITED (15-DAY)		HO	PHHY2019FR070220		52 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycin			S	Oral	250 Mg, Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16129603	EXPEDITED (15-DAY)		DS, HO, LT, OT	PHHY2019GB070397		35 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Psychotic Disorder; Suicide Attempt	Azithromycin			S	Oral	2 Ot, Qd		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
28-Mar-2019	16130076	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019129813		16 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Formication; Hyperhidrosis; Product Use In Unapproved Indication; Seizure	Zithromax			S	Oral	4 Df, Unk		Pfizer	
	Cytotec			S	Oral	Unk (According To Mother, Taken 8 + 2 Tablets/ According To Hospital, Taken 2 Tablets)		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2019	16130731	NON-EXPEDITED			PHEH2019US013183			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain	Azithromycin			S	Oral	2 Df, Once/Single		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16128994	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019129937		51 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancytopenia; Product Use Issue	Pantoprazole			S	Oral	40 Mg, 1x/Day		Pfizer
	Zithromax			S	Oral	3 Df, Weekly		Pfizer
	Pentacarinat			S		Unk		Not Reported
	Zelitrex			S	Oral	2 Df, 1x/Day		Not Reported
	Oracilline [Phenoxymethylpenicillin]			S	Oral	2 Df, 1x/Day		Not Reported
	Quizartinib			S		Unk		Not Reported
	Folinoral			C		Unk		Not Reported
	Celluvisc [Carmellose Sodium]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16131772	EXPEDITED (15-DAY)		DE, OT	JP-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-203348		70 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Cirrhosis; Hypoalbuminaemia; Peritonitis Bacterial; Pneumonia; Sepsis; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Sun

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16132022	EXPEDITED (15-DAY)		OT	BR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-203022		34 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Azithromycin			S	Unknown	Unk		Sun	
	Cephalexin			S	Unknown	Unk		Sun	
	Azathioprine			S	Unknown	Unk		Not Reported	
	Oxacillin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16132051	EXPEDITED (15-DAY)		HO, OT	RO-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-203199		25 YR	Male	ROM
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Suicide Attempt; Toxicity To Various Agents	Paracetamol		Y	S	Unknown	Unk		Ranbaxy	
	Azitrox			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16132397	EXPEDITED (15-DAY)		HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-181044		14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Minocycline			S	Unknown	100 Milligram, Bid		Ranbaxy	
	Methylprednisolone			S	Unknown	60 Milligram, 1dose/6hour		Not Reported	
	Acetaminophen		Y	S	Unknown	650 Milligram, 1dose/4hour		Sun	
	Ibuprofen			S	Unknown	500 Milligram, 1dose/6hour		Ranbaxy	
	Clindamycin			S	Unknown	600 Milligram,		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Azithromycin		S	Unknown	1dose/6hour 500 Milligram, 1dose/6hour		Sun	
		Magic Mouthwash		S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133022	NON-EXPEDITED			US-PFIZER INC- 2019134608		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133380	NON-EXPEDITED			US-PFIZER INC- 2019129773		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16133632	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX- 2019AP010176		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Salbutamol			S	Unknown	100 Mg, Unk		Apotex	
	Alvesco			S	Unknown	2 Df, Qd		Not Reported	
	Spiriva			S	Unknown	2 Df, Bid		Not Reported	
	Zenhale			S	Unknown	2 Df, Bid		Not Reported	
	Zithromax			S	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16134592	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2019019285			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; C-Reactive Protein Increased; Candida Infection; Condition Aggravated; Device Related Sepsis; Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Tygacil			S		Unk		Pfizer	
	Tygacil			S				Pfizer	
	Sulbactam Sodium			S		Unk		Pfizer	
	Sulbactam Sodium			S				Pfizer	
	Colistin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Colistin			S		Unk (Aerosol)		Not Reported	
	Rifoldin			S		Unk		Not Reported	
	Rifoldin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16135193	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2019125847		26 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Drug Resistance	Azithromycin			S		500 Mg, Daily		Pfizer	
	Prednisolone			S		30 Mg, Daily		Not Reported	
	Prednisolone			S		60 Mg, Daily (Increased)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16136048	EXPEDITED (15-DAY)		OT	PHHY2019CA069377			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Diarrhoea; Dyspnoea; Nausea	Azithromycin Sandoz			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16136204	NON-EXPEDITED			US-PFIZER INC-2019136254			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2019	16136958	EXPEDITED (15-DAY)		LT	PHHY2019IT071700		83 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Hypersensitivity; Hypertensive Crisis; Rash	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Total		Novartis	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2019	16137285	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2019-010663			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Treatment Failure	Azithromycin			S	Unknown	Unk		Aurobindo	
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	13548937	NON-EXPEDITED			US-PFIZER INC-2017206505			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Cipro			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	14370669	NON-EXPEDITED			US-PFIZER INC-2018007348			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	14524367	NON-EXPEDITED			US-PFIZER INC-2018061618		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Malaise	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	14607911	NON-EXPEDITED			US-PFIZER INC-2018087518		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	15749577	EXPEDITED (15-DAY)		OT	HU-BAUSCH-BL-2018-035257		16 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Clindamycin			S	Unknown			Not Reported	
Dysphagia; Hyperaemia;	Azithromycin			S	Unknown			Not Reported	
Leukocytosis; Lymph	Azithromycin			S				Not Reported	
Node Palpable;									
Oropharyngeal Pain;									
Pyrexia; Streptococcal									
Infection; Tonsillar									
Hypertrophy									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	15953147	NON-EXPEDITED			US-PFIZER INC-2019060691		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Fungal Infection	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16139750	EXPEDITED (15-DAY)		OT	CA-ACS-001362		55 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jarisch-Herxheimer Reaction	Ceftriaxone			S	Intramuscular	Reconstituted With 0.9 Ml Of 1% Lidocaine		Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Trazodone			C	Unknown			Not Reported	
	Esomeprazole			C	Unknown			Not Reported	
	Telmisartan-Amlodipine			C	Unknown			Not Reported	
	Emtricitabine 200 Mg-Tenofovir 300 Mg			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16139954	NON-EXPEDITED		OT	US-APOTEX-2019AP010459			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depression; Emotional Disorder; Hypersensitivity; Seizure; Urticaria	Azithromycin			S	Unknown	Unk		Apotex	
	Bupropion			S	Unknown	Unk		Apotex	
	Tizanidine			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16142863	EXPEDITED (15-DAY)		DE, HO, OT	NL-MYLANLABS-2019M1028762		79 YR	Male	NLD

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
C-Reactive Protein Increased; Cardiac Failure Congestive; Condition Aggravated; Drug Ineffective; Hypoxia; Leukocytosis; Respiratory Failure; Tachycardia; Tachypnoea	Ciprofloxacin			S		Unk		Not Reported	
	Amoxicillin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Cefuroxime			S		Unk		Mylan	
	Ceftriaxone			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16143274	EXPEDITED (15-DAY)		HO, OT	PT-JNJFOC-20190342352		39 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis	Risperidone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Fluvoxamine			S	Unknown			Not Reported	
	Chlorpromazine			S	Unknown			Not Reported	
	Amlodipine W/Perindopril			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2019	16143570	NON-EXPEDITED			US-NEOPHARMA INC-000050			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Mental Status Changes	Amoxicillin/Clavulanate			S				Not Reported	
	Potassium								
	Morphine			S				Not Reported	
	Phenytoin			S				Not Reported	
	Sulfasalazine			S				Not Reported	
	Azithromycin			S				Not Reported	
	Codeine			S				Not Reported	
	Tramadol			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	14404119	NON-EXPEDITED			US-PFIZER INC-2018018175			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Rifampicin			S		Unk		Unknown	
	Keflex			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	
	Norco			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	15979851	EXPEDITED (15-DAY)		HO	PT-ACCORD-107114		65 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Cough; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Therapeutic Response Decreased	Amoxicillin/Clavulanic Acid			S	Unknown			Not Reported	
	Lisinopril			S	Unknown			Accord	
	Alendronate Sodium			S	Unknown			Not Reported	
	W/Calcium/Colecalciferol			S	Unknown			Not Reported	
	Indapamide/Perindopril			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145528	EXPEDITED (15-DAY)		HO, OT	FR-SA-2019SA087953		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Malaise; Rhabdomyolysis;	Rifadine			S	Oral	1 Df, Qd		Sanofi	
	Azithromycin Monohydrate			S	Oral	250 Mg, Qd		Not Reported	
	Lamprene [Clofazimine]			S	Oral	1 Df, Qd		Not Reported	
	Paracetamol			C				Not Reported	
	Lactulose			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transaminases Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16145954	EXPEDITED (15-DAY)		HO	PL-AUROBINDO-AUR-APL-2019-015281			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Rash; Urticaria	Azithromycin			S	Unknown	Unk		Aurobindo
	Cefuroxime			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Taromentin (Amoxicillin\Clavulanic Acid)			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Immunglobulin			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Cefotaxime			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16146410	EXPEDITED (15-DAY)		HO	FR-ZYDUS-035189		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycin			S	Oral			Zydu Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16149032	EXPEDITED (15-DAY)		HO	SK-TEVA-2019-SK-1032128			Female	SVK

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Maculo-Papular	Sumamed			S	Oral	500 Milligram Daily; 0-1-0		Not Reported
	Dalacin C			S	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16149401	NON-EXPEDITED			US-TEVA-2019-US-1025897			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour	Azithromycin			S	Oral	Form Strength : Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2019	16149699	EXPEDITED (15-DAY)		HO	PHHY2019FR070165		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline	Lamprene			S	Oral	1 Df, Qd		Novartis	
Phosphatase Increased;	Azithromycin Monohydrate			S	Oral	250 Mg, Qd		Not Reported	
Electrocardiogram Qt	Rifadine			S	Oral	1 Df, Qd		Not Reported	
Prolonged; General	Paracetamol			C	Unknown	Unk		Not Reported	
Physical Health	Lactulose			C	Unknown	Unk		Not Reported	
Deterioration; Malaise;									
Rhabdomyolysis;									
Transaminases Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	13974125	EXPEDITED (15-DAY)		HO, OT	ES-ROCHE-1990170		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Pain; Fatigue; Flank Pain; Gait Disturbance;	Prograf			S	Oral	1 In Morning And 1 Before Dinner		Not Reported	
Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Prograf			S	Oral	4.5 Mg Before Breakfast And 4 Mg Before Dinner		Not Reported	
	Prograf			S	Oral			Not Reported	
	Valcyte			S	Oral	At Lunch Time		Not Reported	
	Valcyte			S				Not Reported	
	Cellcept			S	Oral	2 At Breakfast And 2 At Dinner		Not Reported	
	Cellcept			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zitromax	S	Oral	On L-X-V At Lunch	Not Reported
Zitromax	S	Oral	250 Mg/ 48 Hours	Not Reported
Septrin	S	Oral	Sulfamethoxazole 400 Mg/Trimethoprim 80 Mg At Lunch Time	Not Reported
Septrin	S	Oral	Unk, Qd	Not Reported
Prednisone	S	Oral	At Breakfast Time	Not Reported
Prednisone	S	Oral		Not Reported
Prednisone	S	Oral		Not Reported
Omeprazole	C	Oral	At Breakfast	Not Reported
Paracetamol	C	Oral	(2 At Breakfast - 2 At Lunch - 2 At Dinner)	Not Reported
Abelcet	C	Respiratory (inhalation)	Via Resp Inhalation 1/2 Vial Of 100 Mg (On Mondays In The Afternoon)	Not Reported
Lorazepam	C	Oral	At Bedtime	Not Reported
Dexketoprofen	C	Oral	1 At Breakfast - 1 At Lunch - 1 At Dinner	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	14438620	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-003027			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Fatigue; Flank Pain; Gait Disturbance; Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Valganciclovir Film Coated Tablets			S	Oral	900 Milligram, Once A Day		Aurobindo
	Valganciclovir Film Coated Tablets			S				Aurobindo
	Cellcept			S	Oral	1000 Mg, 2x/Day (Bid), 500 Mg, 4x/Day (2 At Breakfast And 2 At Dinner)		Not Reported
	Cellcept			S	Oral	2000 Milligram (500 Mg, 4x/Day (Qid))		Not Reported
	Prograf			S	Oral	5 Mg, 2x/Day (1 In The		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

				Morning And 1 Before Dinner)	
Prograf	S	Oral		4.5 Milligram, Two Times A Day(4.5 Mg Before Breakfast And 4 Mg Before Dinner)	Not Reported
Prednisone	S	Oral		30 Mg, 2x/Day (Bid)	Not Reported
Prednisone	S	Oral		20 Milligram, Once A Day	Not Reported
Prednisone	S	Oral		20 Milligram, Once A Day	Not Reported
Prednisone	S	Oral		60 Milligram, Once A Day (30 Mg, 2x/Day (At Breakfast Time))	Not Reported
Septrin	S	Oral		Once Daily (Qd) 400 Mg/80 Mg (1)	Not Reported
Septrin	S	Oral		Unk, Once A Day	Not Reported
Zitromax	S	Oral		250 Milligram (250 Mg, At Lunch Time Every 48 Hours)	Not Reported
Zitromax	S	Oral		Unk	Not Reported
Dexketoprofen	C	Oral		At 25 Mg (1 At Breakfast, 1 At Lunch, 1 At Dinner), As Needed	Not Reported
Abelcet	C	Respiratory (inhalation)		50 Mg, Weekly (On Mondays In The Afternoon)	Not Reported
Calcium W/Ergocalciferol	C	Oral		Unk Unk, 2x/Day (Bid) (2)	Not Reported
Calcium W/Ergocalciferol	C	Oral		1 Dosage Form, Two Times A Day	Not Reported
Omeprazole	C	Oral		20 Milligram, Once A Day (20 Mg, 1x/Day (At Breakfast))	Not Reported
Lorazepam	C	Oral		1 Milligram, Once A Day (1 Mg, 1x/Day (At Bedtime))	Not Reported
Paracetamol	C	Oral		At 500 Mg (2 At Breakfast, 2 At Lunch, 2 At Dinner),	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

As Needed

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	15285336	NON-EXPEDITED			US-INCYTE CORPORATION-2018IN006859			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Jakafi			S	Unknown	10 Mg, Bid		Incyte	
Abdominal Pain Upper;	Jakafi			S	Oral	5 Mg, Bid		Incyte	
Anxiety; Blood Alkaline Phosphatase Decreased;	Z-Pak			S	Unknown	Unk		Not Reported	
Blood Cholesterol Increased; Blood Count Abnormal; Diarrhoea;	Atorvastatin			C	Unknown			Not Reported	
Mean Cell Haemoglobin Increased; Mean Cell Volume Increased;	Prozac			C	Unknown			Not Reported	
Pharyngitis Streptococcal;	Levothyroxine			C	Unknown			Not Reported	
Pruritus; Red Blood Cell Count Decreased; Stress;	Aspirin /00002701/			C	Unknown			Not Reported	
Vomiting	Lipitor			C	Unknown			Not Reported	
	Vitamin B			C	Unknown			Not Reported	
	Vitamin C /00008001/			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	15981618	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190107416		38 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Pharyngitis Streptococcal	Stelara			S	Subcutaneous	Strength = 90 Mg		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Seroquel			C	Unknown			Not Reported	
	Maxalt			C	Unknown			Not Reported	
	Celebrex			C	Unknown			Not Reported	
	Ativan			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16046868	NON-EXPEDITED			US-PFIZER INC-2019096871			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Sertraline Hcl			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S		Unk		Not Reported	
	Buspirone			S		Unk		Not Reported	
	Duloxetine			S		Unk		Not Reported	
	Paxil			S		Unk		Not Reported	
	Ultram [Paracetamol;Tramadol Hydrochloride]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16102873	EXPEDITED (15-DAY)		HO, OT	PHHY2019SI060470		29 YR	Male	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Bilirubin Increased; C-Reactive Protein Increased; Chest Pain; Chromaturia; Cough; Drug Ineffective; Ejection Fraction Decreased; Faeces Pale; Fatigue; Gamma-Glutamyltransferase Increased; Hepatic Enzyme Increased; Hepatic Pain; Hepatosplenomegaly; Jaundice; Left Ventricular Dysfunction; Left Ventricular End-Diastolic	Lekadol Plus C			S	Unknown	Unk, (4-5 Bags Per Day)		Not Reported	
	Lekadol Plus C			S				Not Reported	
	Sumamed			S	Unknown	Unk		Not Reported	
	Sumamed			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pressure Increased; Left
Ventricular Enlargement;
Left Ventricular Failure;
Liver Injury; Malaise;
Myocarditis Mycotic;
Pericardial Effusion;
Pleural Effusion; Pyrexia;
Rash; Respiratory Rate
Increased; Tricuspid Valve
Incompetence; Troponin
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16150769	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT072794		39 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis	Risperidone			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	
	Chlorpromazine			S	Unknown	Unk		Not Reported	
	Fluvoxamine			S	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2019	16151167	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2019140418			Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Of Eyelid; Eyelid Oedema; Oxygen Saturation Decreased; Somnolence	Azithromycin			S	Intravenous drip	0.1 G, 1x/Day		Pfizer	
	Ceftriaxone Sodium			S	Intravenous drip	0.8 G, 1x/Day		Not Reported	
	Sodium Chloride			C	Intravenous drip	100 MI, 1x/Day		Not Reported	
	Glucose Injection			C	Intravenous drip	100 MI, 1x/Day		Not Reported	
	Budesonide			C		1 Mg, Unk		Not Reported	
	Terbutaline			C		2.5 Mg, Unk		Not Reported	
	Ipratropium Bromide			C		250 Ug, 2x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16151834	NON-EXPEDITED			US-PFIZER INC-2019138416			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Apr-2019	16154271	EXPEDITED (15-DAY)		OT	PHHY2019PT065223		73 YR	Male	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective; Treatment Failure	Amoxicillin + Clavulanate			S	Unknown	Unk		Novartis	
	Potassium Azithromycin			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	14250693	NON-EXPEDITED			US-PFIZER INC-2017518527			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lodine			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	14767537	NON-EXPEDITED			US-PFIZER INC-2018157335		9 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	15306087	NON-EXPEDITED			US-PFIZER INC-2018338062		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Hcl			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Cefaclor			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Naproxen			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	15786580	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2018M1097742		57 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Levofloxacin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Olmotec Comp			C		20 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	15998947	NON-EXPEDITED		OT	US-JNJFOC-20190207802			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Ineffective; Nausea; Product Use Complaint	Symtuza			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Acyclovir			C				Not Reported	
	Vitamin D3			C				Not Reported	
	Bactrim			C				Not Reported	
	Ferrous Sulfate			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16006442	NON-EXPEDITED			US-PFIZER INC-2019076914		68 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Drug Ineffective	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16068190	EXPEDITED (15-DAY)			GR-PFIZER INC-2019107536		66 YR	Female	GRC
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
No Adverse Event	Azithromycin			S		Unk (For 3 Days)		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16133007	NON-EXPEDITED			US-PFIZER INC-2019134235		43 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Arava			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Apr-2019	16155784	EXPEDITED (15-DAY)		OT	BR-AUROBINDO-AUR-APL-2019-017829			Unknown	BRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Generalised	Oxacillin			S	Unknown	Unk		Aurobindo	
Exanthematous	Cephalexin			S	Unknown	Unk		Aurobindo	
Pustulosis; Face Oedema;	Azathioprine			S	Unknown	Unk		Not Reported	
Leukocytosis; Papule;	Azithromycin			S	Unknown	Unk		Not Reported	
Pustule; Rash									
Erythematous									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16156316	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1033254		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycine Anhydre			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16157290	NON-EXPEDITED			US-PFIZER INC-2019141493		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Omnicef Omni-Pac			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16157426	NON-EXPEDITED			US-PFIZER INC-2019140765		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Swelling	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16157449	NON-EXPEDITED			US-PFIZER INC-2019141049		41 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ultram			S		Unk		Not Reported	
	Compazine Spansule			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Imitrex		S			Unk			Not Reported
	Zomig		S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16157667	EXPEDITED (15-DAY)		HO	FR-ZYDUS-035226		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline	Azithromycin			S	Oral			Zydus Pharm	
Phosphatase Increased;	Rifampicin			S	Oral			Not Reported	
Electrocardiogram Qt	Clofazimine			S	Oral			Not Reported	
Prolonged; General	Paracetamol			C	Unknown			Not Reported	
Physical Health	Lactulose			C	Unknown			Not Reported	
Deterioration; Malaise;									
Rhabdomyolysis;									
Transaminases Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16159417	NON-EXPEDITED			US-PFIZER INC-2019143788			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2019	16296704	DIRECT		HO				Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Azithromycin 250mg Tablet			S				Not Reported	
Hypersensitivity;									
Supraventricular									
Tachycardia									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	13910906	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2017363662		66 YR	Male	ESP

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Fatigue; Flank Pain; Gait Disturbance; Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Zitromax			S	Oral	250 Mg, Every 48 Hour On L-X-V At Lunch		Pfizer
	Zitromax			S		Unk		Pfizer
	Prograf			S	Oral	4.5 Mg, 2x/Day (Every 12 Hours) 4.5 Mg Before Breakfast And 4 Mg Before Dinner		Not Reported
	Prograf			S	Oral	5 Mg, 2x/Day (1 In The Morning And 1 Before Dinner)		Not Reported
	Prednisone			S	Oral	30 Mg, 2x/Day (At Breakfast Time)		Not Reported
	Prednisone			S	Oral	20 Mg, Daily		Not Reported
	Prednisone			S	Oral	60 Mg, 1x/Day		Not Reported
	Cellcept			S	Oral	500 Mg, 4x/Day (Tablet 2 At Breakfast And 2 At Dinner 1000 Mg, 2x/Day (Bid), 500 Mg, 4x/Day (2 At Bre		Not Reported
	Valcyte			S	Oral	900 Mg, 1x/Day (At Lunch Time)		Not Reported
	Septrin			S	Oral	1 Df, 1x/Day (Once A Day (At Lunch Time)		Not Reported
	Septrin			S				Not Reported
	Abelcet			C	Respiratory (inhalation)	50 Mg, Weekly (On Mondays In The Afternoon)		Not Reported
	Paracetamol			C	Oral	500 Mg (2 At Breakfast, 2 At Lunch, 2 At Dinner), As Needed		Not Reported
	Dexketoprofen			C	Oral	At 25 Mg (1 At Breakfast, 1 At Lunch, 1 At Dinner), As Needed		Not Reported
	Omeprazole			C	Oral	20 Mg, 1x/Day (At		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lorazepam	C	Oral	Breakfast)	
Calcium + Vitamin D	C	Oral	1 Mg, 1x/Day (At Bedtime)	Not Reported
			1 Df, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	14739939	NON-EXPEDITED			US-PFIZER INC-2018145998		10 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	15698829	NON-EXPEDITED			US-PFIZER INC-2018499669		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Vomiting	Azithromycin			S	Oral	Unk (2 Tabs On Days 1 Then 1 Tab Daily)		Pfizer
	Erythromycin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	15853108	EXPEDITED (15-DAY)		HO, LT, OT	PT-AUROBINDO-AUR-APL-2019-002307			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conjunctival Hyperaemia; Leukocytosis; Odynophagia; Off Label Use; Oral Mucosal Exfoliation; Oropharyngeal Plaque; Pyrexia; Rash; Rash Pustular; Stevens-Johnson Syndrome	Amoxicillin+Clavulanic Acid Film-Coated Tablets			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid Film-Coated Tablets			S	Oral	Unk		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Oral	Unk		Aurobindo
	Cefuroxime			S	Unknown	Unk		Aurobindo

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16160505	EXPEDITED (15-DAY)		HO	FR-ROCHE-2297243		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Myeloid Leukaemia	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Kineret			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Xarelto			C	Unknown			Not Reported	
	Bisoprolol Fumarate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16161643	EXPEDITED (15-DAY)		HO	HR-ACCORD-118246		60 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Oedema; Haematoma; Periorbital Oedema; Pruritus; Pyrexia; Rash; Skin Lesion; Skin Plaque; Urticaria	Quetiapine			S	Oral	Dose: 1 (Unit Unspecified)		Not Reported	
	Pregabalin			S	Oral			Not Reported	
	Detralex			S	Oral	2x1		Not Reported	
	Sumamed			S	Oral	500 Mg; 1x1 3 Days		Not Reported	
	Acetylsalicylic Acid			S	Oral	300 Mg; 2x1		Not Reported	
	Spasmomen			S	Oral			Not Reported	
	Normabel			S	Oral	5 Mg; Pp		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16161794	NON-EXPEDITED			US-PFIZER INC-2019144686		60 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Terbutaline			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16161808	NON-EXPEDITED			US-PFIZER INC-2019140763		58 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Palpitations	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16162296	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-017729			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycin			S	Oral	250 Milligram		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16164792	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019142720		76 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flushing; Hypoaesthesia; Oedema	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2019	16164997	NON-EXPEDITED			US-PFIZER INC-2019141092		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clindamycin Hcl	S	Unk	Pfizer
Doxycycline Hyclate	S	Unk	Pfizer
Flomax [Tamsulosin Hydrochloride]	S	Unk	Not Reported
Motrin	S	800 Mg, Unk	Not Reported
Lovastatin	S	Unk	Not Reported
Zithromycin	S	Unk	Not Reported
Clarithromycin	S	Unk	Not Reported
Naproxen	S	Unk	Not Reported
Sulfamethoxazole	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2019	16169268	DIRECT					17 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Fatigue; Presyncope	Azithromycin			S	Oral	Quantity:2 Tablet(S);	5 DAY	Lupin
	Hydroxyzine			C				Not Reported
	Prozac			C				Not Reported
	Gabapentine			C				Not Reported
	Flovent			C				Not Reported
	Albuterol			C				Not Reported
	Xyrtec			C				Not Reported
	Flonase			C				Not Reported
	Enlighten			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	14641056	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2018-013577			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Fatigue; Flank Pain; Gait Disturbance; Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Valganciclovir			S	Oral	900 Mg, 1x/Day (At Lunch Time)		Aurobindo
	Prograf			S	Oral	5 Milligram, Once A Day(5 Mg, 2x/Day (1 In The Morning And 1 Before		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prograf	S	Oral	Dinner) 4.5 Milligram, Two Times A Day	Not Reported
Prograf	S	Oral	4.5 Mg Before Breakfast And 4 Mg Before Dinner	Not Reported
Zitromax	S	Oral	250 Milligram(250 Mg, At Lunch Time Every 48 Hours)	Not Reported
Septrin	S	Oral	Unk Unk, 1x/Day	Not Reported
Septrin	S	Oral	1 Dosage Form, Once A Day	Not Reported
Prednisone	S	Oral	30 Mg, 2x/Day (At Breakfast Time)	Not Reported
Prednisone	S	Oral	20 Mg, Daily	Not Reported
Cellcept	S	Oral	500 Mg, 4x/Day	Not Reported
Cellcept	S	Oral	500 Milligram, Four Times/Day	Not Reported
Abelcet	C	Respiratory (inhalation)	50 Mg, Weekly (On Mondays In The Afternoon)	Not Reported
Omeprazole	C	Oral	20 Mg, 1x/Day (At Breakfast)	Not Reported
Paracetamol	C	Oral	At 500 Mg (2 At Breakfast, 2 At Lunch, 2 At Dinner), As Needed	Not Reported
Vitamin D2	C	Oral	1 Dosage Form, Two Times A Day	Not Reported
Lorazepam	C	Oral	1 Mg, 1x/Day (At Bedtime)	Not Reported
Dexketoprofen	C	Oral	At 25 Mg (1 At Breakfast, 1 At Lunch, 1 At Dinner), As Needed	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	14972719	NON-EXPEDITED			US-PFIZER INC- 2018225421		46 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Amlodipine Besilate			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Piroxicam			S		Unk		Pfizer
	Advil			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Bystolic			S		Unk		Not Reported
	Elavil			S		Unk		Not Reported
	Crestor			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Paxil [Paroxetine Hydrochloride]			S		Unk		Not Reported
	Coreg Cr			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16167886	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-018480			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Rhabdomyolysis	Azithromycin			S	Unknown	Unk		Aurobindo
	Fluvoxamine			S	Unknown	Unk		Not Reported
	Risperidone			S	Unknown	Unk		Aurobindo
	Chlorpromazine			S	Unknown	Unk		Not Reported
	Amlodipine;Perindopril			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16168050	NON-EXPEDITED			US-PFIZER INC- 2019146540			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16168070	NON-EXPEDITED			US-PFIZER INC-2019142382		30 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Face Oedema; Urticaria	Advil Cold And Sinus			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16169397	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20190407116		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Myeloid Leukaemia	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
	Enbrel			S	Subcutaneous			Not Reported	
	Kineret			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Novatrex			S	Oral			Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)			Not Reported	
	Xarelto			C	Unknown			Not Reported	
	Bisoprolol Fumarate			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16170468	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2019144057		25 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Abnormal; Chest Pain; Dizziness;	Azithromycin			S		500 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Eructation; Fatigue;
Headache; Heart Rate
Abnormal; Listless;
Myalgia; Palpitations;
Paraesthesia; Tunnel
Vision

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2019	16170554	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2019141382		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	14993153	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2018M1032441		60 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Azithromycin			S	Unknown	250 Mg, Qod		Not Reported	
	Azithromycin			S	Unknown	250 Milligram, Bid (Alternate Day (Every Other Day For Three Months))		Not Reported	
	Montelukast			S	Unknown	10 Milligram, Qd		Mylan	
	Levocetirizine			S	Unknown	5 Mg, Qd		Mylan	
	Fluticasone			S	Nasal	1000 Microgram, Qd		Mylan	
	Fluticasone			S	Nasal	55 Gram, Qd		Mylan	
	Fluticasone			S	Nasal	0.055 Milligram, Qd		Mylan	
	Fluticasone			S		1 Milligram, Qd		Mylan	
	Fluticasone			S	Unknown	1000 Microgram, Qd		Mylan	
	Salbutamol /00139502/			S	Unknown	6 Df, Qd,(6 Puffs Per Day)		Mylan	
	Salmeterol			S	Unknown	Unk,(6 Puffs/Day; 100 ?G/Day)		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Salmeterol			S		0.1 Milligram, Qd			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	15165773	EXPEDITED (15-DAY)		DE, HO, LT, OT	FR-TAKEDA-2018TUS022608		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure;	Iclusig			S	Unknown	45 Milligram, Qd		Takeda	
Drug Interaction; Drug	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported	
Interaction; Drug Level	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported	
Above Therapeutic;	Voriconazole			S	Unknown	400 Milligram, Qd		Not Reported	
Hepatic Failure;	Voriconazole			S	Unknown	400 Milligram, Bid		Not Reported	
Hepatocellular Injury;	Voriconazole			S	Unknown	Unk		Not Reported	
Hepatotoxicity; Off Label	Voriconazole			S	Unknown	200 Milligram, Qd		Not Reported	
Use	Voriconazole			S	Unknown	400 Milligram, Qd		Not Reported	
	Voriconazole			S	Unknown	200 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	15963292	EXPEDITED (15-DAY)		CA, DE	FR-MYLANLABS-2019M1012708			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During	Azithromycin			S	Transplacental	1 Gram, Qd		Not Reported	
Pregnancy; Foetal	Eviplera			S	Transplacental	1 Dosage Form, Qd		Mylan	
Malformation; Limb									
Deformity									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16117734	EXPEDITED (15-DAY)			JP-TEVA-2019-JP-001226J		47 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Face Oedema; Insomnia;	Azithromycin Tablet 250mg Teva			S	Oral			Not Reported	
Malaise; Pruritus; Pyrexia;	Bilanoa			S	Oral			Not Reported	
Rash									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Resplen	S	Oral		Not Reported
Adetphos	C	Oral	3 Gram Daily;	Not Reported
Methycobal	C	Oral	1500 Microgram Daily;	Not Reported
Biofermin R	C	Oral	6 Dosage Forms Daily;	Not Reported
Tamoxifen	C	Oral	20 Milligram Daily;	Not Reported
L-Carbocysteine	C	Unknown		Not Reported
Mecobalamin	C	Unknown	1500 Microgram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16171905	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20190338347			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Exposure During Pregnancy; Foetal Death	Paracetamol		Y	S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Ibuprofen		Y	S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Doxylamine		Y	S	Unknown			Not Reported
	Naproxen		Y	S	Unknown			Not Reported
	Hydrocortisone		Y	S	Topical			Not Reported
	Ranitidine Hydrochloride		Y	S	Unknown			Not Reported
	Amoxicillin			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Metronidazole			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Betamethasone			S	Topical			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Erythromycin			S	Unknown			Not Reported
	Trimethoprim Sulfamethoxazole			S	Unknown			Not Reported
	Phenoxyethylpenicillin			S	Unknown			Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Labetalol	S	Unknown	Not Reported
Acyclovir	S	Topical	Not Reported
Hydrocortisone	S	Rectal	Not Reported
Progesterone	S	Unknown	Not Reported
Clindamycin	S	Unknown	Not Reported
Fluticasone	S	Respiratory (inhalation)	Not Reported
Lorazepam	S	Unknown	Not Reported
Insulin Human	S	Unknown	Not Reported
Mometasone	S	Respiratory (inhalation)	Not Reported
Cloxacillin	S	Unknown	Not Reported
Citalopram	S	Unknown	Not Reported
Fusidic Acid	S	Topical	Not Reported
Venlafaxine	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Paroxetine	S	Unknown	Not Reported
Sertraline	S	Unknown	Not Reported
Alprazolam	S	Unknown	Not Reported
Fluoxetine	S	Unknown	Not Reported
Cefalexin	S	Unknown	Not Reported
Diclofenac	S	Unknown	Not Reported
Epinephrine	S	Other	Not Reported
Diazepam	S	Unknown	Not Reported
Triamcinolone	S	Topical	Not Reported
Ampicillin	S	Unknown	Not Reported
Nitrofurantoin	S	Unknown	Not Reported
Codeine	S	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16171933	EXPEDITED (15-DAY)		LT, OT	IT-AUROBINDO-AUR-APL-2019-017961			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Hypersensitivity; Hypertensive Crisis; Rash	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram In Total		Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram In Total		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16171992	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-AUROBINDO-AUR-APL-2019-018086			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder; Suicide Attempt	Azithromycin 500 Mg			S	Oral	Unk (2), Daily		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16172003	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-018100			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Malaise; Rhabdomyolysis; Transaminases Increased	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo	
	Lamprene			S	Oral	1 Dosage Form, Daily		Not Reported	
	Rifadine			S	Oral	1 Dosage Form, Daily		Not Reported	
	Lactulose			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16172179	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1036521		80 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asphyxia; Oedema		Sumamed 500 Mg		S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16172185	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1036520		72 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Oedema		Sumamed 500 Mg		S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16174924	EXPEDITED (15-DAY)		OT	US-PENTEC HEALTH-2019PEN00025		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Vancomycin Hydrochloride			S	Unknown				Pentec - Compounding
	Azithromycin			S	Unknown				Not Reported
	Clindamycin			S	Unknown				Not Reported
	Gentamicin			S	Unknown				Not Reported
	Piperacillin/Tazobactam			S	Unknown				Not Reported
	Amoxicillin			S	Unknown				Not Reported
	Meropenem			S	Unknown				Not Reported
	Metronidazole			S	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16175115	EXPEDITED (15-DAY)		OT	NL-APOTEX-2019AP010864		25 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Abnormal; Chest Pain; Dizziness; Eructation; Fatigue; Headache; Heart Rate Abnormal; Myalgia; Palpitations; Paraesthesia; Tunnel Vision	Azithromycin			S	Unknown	500 Mg, Qd, 1 Per Dag Om +/- Om 12 Uur			Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16175194	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019145620		73 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blood Alkaline	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
Phosphatase Increased;	Rifadine [Rifampicin]			S	Oral	1 Df, 1x/Day		Not Reported	
Electrocardiogram Qt	Lamprene [Clofazimine]			S	Oral	1 Df, 1x/Day		Not Reported	
Prolonged; General	Paracetamol			C		Unk		Not Reported	
Physical Health	Lactulose			C		Unk		Not Reported	
Deterioration; Malaise;	Dietary Supplement			C		Unk		Not Reported	
Rhabdomyolysis;									
Transaminases Increased									
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16175204	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019143997		9 YR	Female	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cholestasis; General	Zithromax			S	Oral	7.5 MI, Unk		Pfizer	
Physical Health	Zithromax			S	Oral	3.75 MI, Unk		Pfizer	
Deterioration; Liver									
Disorder; Pyrexia									
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16175665	NON-EXPEDITED			US-AKRON, INC.-2065578			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation	Azasite			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16175700	NON-EXPEDITED			US-AKRON, INC.-2065579			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort; Diarrhoea		Azasite		S		Ophthalmic		Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16175971	NON-EXPEDITED			US-AKRON, INC.- 2065588			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dry Eye; Ocular Hyperaemia	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16175977	NON-EXPEDITED			US-AKRON, INC.- 2065590			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Disorder; Eye Pruritus; Ocular Hyperaemia	Azasite			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16176073	NON-EXPEDITED			US-AKRON, INC.- 2065592			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azasiite Ophtlamic Solution			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
09-Apr-2019	16176074	NON-EXPEDITED			US-AKRON, INC.- 2065593			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Pain; Photophobia; Vision Blurred; Vision Blurred	Azasite			S	Ophthalmic			Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16176836	NON-EXPEDITED			US-ACTELION-A-NJ2019-187967			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dysphagia; Oedema Peripheral; Peripheral Swelling	Tracleer			S	Oral			Actelion	
	Revatio			S	Oral	20 Mg, Tid		Not Reported	
	Erythromycin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Latanaprost/Timolol			S	Ophthalmic			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2019	16318560	DIRECT					61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anorectal Discomfort; Arthralgia; Cardiac Flutter; Dysphonia; Faeces Discoloured; Tinnitus	Azithromycin Tablets, 250mg	Y		S	Oral	Quantity:6 Df Dosage Form;		Sandoz	
	Alprazolam			C				Not Reported	
	Vit C			C				Not Reported	
	Vit D3			C				Not Reported	
	9 Amino Acids			C				Not Reported	
	Omega XI			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	14468063	NON-EXPEDITED			US-PFIZER INC-2018041421		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	14918698	NON-EXPEDITED			US-PFIZER INC-2018204418		64 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Depressed Mood; Joint Swelling; Musculoskeletal Stiffness; Neck Pain; Weight Decreased	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer	
	Xeljanz Xr			S	Oral	11 Mg, Daily		Pfizer	
	Z-Pak			S		500 Mg, Daily		Not Reported	
	Methotrexate			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15213308	NON-EXPEDITED			US-PFIZER INC-2018305594		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Gastrointestinal Disorder	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15554389	NON-EXPEDITED			US-PFIZER INC-2018439885			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Neosporin			S		Unk		Pfizer	
	Percocet			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Remeron			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	15585492	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2018435966		23 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophil Count Increased; Lymphadenopathy;	Lyrica Od 25mg			S	Oral	150 Mg, Daily (6 Tablets Daily)		Pfizer	
	Zithromac			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pyrexia; Rash

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15670397	NON-EXPEDITED			US-PFIZER INC-2018490400		38 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin Hcl			S		Unk		Unknown	
	Ibuprofen			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Clarithromycin			S		Unk		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	15903261	EXPEDITED (15-DAY)		HO	PHEH2019US005048		64 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dysstasia; Fall; Nasopharyngitis; Nystagmus; Vertigo; Vomiting	Azithromycin Sandoz			S	Oral	200 Mg, Unk		Novartis	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177326	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-204698		52 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycin			S	Oral	250 Milligram, Unk		Sun	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
10-Apr-2019	16177349	EXPEDITED (15-DAY)		HO	FR-ACCORD-119566		14 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Kidney Injury; Drug Interaction; Drug Level Increased	Tacrolimus	S	Oral		Accord
	Zithromax	S	Oral	250 Mg, 3 Times Per Week,Also Received 500 Mg, Alternate Day	Not Reported
	Vfend	S	Oral	200 Mg, 2x/Day	Not Reported
	Candidas	S	Intravenous (not otherwise specified)	1 Df, 1x/Day	Not Reported
	Rifadine	S	Oral	600 Mg, 1x/Day	Not Reported
	A 313	C		Unk	Not Reported
	Rimifon	C		Unk	Not Reported
	Cellcept	C		Unk	Not Reported
	Creon	C		Unk	Not Reported
	Insulin	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16177793	EXPEDITED (15-DAY)		DS, OT	CZ-TEVA-2019-CZ-1033957			Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Unilateral	Azithromycin 500			S	Oral	500 Milligram Daily; The Package Of 3 Tablets		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16177946	NON-EXPEDITED			CN-ALKEM LABORATORIES LIMITED-CN-ALKEM-2018-07150		26 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea	Quetiapine Fumarate			S	Unknown	Unknown		Alkem
	Azithromycin			S	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16179043	EXPEDITED (15-DAY)		HO, LT	PHHY2019US078922		50 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dyspnoea; Hypoxia; Lethargy; Lung Disorder; Lung Infiltration; Pneumocystis Jirovecii Pneumonia; Pneumonia Aspiration; Pulmonary Embolism; Sepsis	Etanercept			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
	Hydrocortisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16179837	EXPEDITED (15-DAY)		LT	IT-PFIZER INC- 2019148485		83 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Hypersensitivity; Hypertensive Crisis; Rash	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Total		Pfizer	
	Meropenem			S		1 G, 3x/Day		Pfizer	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 G, Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16179865	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR- 1033961		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Malaise; Rhabdomyolysis; Transaminases Increased	Azithromycine Monohydratee			S	Oral	250 Milligram Daily;		Not Reported	
	Rifadine 300 Mg, Gelule			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Lamprene 100 Mg, Capsule			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Molle(Clofazimine)								
	Paracetamol			C				Not Reported	
	Lactulose			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16180521	NON-EXPEDITED			US-PFIZER INC- 2019149549		63 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181033	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-TEVA-2019-GB-1034145		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder; Suicide Attempt	Azithromycin			S	Oral	N/A		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181486	NON-EXPEDITED			US-PFIZER INC-2019154005			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181630	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1033066		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zithromax			S	Intravenous (not otherwise specified)	500 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2019	16181758	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1033272		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophil Count Increased; Hepatocellular Injury; Pyrexia; Rash	Vancomycine Mylan 1 G, Poudre Pour Solution Pour Perfusion			S	Intravenous drip	1.5 Gram, Qd		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pruritic	Ordipha	S	Oral	1 Dosage Form, Qd	Mylan				
	Tazocilline	S	Intravenous drip	16 Gram, Qd	Mylan				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16182214	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-204747		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Alkaline Phosphatase Increased; Electrocardiogram Qt Prolonged; General Physical Health Deterioration; Malaise; Rhabdomyolysis; Transaminases Increased	Azithromycin			S	Oral	250 Milligram, Daily		Sun	
	Rifadine 300 Mg, Gelule			S	Oral	1 Dosage Form, Daily		Not Reported	
	Lamprene 100 Mg, Capsule			S	Oral	1 Dosage Form, Daily		Not Reported	
	Molle(Clofazimine)			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184537	NON-EXPEDITED			US-PFIZER INC- 2019145942		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Methylprednisolone			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184851	NON-EXPEDITED			US-PFIZER INC- 2019149449		62 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Glucotrol			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Amaryl			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cartia Xt			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16184963	NON-EXPEDITED			US-PFIZER INC-2019151562		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Minocycline			S		Unk		Pfizer	
	Naproxen Sodium			S		Unk		Pfizer	
	Tylenol [Paracetamol]			S		Unk		Not Reported	
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported	
	Keflex [Cefalexin]			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Oxycontin			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16186493	NON-EXPEDITED			US-AKRON, INC.-2065699			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Erythema; Eye Pain; Swelling Face; Urticaria	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16186811	NON-EXPEDITED			US-AKRON, INC.-2065710			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2019	16186845	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2019152413		49 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malignant Melanoma	Novatrex			S	Oral	7.5 Mg, Weekly		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16005226	NON-EXPEDITED			US-PFIZER INC-2019081772		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Pristiq			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16188945	NON-EXPEDITED			US-TEVA-2019-US-1033816		1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16190614	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019152478		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Neutropenia; Off Label Use; Thrombocytopenia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Rifadine [Rifampicin]			S	Oral	2 Df, 1x/Day		Not Reported	
	Dexambutol			S	Oral	2 Df, 1x/Day		Not Reported	
	Ansatispine			S	Oral	4 Df, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16191067	EXPEDITED (15-DAY)		LT	PHHY2019CM083405		52 YR	Male	CMR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Gastroesophageal Reflux Disease	Binozyt			S	Oral	500 Mg, (1 G) Qd		Novartis	
	Binozyt			S				Novartis	
	Metronidazole			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2019	16191461	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC- 2019151502		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Multiple Organ Dysfunction Syndrome; Respiratory Failure	Levofloxacin			S	Oral	Unk		Pfizer	
	Piperacillin/Tazobactam			S		Unk		Unknown	
	Azithromycin			S		Unk		Pfizer	
	Cidofovir			S	Intravenous (not otherwise specified)	3 Mg/Kg, Unk (3 Mg/Kg I.V X 2 Doses)		Not Reported	
	Igg			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Ribavirin			S	Respiratory (inhalation)	6 G, Unk (6 G Inhalation X 1 Dose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2019	16193666	EXPEDITED (15-DAY)		OT	HK-009507513- 1904HKG005005		15 YR	Female	HKG
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Tube Insertion; Weight Decreased	Raltegravir Potassium			S				Merck	
	Truvada			S				Not Reported	
	Azithromycin			S				Not Reported	
	Clofazimine			S				Not Reported	
	Bedaquiline			S				Not Reported	
	Rifabutin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Septtrin		S		Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2019	16193881	NON-EXPEDITED		OT	PHEH2019US015309			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacteraemia; Drug Resistance	Linezolid			S	Unknown	Unk		Novartis	
	Linezolid			S				Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Tigecycline			S	Unknown	Unk		Not Reported	
	Tigecycline			S				Not Reported	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Clarithromycin			S				Not Reported	
	Amikacin			S	Unknown	Unk		Not Reported	
	Amikacin			S				Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Meropenem			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2019	16194412	NON-EXPEDITED			US-TEVA-2019-US-1035039			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cognitive Disorder; Drug Ineffective; Impulsive Behaviour; Irritability; Mood Swings; Product Taste Abnormal; Psychomotor Hyperactivity; Restlessness	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2019	16194695	EXPEDITED (15-DAY)		HO	FR-BIOVITRUM-2019FR0691		80 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Myeloid Leukaemia	Kineret			S	Subcutaneous	Not Informed		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Not Informed. 100 Mg, Powder For Concentrate For Solution For Infusion		Not Reported	
	Enbrel			S	Subcutaneous	Not Informed		Not Reported	
	Novatrex			S	Oral	Not Informed, 2.5 Mg Tablet		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Not Informed,		Not Reported	
	Humira			S	Subcutaneous	Not Informed		Not Reported	
	Xarelto			C		Non Renseign��e		Not Reported	
	Bisoprolol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	11164365	NON-EXPEDITED			US-PFIZER INC-2015185806		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	15221455	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2018301764		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Headache; Influenza; Rheumatoid Arthritis; Sinus Disorder; Upper Respiratory Tract Infection	Enbrel			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16182025	NON-EXPEDITED			US-PFIZER INC-2019148909			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Benzonatate			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Cephalexine			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197110	NON-EXPEDITED			US-PFIZER INC-2019155944			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197189	NON-EXPEDITED			US-PFIZER INC-2019153314		64 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Levaquin			S				Not Reported	
	Requip			S		Unk		Not Reported	
	Voltaren			S		Unk		Not Reported	
	Acesulfame			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197372	NON-EXPEDITED			US-NEOPHARMA INC-000088			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Augmentin			S	Oral	1 Capsule Twice A Day, 90 Days		Not Reported	
	Lyrica			S				Not Reported	
	Zithromax			S				Not Reported	
	Heparin			S				Not Reported	
	Lipitor			S				Not Reported	
	Neurontin			S				Not Reported	
	Sertraline			S				Not Reported	
	Aspirin			S				Not Reported	
	Tetracaine			S				Not Reported	
	Iodine			S				Not Reported	
	Enoxaparin			S				Not Reported	
	Pramipexole			S				Not Reported	
	Requip			S				Not Reported	
	Keppra			S				Not Reported	
	Sinemet			S				Not Reported	
	Motrin (Ibuprofen)			S				Not Reported	
	Naprosyn			S				Not Reported	
	Spira			S				Not Reported	
	Prozac			S				Not Reported	
	Xyrem			S				Not Reported	
	Daleron			S				Not Reported	
	Omega 3			S				Not Reported	
	Coq10			S				Not Reported	
	Allegra			S				Not Reported	
	Mometasone			S				Not Reported	
	Tylenol With Codeine No.3			S				Not Reported	
	Nystatin			S				Not Reported	
	Vitamin D2			S				Not Reported	
	Armour Thyroid			S				Not Reported	
	Crestor			S				Not Reported	
	Vitamin D3			S				Not Reported	
	Niacinamide			S				Not Reported	
	Biotin			S				Not Reported	
	Riboflavin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dhea			S			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197547	NON-EXPEDITED			US-NEOPHARMA INC-000109			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Augmentin			S	Unknown			Not Reported	
	Lyrica			S	Oral			Not Reported	
	Cephalexin			S	Unknown			Not Reported	
	Aspirin			S	Unknown			Not Reported	
	Tuberculin Ppd			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197596	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019156632		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Myeloid Leukaemia	Enbrel			S	Subcutaneous	Unk		Pfizer	
	Novatrex			S	Oral	Unk		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Rituximab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Kineret			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Xarelto			C		Unk		Not Reported	
	Bisoprolol Fumarate			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197687	NON-EXPEDITED			US-NEOPHARMA INC-000115			Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Augmentin			S	Unknown			Not Reported	
	Omnicef			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16197706	NON-EXPEDITED			US-NEOPHARMA INC-000119			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Augmentin			S				Not Reported	
	Gabapentin			S				Not Reported	
	Keflex			S				Not Reported	
	Zithromycin			S				Not Reported	
	Antiseptic			S				Not Reported	
	Sulfa			S				Not Reported	
	Hydrochlorothiazide			S				Not Reported	
	Compazine			S				Not Reported	
	Prednisone			S				Not Reported	
	Morphine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16199326	EXPEDITED (15-DAY)		HO	BR-ANIPHARMA-2019-BR-000028		34 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Generalised Exanthematous Pustulosis	Oxacillin (Non-Specific)			S				Ani	
	Azathioprine			S				Not Reported	
	Azithromycin			S				Not Reported	
	Cephalexin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2019	16201683	DIRECT		DS, HO, LT, OT			36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiovascular Disorder; Fall; Hypoaesthesia; Loss	Azithromycin Tablets, Usp	Y		S	Oral	Quantity:1 Tablet(S);		Viiv	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Of Proprioception; Panic
Attack; Paraesthesia;
Peripheral Sensory
Neuropathy;
Polyneuropathy; Pruritus;
Quadriplegia; Urticaria

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	14927362	EXPEDITED (15-DAY)		OT	PHHY2018FR001520		28 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Salbutamol Sulphate			S	Unknown	1 Df, Qd (48 Puffs/Day)		Not Reported
	Salbutamol Sulphate			S	Unknown	6 Puff/Day		Not Reported
	Ebastine			S	Unknown	10 Mg, Once A Day		Not Reported
	Montelukast Sodium			S	Unknown	10 Mg, Once A Day		Novartis
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Azithromycin			S	Unknown	250 Mg,Every Other Day For 3 Months		Not Reported
	Levocetirizine			S	Unknown	5 Mg, Qd		Not Reported
	Fluticasone			S	Nasal	55 Mcg And 75mg, Once A Day		Not Reported
	Fluticasone			S	Nasal	55 G, Qd		Not Reported
	Fluticasone			S	Unknown	1000 ?G/Day		Not Reported
	Omalizumab			S	Unknown	300 Mg, Qw4		Not Reported
	Salmeterol			S	Unknown	100 G, Qd, 6 Puffs/Day		Not Reported
	Tiotropium			C	Unknown	5 Mcg, Once A Day		Not Reported
	Beclomethasone			C	Unknown	800 Mcg, Once A Day		Not Reported
	Erythromycin			C	Unknown	500 Mg, Tid		Not Reported
	Formoterol			C	Unknown	24 Mcg, Once A Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16062856	EXPEDITED (15-DAY)		HO	CZ-APOTEX-2019AP009007		25 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Drug Ineffective; Leukocytosis; Nausea; Polycythaemia; Prescribed Overdose	Desloratadine			S	Unknown	5 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	500 Mg, Qd		Apotex
	Azithromycin			S	Unknown	Unk		Apotex
	Bilastine			S	Unknown	20 Mg, Qd		Not Reported
	Bilastine			S	Unknown	60 Mg, Qd		Not Reported
	Bilastine			S	Unknown	60 Mg, Unk		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Amoxicillin			S				Not Reported
	Amoxicillin			S	Oral	1 Gram, Q12h		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Milligram, Qd		Not Reported
	Prednisone			S	Unknown	60 Mg, Qd (60 Mg, Unk)		Not Reported
	Prednisone			S	Oral	40 Mg, Qd		Not Reported
	Betamethasone			C	Topical	Unk		Not Reported
	Betamethasone Sodium Phosphate			C	Unknown	Unk		Not Reported
	Betamethasone Sodium Phosphate			C	Intramuscular	Unk		Not Reported
	Bisulepin Hydrochloride			C	Unknown	Unk		Not Reported
	Betamethasone Dipropionate			C	Intramuscular	Unk		Not Reported
	Betamethasone Dipropionate			C	Unknown	Unk		Not Reported
	Omalizumab			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16186197	EXPEDITED (15-DAY)		OT	CO-BAYER-2019-070737		16 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intentional Overdose; Suicide Attempt; Vomiting	Aspirina 100 Mg	S	Oral	60 Df, Unk	Bayer
	Albendazole	S	Oral	1 Df, Unk	Not Reported
	Atorvastatin	S	Oral	2 Df, Unk	Not Reported
	Azithromycin	S	Oral	2 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16202680	NON-EXPEDITED			US-DRREDDYS- USA/USA/19/0109534		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Fluconazole 200 Mg			S	Oral			Not Reported	
	Ibrutinib			S	Oral			Not Reported	
	Ibrutinib			S	Oral			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Piperacilline/Tazobactam			S	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Prednisone			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16203276	EXPEDITED (15-DAY)		OT	CA-JNJFOC- 20190415313		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Vaginal Infection; Vulvovaginal Pruritus	Stelara			S	Intravenous (not otherwise specified)	Strength = 390 Mg		Not Reported	
	Cortisone			S	Unknown			Not Reported	
	Sandoz Azithromycin			S	Unknown			Not Reported	
	Clotrimazole			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16203698	EXPEDITED (15-DAY)		HO	PHHY2019ES082316		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coagulopathy; Hepatitis; Hyperbilirubinaemia	Azitromicina	S	Oral	1 Df, Qd	Novartis
	Pazital	C	Oral	Unk	Not Reported
	Loratadina	C	Oral	Unk	Not Reported
	Algidol	C	Oral	1 Df, Q8h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16204580	EXPEDITED (15-DAY)		HO, LT	FR-MYLANLABS-2019M1036374		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant	Aciclovir			S	Oral	Unk			Not Reported
	Azithromycin			S	Oral	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2019	16341211	DIRECT		DS			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Insomnia; Product Packaging Difficult To Open; Urticaria	Azithromycin-250mg-White Oral Y Tablet			S	Oral	Quantity:6 Df Dosage Form;			Unknown
	Atorvastatin			C					Not Reported
	Enalapril			C					Not Reported
	Hctz			C					Not Reported
	Estradiol Patch			C					Not Reported
	Multi-Vitamin			C					Not Reported
	Vit. B-12			C					Not Reported
	Ca			C					Not Reported
	Probiotic			C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	15625832	EXPEDITED (15-DAY)		HO, LT, OT	FR-GLAXOSMITHKLINE-FR2018207160		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Fulminant	Aciclovir			S	Oral	Unk			Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycine			S	Oral	Unk	Glaxosmithkline			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16170959	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1031751		30 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acoustic Neuroma; Balance Disorder; Deafness Neurosensory; Facial Paralysis; Fatigue; Insomnia; Ototoxicity	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Minocycline			S	Oral	200 Milligram, Qd (100 Mg, Bid)		Not Reported	
	Amikacin			S	Unknown	1000 Milligram, Qd (500 Mg, Bid)		Mylan	
	Moxifloxacin			S	Oral	400 Mg, Qd		Mylan	
	Clofazimine			S	Oral	100 Mg, Qd		Mylan	
	Meropenem			S	Intravenous (not otherwise specified)	2 Gram, Tid		Mylan	
	Tigecycline			S	Intravenous (not otherwise specified)	50 Milligram, Bid		Mylan	
	Imipenem			S	Intravenous (not otherwise specified)	Unk		Mylan	
	Amikacin			S	Intravenous (not otherwise specified)	525 Milligram, Bid		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16206984	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP011721		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Pneumonia	Amoxicillin			S	Unknown	500 Mg, Every 5 Days		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Every 3 Days		Apotex	
	Stelara			S	Subcutaneous	45 Mg, 1 Every 8 Weeks		Not Reported	
	Stelara			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16207816	EXPEDITED (15-DAY)		OT	FR-ROCHE-2305368		28 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Ineffective; Hypogammaglobulinaemia ; Pneumonia; Sinusitis	Omalizumab			S	Unknown			Not Reported
	Salbutamol Sulphate			S	Unknown	(48 Puffs/Day)		Not Reported
	Salbutamol Sulphate			S	Unknown	6 Puff/Day		Not Reported
	Ebastine			S	Unknown			Not Reported
	Montelukast Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S				Not Reported
	Prednisone			S				Not Reported
	Azithromycin			S	Unknown	250 Mg,Every Other Day For 3 Months		Not Reported
	Levocetirizine			S	Unknown			Not Reported
	Fluticasone			S	Nasal	55 Mcg And 75mg, Once A Day		Not Reported
	Fluticasone			S	Nasal			Not Reported
	Fluticasone			S	Unknown	1000 G/Day		Not Reported
	Salmeterol			S	Unknown	6 Puffs/Day		Not Reported
	Tiotropium			C	Unknown	5 Mcg, Once A Day		Not Reported
	Beclomethasone			C	Unknown	800 Mcg, Once A Day		Not Reported
	Erythromycin			C	Unknown			Not Reported
	Formoterol			C	Unknown	24 Mcg, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2019	16207913	NON-EXPEDITED			US-PFIZER INC- 2019161881		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	14262724	NON-EXPEDITED			US-PFIZER INC-2017522911		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Buspar			S		Unk		Not Reported	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	14679277	NON-EXPEDITED			US-PFIZER INC-2018124678			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	15220133	NON-EXPEDITED			US-PFIZER INC-2018307629		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hallucination; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16066762	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2019M1022728		10 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	Unk		Not Reported	
	Hydrocortisone			S	Topical	Unk		Mylan	
	Clotrimazole			S		Unk		Mylan	
	Clotrimazole			S	Topical	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Betamethasone Dipropionate	S	Topical	Unk	Mylan
Betamethasone Dipropionate	S		Unk	Mylan
Gentamicin	S	Topical	Unk	Mylan
Clotrimazole / Betameth	S	Topical	Unk	Mylan
Betamethasone Dipropionate W/Gentam/00619001/	S	Topical	Unk	Mylan
Betamethasone Dipropionate;Clotrimazole;Genta	S	Topical	Unk	Mylan
Sodium Chloride	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16211325	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-020132			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Pantoprazole			S	Intravenous (not otherwise specified)	8 Milligram, Every Hour		Aurobindo
	Amiodarone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Milligram, Every Four Hour		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	10 Milligram, Every Hour		Not Reported
	Diltiazem Cd			S	Oral	180 Milligram		Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Milligram, Every Four Hour		Not Reported
	Doxorubicin			S	Intravenous (not otherwise specified)	106 Milligram, One Every 14 Days		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Furosemide			S	Oral	40 Milligram, Once A Day		Not Reported
	Hydralazine			S	Intravenous (not otherwise specified)	10 Milligram, Every Four Hour		Not Reported
	Hydromorphone			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Milligram, One Every 6 Hours		Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Milligram, 1 Every 6 Hours		Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Milligram, 1 Every 6 Hours		Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)	1 Every 10 Minutes		Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Milligram, 1 Every 14 Days		Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Milligram, Once A Day		Not Reported
Trastuzumab	S	Unknown	Unk		Not Reported
Emend	C	Unknown	Unk		Not Reported
Filgrastim	C	Unknown	Unk		Not Reported
Gabapentin	C	Unknown	Unk		Not Reported
Metoclopramide	C	Unknown	Unk		Not Reported
Ondansetron	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16211921	EXPEDITED (15-DAY)		HO	PHHY2019IT088715		6 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Ecchymosis; Petechiae	Azithromycin			S	Oral	300 Mg, Qd		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16212324	NON-EXPEDITED			US-PFIZER INC-2019160667		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Doxycycline Hyclate	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Ibuprofen	S	Unk	Pfizer
	Asa	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported
	Levaquin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16212775	NON-EXPEDITED			US-ASTELLAS-2019US008484			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lexiscan			S	Unknown	Unk Unk, Unknown Freq.		Astellas	
	Azithromycin			S	Unknown	Unk Unk, Unknown Freq.		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16213091	EXPEDITED (15-DAY)		OT	GB-VERTEX PHARMACEUTICALS-2019-003270			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Kalydeco			S	Oral			Vertex	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16214074	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1036640		75 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalitis	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Cefotaxime			S	Intravenous (not otherwise specified)	3 Gram, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2019	16352452	DIRECT		OT			68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Balance Disorder; Dizziness; Eating Disorder; Eructation; Headache; Nausea; Vomiting	Azithromycin Tablets 250mg Distran Tec Greenstone LLC Peapack, NJ 07977-Made In India			S	Oral	Quantity:6 Df Dosage Form;Other Frequency:2 1st Day; 1/Day;		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16215628	EXPEDITED (15-DAY)		OT	PT-TEVA-2019-PT- 1040696		83 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16215721	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA- 1039420		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Amoxicillin Trihydrate/Clavulanate Potassium Azithromycin			S	Unknown			Teva	
	Aspirin /00002701/			S	Oral	500 Milligram Daily;		Not Reported	
	B12 /00056201/			C	Oral	81 Milligram Daily;		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Hydrochlorothiazide/Triamterene			C	Oral	1 Milligram Daily;		Not Reported	
	Infliximab			C	Oral	25 Milligram Daily;		Not Reported	
	Methotrexate			C	Intravenous (not otherwise specified)			Not Reported	
				C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pantoloc /01263201/

C

Oral

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16215728	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039429		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Aciclovir			S	Transplacental			Teva
	Azithromycin			S	Transplacental			Not Reported
	Tenofovir			S	Transdermal			Teva
	Abacavir			S	Transplacental			Not Reported
	Bactrim			S	Transplacental			Not Reported
	Intelence			S	Transplacental			Not Reported
	Lamivudine			S	Transplacental			Not Reported
	Prezista			S	Transplacental			Not Reported
	Raltegravir Potassium			S	Transplacental			Not Reported
	Ritonavir			S	Transplacental			Not Reported
	Zidovudine			S	Transplacental			Not Reported
	Folic Acid			C				Not Reported
	Iron			C				Not Reported
	Magnesium Gluconate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16215935	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039353		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Use In Unapproved Indication; Pulmonary Fibrosis	Azithromycin			S	Oral	.5 Dosage Forms Daily;		Not Reported
	`Xeljanz			C	Oral	5 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216326	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-021112			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo	
	Levofloxacin			S	Unknown	Unk		Aurobindo	
	Arava			S	Unknown	Unk		Not Reported	
	Benadryl			S	Unknown	Unk		Not Reported	
	Celebrex			S	Oral	Unk		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	
	Demerol			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Imuran			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Procytox			S	Unknown	Unk		Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	
	Xeljanz			S	Oral	5.0 Milligram, Two Times A Day		Not Reported	
Ezetrol			C	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216335	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-021145			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo	
	Levofloxacin			S	Unknown	Unk		Aurobindo	
	Arava			S	Unknown	Unk		Not Reported	
	Benadryl			S	Unknown	Unk		Not Reported	
	Celebrex			S	Oral	Unk		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Demerol	S	Unknown	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Unknown	Unk	Not Reported
	Imuran	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Plaquenil	S	Unknown	Unk	Not Reported
	Procytox	S	Unknown	2000 Milligram	Not Reported
	Simponi	S	Unknown	Unk	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Ezetrol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216341	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-021143			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Non-Responder	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Doxycycline			S	Unknown	100 Milligram, Every 5 Days		Not Reported
	Doxycycline			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2019	16216490	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019162603			Unknown	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperpyrexia; Product Packaging Issue	Zithromax			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2019	16219904	EXPEDITED (15-DAY)		OT	PT-SUN PHARMACEUTICAL INDUSTRIES LTD-		83 YR	Female	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2019R1-205785

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Azithromycin			S	Unknown	Unk		Sun	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Apr-2019	16219996	NON-EXPEDITED			US-TEVA-2019-US-1030919		73 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Flatulence; Flushing; Hot Flush	Azithromycin Tablet			S	Unknown			Not Reported	
	Niacin			S	Unknown			Barr	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Apr-2019	16220889	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE088153		2 YR	Female	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Apathy; Intentional Self-Injury; Personality Change; Seizure	Azithromycin Hexal			S	Oral	200mg / 5ml		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16072830	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019106804		82 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Wall Haematoma; Anaemia; Drug Interaction	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Prednisone			S	Oral	25 Mg, 1x/Day		Not Reported	
	Coumadin			S	Oral	5 Mg, 1x/Day		Not Reported	
	Augmentin [Amoxicillin Trihydrate;Clavulanate			S	Oral	2 Df, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Potassium] Zyloric	C	Oral	300 Mg, Unk	Not Reported
Bisoprolol Hemifumarate	C	Oral	1.25 Mg, Unk	Not Reported
Triatec [Ramipril]	C	Oral	1 Df, Unk	Not Reported
Lasix [Furosemide]	C	Oral	50 Mg, Unk	Not Reported
Spiriva Respimat	C	Respiratory (inhalation)	5 Mg, Unk	Not Reported
Amiodarone Hydrochloride	C	Oral	200 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16221650	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1039336		79 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Pruritus	Azithromycin			S	Oral	500.0 Units Once		Not Reported
	Cefazolin			S	Intraperitoneal	1500 Milligram Daily;		Actavis
	Acetylsalicylic Acid			S	Unknown			Not Reported
	Amlodipine			C				Not Reported
	Bisoprolol			C				Not Reported
	Docusate			C				Not Reported
	Eprex Sterile Solution			C		Solution Intravenous		Not Reported
	Ergocalciferol			C				Not Reported
	Fluticasone			C				Not Reported
	Megestrol			C				Not Reported
	Nepafenac			C				Not Reported
	One Alpha			C				Not Reported
	Pantoprazole			C				Not Reported
	Salbutamol			C				Not Reported
	Sevelamer			C				Not Reported
	Sodium Polystyrene			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16222278	EXPEDITED (15-DAY)		HO	ES-ZYDUS-035837		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coagulopathy; Hepatitis; Hyperbilirubinaemia	Azithromycin	S	Oral		Zydus Pharm
	Pazital	C	Oral	37.5 Mg / 325 Mg	Not Reported
	Loratadine	C	Oral		Not Reported
	Ibuprofen	C	Oral	650 Mg / 10 Mg / 500 Mg Granulated For Oral Solution, 12 Sachets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16222841	NON-EXPEDITED			US-PFIZER INC- 2019165474		152 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16223096	EXPEDITED (15-DAY)		OT	SI-PFIZER INC- 2019167520			Female	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mania; Maternal Exposure During Pregnancy	Vancomycin Hcl			S	Transplacental	Unk		Pfizer
	Cilastatin/Imipenem			S	Transplacental	Unk		Unknown
	Ceftriaxone			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Oseltamivir			S	Transplacental	Unk		Not Reported
	Cefepim			S	Transplacental	Unk		Not Reported
	Amphotericin B			S	Transplacental	Unk		Not Reported
	Sevoflurane			S	Transplacental	Unk		Not Reported
	Betamethasone			S	Transplacental	Unk(Lung Maturation At 24 Weeks)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16223277	NON-EXPEDITED			US-PFIZER INC-		52 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2019165976

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16223287	NON-EXPEDITED			US-PFIZER INC-2019164046		69 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Hydromorphone Hydrochloride			S		Unk		Unknown	
	Dilaudid			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16223496	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2019M1036829		83 YR	Female	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Amoxicillin/Clavulanic Acid			C	Unknown			Mylan	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Apr-2019	16224210	EXPEDITED (15-DAY)		DE	BR-PFIZER INC-2019164894		365 DAY	Male	BRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Accidental Exposure To Product; Toxicity To	Azithromycin			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Various Agents

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16224539	NON-EXPEDITED			US- FOUNDATIONCONSUM ERHC-2018-US-021621		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Tenderness; Dysmenorrhoea; Nausea; Sinusitis	Plan B One-Step (Non-Specific)			S	Oral	1.5 Mg X 1 Dose		Foundation Consumer Healthcare	
	Zithromax			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16224793	EXPEDITED (15-DAY)		HO	ES-PFIZER INC- 2019165446		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Hepatitis; Hyperbilirubinaemia	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Pazital			C	Oral	Unk		Not Reported	
	Loratadine			C	Oral	Unk		Not Reported	
	Algidol [Ascorbic Acid;Codeine Phosphate;Paracetamol]			C	Oral	1 Df, Unk, Every 8 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16224908	NON-EXPEDITED			US-TEVA-2019-US- 1032739		121 DAY	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Eczema; Feeling Abnormal; Gastrooesophageal Reflux Disease; Mucous Stools	Azithromycin For Oral Suspension			S		Dose Strength: 200 Mg/5 ML		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16225090	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2019M1037434		65 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bradycardia	Azithromycin	S	Oral	250 Milligram, Qd	Not Reported
	Lamprene /00224701/	S	Oral	100 Milligram, Qd	Mylan
	Vogalene	S	Oral	Unk	Mylan
	Atarax /00058401/	S	Oral	Unk	Mylan
	Emend /01627301/	S	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2019	16367936	DIRECT	Y	HO, LT, OT			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Increased	Azithromycin			S	Oral			Not Reported	
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	14709436	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC-2018079176		12 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block Complete; Contraindicated Product Administered; Dizziness; Electrocardiogram Qt Prolonged; Nausea; Palpitations; Syncope; Torsade De Pointes; Ventricular Fibrillation	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16112573	NON-EXPEDITED			US-PFIZER INC-2019119481		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax	S	Unk	Pfizer
Morphine Sulfate	S	Unk	Unknown
Dilantin	S	Unk	Pfizer
Vancomycin Hcl	S	Unk	Pfizer
Anaprox	S	Unk	Not Reported
Mestinon	S	Unk	Not Reported
Pyridium	S	Unk	Not Reported
Relafen	S	Unk	Not Reported
Tegretol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16225900	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-205897		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy; Hepatitis; Hyperbilirubinaemia	Azithromycin			S	Oral	1 Dosage Form, Daily		Sun
	Pazital 37,5 Mg/325 Mg Comprimidos Recubiertos Con Película , 20 Co...			C	Oral	()		Not Reported
	Loratadina (2303a)			C	Oral	()		Not Reported
	Algidol 650 Mg/ 10 Mg/ 500 Mg Granulado Para Solucion Oral , 12 Sobres			C	Oral	1 Dosage Form, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16226292	EXPEDITED (15-DAY)		HO	ES-TEVA-2019-ES- 1040917		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Coagulopathy; Hepatitis; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	1 Dosage Forms Daily;		Not Reported
	Pazital 37,5 Mg/325 Mg Comprimidos Recubiertos Con Película , 20 Compr			C	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Loratadina (2303a)	C	Oral					Not Reported	
	Algidol 650 Mg/ 10 Mg/ 500 Mg Granulado Para Solucion Oral , 12 Sobres	C	Oral		Granulated For Oral Solution			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16227679	NON-EXPEDITED			US-PFIZER INC- 2019167977		12 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2019	16227704	NON-EXPEDITED			US-PFIZER INC- 2019169701			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	9852055	NON-EXPEDITED			US-PFIZER INC- 2014020937			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Diclofenac Sodium			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Ceftin			S		Unk		Not Reported	
	Cataflam			S		Unk		Not Reported	
	Erythromycin Base			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oxycontin	S	Unk	Not Reported
Ciprocinonide	S	Unk	Not Reported
Fluocinonide	S	Unk	Not Reported
Procinonide	S	Unk	Not Reported
Vioxx	S	Unk	Not Reported
Fluocinolone	S	Unk	Not Reported
Rofecoxib	S	Unk	Not Reported
Oxycodone	S	Unk	Not Reported
Alendronic Acid	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	15456915	NON-EXPEDITED			US-PFIZER INC-2018396144		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Headache; Rash	Azithromycin			S		Unk		Pfizer
	Hydrocodone			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Tapentadol Hydrochloride			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16233193	EXPEDITED (15-DAY)		HO, LT	NL-MYLANLABS-2019M1036952		82 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angina Pectoris; Cardiac Failure; Condition Aggravated	Salbutamol			S	Respiratory (inhalation)	3x Per Dag 1 Inhalatie		Not Reported
	Azithromycin			S	Oral	1x Per Dag 1 Tablet		Not Reported
	Irbesartan			C		1dd1		Mylan
	Codeinefosfaat			C		3dd1		Mylan
	Isosorbidedinitraat			C		2dd0,5 Tablet		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Nedios		C			1dd1			Mylan	
	Dermovate		C			1dd			Mylan	
	Pravastatine /00880401/		C			1dd1			Mylan	
	Bumetanide		C			1dd1			Mylan	
	Acenocoumarol		C			Unk			Mylan	
	Calci Chew D3		C			1dd1			Mylan	
	Nebivolol		C			1dd0,5 Tablet			Mylan	
	Carbamazepine		C			1dd1			Mylan	
	Prednisolon /00016201/		C			1dd0,5 Tablet			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16233595	NON-EXPEDITED				US-PFIZER INC-2019170794			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Azithromycin				S		Unk		Pfizer	
	Medrol				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16234490	NON-EXPEDITED				US-PFIZER INC-2019170011			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16234526	EXPEDITED (15-DAY)		HO, OT		ES-MYLANLABS-2019M1037066		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Bradycardia; Chest Pain; Hypertensive Crisis	Azithromycin				S	Oral	Azitro/24h 6d			Not Reported
	Capoten				C	Oral	25mg/ 12h			Mylan
	Adiro				C	Oral	0-1-0. En Historia Clínica			Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omeprazol /00661201/
Ibuprofeno

C
C

Oral

Historia Actual De

Mylan
Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2019	16235647	NON-EXPEDITED			US-GLENMARK PHARMACEUTICALS- 2019GMK040112			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Hair Growth Rate Abnormal; Hair Texture Abnormal; Product Label Issue; Weight Increased	Naproxen			S	Unknown	Unk		Glenmark
	Chantix			S	Oral	1 Mg, Bid		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	15902228	EXPEDITED (15-DAY)		DE, OT	US-PFIZER INC- 2019048331			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pneumonia	Azithromycin			S		Unk		Pfizer
	Spiriva Respimat			S		Unk		Not Reported
	Aspirin			S		Unk		Not Reported
	Plavix			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported
	Fish Oil			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16236091	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR- APL-2019-022421			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Ecchymosis; Petechiae	Azithromycin			S	Oral	300 Milligram, Once A Day		Aurobindo

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16238260	NON-EXPEDITED			US-PFIZER INC-2019173654		39 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Epistaxis	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16240364	NON-EXPEDITED			US-PFIZER INC-2019174232		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16240525	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019072447			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Product Dose Omission; Wrong Technique In Product Usage Process	Ventolin Hfa Inhalation Powder			S		2 Puffs Every 4 Hours		Glaxosmithkline	
	Zitromax			S				Glaxosmithkline	
	Prednisone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2019	16240829	NON-EXPEDITED			PHEH2019US017341		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Azithromycin			S	Unknown	2 Df, Unk		Novartis	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Synthroid			C	Unknown	Unk		Not Reported	
	Tekturna			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16242906	EXPEDITED (15-DAY)		DE, OT	US-CIPLA LTD.- 2019US02355			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Cipla	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Clozapine			S	Unknown	Unk		Not Reported	
	Immunoglobulin I.V			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16243387	NON-EXPEDITED			PHEH2019US017349			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea	Azithromycin Sandoz			S	Oral	250 Mg, Bid		Novartis	
	Tikosyn			S	Oral	0.25 Mg, Bid		Not Reported	
	Prednisone			S	Oral	10 Mg, Bid		Not Reported	
	Guaiphenesin			S	Oral	10 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16243699	NON-EXPEDITED			US-PFIZER INC- 2019169510		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Sulfacetamide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16244397	EXPEDITED (15-DAY)		OT	IT-MYLANLABS- 2019M1038191		50 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Atenolol			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16245121	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019178197		6 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Ecchymosis; Petechiae	Azithromycin			S	Oral	300 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16245224	NON-EXPEDITED			US-PFIZER INC-2019173573			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2019	16245431	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1038677		6 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia	Azithromycin			S	Oral	120 Milligram		Not Reported	
	Docusate			C		Unk		Mylan	
	Hydrocortisone			C		Unk		Mylan	
	Domperidone			C		Unk		Mylan	
	Hyoscine Hydrobromide			C		Unk		Mylan	
	Lansoprazole			C		Unk		Mylan	
	Vigabatrin			C		Unk		Mylan	
	Sodium Chloride			C		Twice A Day		Mylan	
	Sodium Chloride			C		Unk, Prn		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Movicol	C		Unk		Mylan
	Cetirizine	C		Unk		Mylan
	Brufen /00109201/	C		Unk Unk, Prn		Mylan
	Buscopan	C		Unk		Mylan
	Baclofen	C		Unk		Mylan
	Sodium Valproate	C		Unk		Mylan
	Zoladex La	C	Subcutaneous	1 Dosage Form		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2019	16177115	NON-EXPEDITED			US-TEVA-2019-US-1025111			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Paraesthesia; Product Dose Omission	Azithromycin Tablet			S		White Oval Tablets Marked Pliva 787		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	12287237	EXPEDITED (15-DAY)		HO, OT	FR-GILEAD-2016-0209074		77 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Exfoliative Generalised; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Hepatic Function Abnormal; Oedema; Off Label Use; Papule; Rash; Rash Erythematous; Skin Exfoliation	Zydelig			S	Oral	100 Mg, Tid		Gilead	
	Zydelig			S	Oral	150 Mg, Qd		Gilead	
	Privigen			S	Intravenous (not otherwise specified)	40 G, Cyclical		Not Reported	
	Privigen			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Privigen			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Privigen			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zithromax			S	Oral	1 Dosage Form Tiw		Not Reported	
	Neo-Codion (Codeine			S	Oral	15 MI, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Camsilate)									
Ergyphilus Confort	S	Oral	2 Df, Bid						Not Reported
Loperamide	S	Oral	1 Df, Qd						Not Reported
Desloratadine	S	Oral	1 Df, Qd						Not Reported
Josir	S	Oral	1 Df, Qd						Not Reported
Avodart	S	Oral	1 Df, Qd						Not Reported
Spasfon	S	Oral	2 Df, Qd						Not Reported
[Phloroglucinol;Trimethylphlorogl ucinol]									
Rituximab	S	Intravenous (not otherwise specified)	Unk						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	13114120	NON-EXPEDITED		OT	US-PFIZER INC- 2017012362		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Drug Hypersensitivity; Dyspnoea; Swelling	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16113371	NON-EXPEDITED			US-PFIZER INC- 2019125138		63 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16248302	NON-EXPEDITED			US-TEVA-2019-US- 1038206		13 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Azithromycin			S	Oral			Not Reported
	Amoxicillin			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Amoxicillin		C					Not Reported
		Nystatin		C					Not Reported
		Nystatin		C					Not Reported
		Dmae Plus		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16248558	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2019-003938			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Azithromycin 250 Mg Tablets Usp Tramadol			S	Oral	2 Dosage Form, Daily		Aurobindo	
				C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16249041	NON-EXPEDITED			US-TEVA-2019-US- 1039872			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Wrong Technique In Product Usage Process	Azithromycin			S	Oral	Strength: 200 Mg/5 MI		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16250951	NON-EXPEDITED			US-PFIZER INC- 2019175823		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Azithromycin			S		Unk		Pfizer	
	Gilenya			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16251923	NON-EXPEDITED			US-PFIZER INC- 2019182607			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gabapentin			S			Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16251987	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2019M1039329		72 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema	Azithromycin			S	Oral	500 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2019	16252410	NON-EXPEDITED			US-PFIZER INC-2019176629		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk			Pfizer
	Ciprofloxacin Hcl			S		Unk			Unknown
	Clarithromycin			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	14184691	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2017M1071835			Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Throat Tightness	Azithromycin			S	Oral	1 Df, Total			Not Reported
	Omeprazole			C	Oral	Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	15762114	NON-EXPEDITED			US-PFIZER INC-2018530610		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Drug Hypersensitivity	Azithromycin			S		500 Mg, 1x/Day			Pfizer
	Azithromycin			S	Oral	250 Mg, Daily [X 4 Days]			Pfizer
	Ceftriaxone			C		Unk			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	15965211	EXPEDITED (15-DAY)		OT	US-009507513-1902USA002928		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Dysphagia	Ganirelix Acetate Injection			S	Subcutaneous	Strength (250 Mcg/.5), Dose: 250 Microgram, Qd		Merck	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16250417	EXPEDITED (15-DAY)		HO	US-CELGENEUS-USA-20190408415			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Urticaria	Revlimid			S	Oral	10 Milligram		Celgene	
	Revlimid			S	Oral	5 Milligram		Celgene	
	Revlimid			S	Oral	5 Milligram		Celgene	
	Azithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253741	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK075150		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Breo Ellipta			S		1.0 Df, Qd		Glaxosmithkline	
	Azithromycine			S	Oral	250.0 Mg, Qd		Glaxosmithkline	
	Salbutamol Sulphate			S		Unk		Glaxosmithkline	
	Singulair			S	Oral	10 Mg, Qd		Glaxosmithkline	
	Atrovent			S		Unk		Not Reported	
	Theophylline			S	Oral	450 Mg, Qd		Glaxosmithkline	
	Ipratropium Bromide + Salbutamol Sulphate			S		Unk		Not Reported	
	Omalizumab			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	otherwise specified)			Not Reported
Seebri Breezhaler	S	Oral	45.0 Unk, Unk		Not Reported
			1 Df(Capsule), Qd		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253806	EXPEDITED (15-DAY)		OT	US- GLAXOSMITHKLINE- US2019GSK075689			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Foetal Growth Restriction	Albuterol			S	Transplacental	Unk, Every 2 Hours		Glaxosmithkline
	Albuterol			S		20 Mg, Per Hour		Glaxosmithkline
	Cefepime			S	Transplacental	Unk		Glaxosmithkline
	Ceftriaxone			S	Transplacental			Glaxosmithkline
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline
	Ipratropium			S	Transplacental	Unk, Every 6 Hours		Not Reported
	Methylprednisolone			S	Transplacental	60 Mg, Bid		Not Reported
	Vancomycin			S	Transplacental	Unk		Not Reported
	Oseltamivir			S	Transplacental	Unk		Not Reported
	Duoneb			S	Transplacental	Unk		Not Reported
	Prednisone			S	Transplacental	Unk		Not Reported
	Methylprednisone Dose Pack			S	Transplacental	80 Mg, Every 6 Hours		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253881	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02173			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Eructation; Nausea; Product Packaging Difficult To Open; Retching; Vomiting	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Milligram, Qd		Lupin

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16253985	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE094327		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatic Fibrosis; Hepatitis Acute; Jaundice	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16254511	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1042642		65 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Lip Swelling; Pruritus; Urticaria	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Cardioaspirin 100 Mg			C				Not Reported	
	Comprese Gastroresistenti								
	Metformin			C				Not Reported	
	Benazepril			C				Not Reported	
	Cloridrato/Ildroclorotiazide								
	Eutirox 25 Microgrammi			C				Not Reported	
	Comprese								
	Zorias 10 Mg Capsule			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255485	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-022042			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Bilirubin Increased; Blood Lactate	Azithromycin			S	Oral	500 Milligram		Aurobindo	
Dehydrogenase	Paracetamol			C	Oral	1 Gram		Not Reported	
Increased; Chills; Dyspnoea; Haemoglobin Decreased; Haemolytic Anaemia; Hepatocellular Injury; Jaundice	Omeprazole			C	Oral	20 Milligram		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255546	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-022481			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Resistance; Urethritis Mycoplasmal; Urinary Tract Infection	Azithromycin			S	Unknown	1 G, Unk		Aurobindo	
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo	
	Doxycycline			S	Intracardiac	Unk		Not Reported	
	Moxifloxacin			S	Intracardiac	Unk (One Dose)		Not Reported	
	Pristinamycin			S	Intracardiac	1 G, Qd		Not Reported	
	Pristinamycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255797	EXPEDITED (15-DAY)		OT	BE-PFIZER INC- 2019181178		33 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness	Linezolid			S	Oral	Unk		Pfizer	
	Azithromycin			S	Oral	Unk		Pfizer	
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Cefoxitin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Amikacin			S	Nasal	Unk (Inhaled)		Not Reported	
	Moxifloxacin			S		Unk		Not Reported	
	Moxifloxacin			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255865	NON-EXPEDITED			US-PFIZER INC- 2019177339		15 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16255914	NON-EXPEDITED			US-PFIZER INC-2019181495			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16256162	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2019M1040239		5 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea	Azithromycin			S		Unk		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16256784	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1040348		33 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Response Unexpected; Unintended Pregnancy	Ethinylestradiol/Levonorgestrel			S	Oral	1 Dosage Form, Cycle, Extra Info: 1x Daags 1 Tablet Gedurende 3 Weken, Daarna 1 Week Stoppen		Not Reported	
	Claritromycine			S	Oral	1000 Milligram, Qd		Mylan	
	Azitromycine			S	Oral	750 Milligram, Qw		Mylan	
	Omecat			C	Oral	80 Milligram, Qd		Mylan	
	Vesicare			C	Oral	5 Milligram, Qd		Mylan	
	Codeinefosfaat			C	Oral	20 Milligram, Asnecessary, 1 Dd 1 Vn Zn		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diclofenac Na	C	Oral	100 Milligram, Qd, Asnecessary, 1dd 1-2 X Per Dag 1 Tablet	Mylan
Desmopressine Acetaat	C	Oral	0.0 Milligram, Qd, 1 Dd 2	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16258080	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2018GSK153371		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased; Blood Test Abnormal; Cough; Distal Intestinal Obstruction Syndrome; Dyspnoea; Eosinophil Count Increased; Glucose Tolerance Impaired; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Obstructive Airways Disorder; Pancreatic Failure; Productive Cough; Renal Failure; Therapeutic Product Effect Incomplete	Fluticasone			S		1 Puff(S), Bid		Glaxosmithkline
	Propionate+Salmeterol							
	Xinafoate							
	Ventolin			S		2 Puff(S), Prn		Glaxosmithkline
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Ciprofloxacin			S	Oral	750 Mg, Bid		Glaxosmithkline
	Ciprofloxacin			S	Oral	500 Mg, Bid		Glaxosmithkline
	Septra			S	Oral	2 Df, Bid(Tablet)		Glaxosmithkline
	Azithromycin			S		250 Mg, Qd		Glaxosmithkline
	Ceftazidime			S		2 G, Bid		Glaxosmithkline
	Zopiclone			S		7.5 Mg, Prn		Glaxosmithkline
	Singulair			S		10 Mg, Qd		Glaxosmithkline
	Spiriva			S		18 Mg, Qd		Not Reported
	Pulmicort			S		2 Puff(S), Bid		Not Reported
	Prednisone			S		45 Mg, Qd		Not Reported
	Nystatin			S		Unk Unk, Qid		Not Reported
	Vitamin D Nos			C		Unk Unk, Qd		Glaxosmithkline
	Cayston			C		75 Mg, Tid		Not Reported
	Pulmozyme			C		2.5 Mg, Unk(Daily)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2019	16258653	EXPEDITED (15-DAY)		OT	PHHY2019SI095815		29 YR	Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Delivery	Oxytocin			S	Unknown	5 Mu/Min		Not Reported	
	Azithromycin			S	Unknown			Novartis	
	Ceftriaxone			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Betamethasone			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown			Not Reported	
	Sevoflurane			S	Unknown			Not Reported	
	Cefepim			S	Unknown			Not Reported	
	Imipenem/Cilastatin			S	Unknown			Not Reported	
	Amphotericin B			S	Unknown			Not Reported	
	Protamine Sulfate			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	14726493	NON-EXPEDITED			US-PFIZER INC-2018139882		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Tizanidine			S		Unk		Not Reported	
	Flexeril			S		Unk		Not Reported	
	Coclox			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Ceclor			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16242839	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS-2019M1039557		17 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Intentional Overdose; Malaise; Mydriasis; Product Use Issue; Somnolence; Suicide Attempt; Toxicity To Various Agents; Vomiting	Azithromycin			S	Oral	1500 Milligram, Total		Not Reported
	Escitalopram			S	Oral	140 Milligram, Qd		Not Reported
	Prednisolone			S	Oral	200 Milligram, Total		Not Reported
	Paracetamol			S	Oral	79 Gram, Total		Not Reported
	Cefpodoxime			S	Oral	2000 Milligram, Total		Not Reported
	Trimebutine			S	Oral	14000 Milligram, Total		Not Reported
	Amoxicillin/Clavulanic Acid			S	Oral	6 Gram, Qd		Not Reported
	Loperamide			S	Oral	30 Milligram, Total		Not Reported
	Arestal			S	Oral	30 Milligram, Total		Mylan
	Seresta			S	Oral	310 Milligram, Total		Mylan
	Inorial			S	Oral	120 Milligram, Total		Mylan
	Augmentin /00756801/			S	Oral	6 Gram, Qd		Mylan
	Oxazepam			S	Oral	310 Milligram, Total		Mylan
	Bilastine			S	Oral	120 Milligram, Total		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260124	NON-EXPEDITED			US-PFIZER INC-2019181038		44 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Gastrointestinal Disorder	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260165	NON-EXPEDITED			US-PFIZER INC-2019179772		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Hot Flush; Nausea		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260246	NON-EXPEDITED			US-PFIZER INC-2019181472		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260511	EXPEDITED (15-DAY)		OT	PHHY2019SI095818			Female	SVN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Oxytocin			S	Transplacental	Unk		Not Reported	
	Azithromycin			S	Transplacental	Unk		Novartis	
	Vancomycin			S	Transplacental			Not Reported	
	Betamethasone			S	Transplacental			Not Reported	
	Ceftriaxone			S	Transplacental			Not Reported	
	Oseltamivir			S	Transplacental			Not Reported	
	Sevoflurane			S	Transplacental			Not Reported	
	Cefepim			S	Transplacental			Not Reported	
	Imipenem/Cilastatin			S	Transplacental			Not Reported	
	Amphotericin B			S	Transplacental			Not Reported	
	Protamine Sulphate			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16260626	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1040960		34 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoptysis; Mediastinitis; Pleural	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Effusion; Pneumonia	Azithromycin	S	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16261632	NON-EXPEDITED			US-PFIZER INC-2019181757		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16261872	NON-EXPEDITED			US-PFIZER INC-2019184564			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infusion Site Extravasation; Pain; Swelling	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2019	16262003	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019180572		65 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Lip Swelling; Pruritus; Urticaria	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Cardio Aspirin			C		Unk		Not Reported	
	Benazepril Hydrochloride/Hydrochlorothiazide			C		Unk		Not Reported	
	Eutirox			C		Unk		Not Reported	
	Metformin			C				Not Reported	
	Zorias			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	15454375	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I		53 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

NC./RIDGEFIELD-2018-
BI-04

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Atrovent			S	Unknown			Boehringer Ingelheim
	Combivent			S	Unknown			Boehringer Ingelheim
	Azithromycin			S	Oral			Not Reported
	Breo Ellipta			S	Unknown	Formulation: Inhalation		Not Reported
	Prednisone			S	Oral			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Seebri Breezhaler			S	Unknown			Not Reported
	Singulair			S	Oral			Not Reported
	Theophylline			S	Oral			Not Reported
	Xolair			S	Intravenous (not otherwise specified)	Formulation: Powder For Solution Subcutaneous		Not Reported
	Xolair			S	Intravenous (not otherwise specified)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16006915	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019073116		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blindness; Malaise; Near Death Experience; Off Label Use; Product Use In Unapproved Indication; Stevens-Johnson Syndrome	Zithromax			S		10 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16133189	EXPEDITED (15-DAY)		HO, OT	DE-NODEN PHARMA DAC-NOD-2019-000032		62 YR	Female	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bladder Transitional Cell Carcinoma	Rasilez			S	Unknown	Unk		Noden Pharma
	Rasilez			S	Unknown	Unk		Noden Pharma
	Moronal			S	Unknown	Unk		Not Reported
	Clindamycin Al			S	Unknown	Unk		Not Reported
	Clindamycin Al			S	Unknown	Unk		Not Reported
	Hygroton			S	Unknown	Unk		Not Reported
	Hygroton			S	Unknown	Unk		Not Reported
	Lonolox			S	Unknown	Unk		Not Reported
	Lonolox			S	Unknown	Unk		Not Reported
	Valsacor Comp			S	Unknown	Unk		Not Reported
	Ibu 1a Pharma			S	Unknown	Unk		Not Reported
	Ibu 1a Pharma			S	Unknown	Unk		Not Reported
	Mometahexal			S	Nasal	Unk		Not Reported
	Mometahexal			S	Unknown	Unk		Not Reported
	Alfason Crelo			S	Unknown	Unk		Not Reported
	Valsartan Ratiopharm Comp			S	Unknown	Unk		Not Reported
	Valsartan Ratiopharm Comp			S	Unknown	Unk		Not Reported
	Hct Hexal			S	Unknown	Unk		Not Reported
	Ciprofloxacin Aristo			S	Unknown	Unk		Not Reported
	Codeintropfen Ct			S	Unknown	Unk		Not Reported
	Linola H Fett N			S	Unknown	Unk		Not Reported
	Monuril			S	Unknown	Unk		Not Reported
	Monuril			S	Unknown	Unk		Not Reported
	Nebivolol Actavis			S	Unknown	Unk		Not Reported
	Valsartan Hexal			S	Unknown	Unk		Not Reported
	Valsartan Hexal			S	Unknown	Unk		Not Reported
	Novaminsulfon			S	Unknown	Unk		Not Reported
	Ciprofloxacin Al			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valsartan 1a Pharma Plus	S	Unknown	Unk	Not Reported
Valsartan 1a Pharma Plus	S	Unknown	Unk	Not Reported
Ampho Moronal	S	Unknown	Unk	Not Reported
Eferox	S	Unknown	Unk	Not Reported
Spironolacton Aristo	S	Unknown	Unk	Not Reported
Decortin H	S	Unknown	Unk	Not Reported
Doxagamma	S	Unknown	Unk	Not Reported
Eutirox	S	Unknown	Unk	Not Reported
Fluconazol Puren	S	Unknown	Unk	Not Reported
Fluconazol Puren	S	Unknown	Unk	Not Reported
Cefpodoxime Proxetil	S	Unknown	Unk	Not Reported
Doxycyclin 1a Pharma	S	Unknown	Unk	Not Reported
Doxycyclin 1a Pharma	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S		Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Cefpodoxime	S	Unknown	Unk	Not Reported
Pantoprazol	S	Unknown	Unk	Not Reported
Locacortene Vioforme	S	Unknown	Unk	Not Reported
Ampicillin Ratiopharm /00000502/	S	Unknown	Unk	Not Reported
Levothyroxine	S	Unknown	Unk	Not Reported
Roxithromycin	S	Unknown	Unk	Not Reported
Roxithromycin	S	Unknown	Unk	Not Reported
Clindasol /00166002/	S	Unknown	Unk	Not Reported
Dolgit	S	Unknown	Unk	Not Reported
Azithromycin 1a Pharma /00944301/	S	Unknown	Unk	Not Reported
Valsartan/Hydrochlorothiazide	S		Unk	Not Reported
Valsartan/Hydrochlorothiazide	S	Unknown	Unk	Not Reported
Clindahexal /00166002/	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxazosin 1 A Pharma	S	Unknown	Unk	Not Reported
Clinda-Saar /00166002/	S	Unknown	Unk	Not Reported
Ibuflam /00109201/	S	Unknown	Unk	Not Reported
Ciprofloxacin	S	Unknown	Unk	Not Reported
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Not Reported
Lercanidipino Ratiopharm	S	Unknown	Unk	Not Reported
Cotrimox Forte	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16144525	EXPEDITED (15-DAY)		HO, OT	PHHY2019DE069903		62 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bladder Transitional Cell Carcinoma	Rasilez			S	Unknown	Unk		Not Reported
	Rasilez			S				Not Reported
	Valsartan + Hct			S	Unknown	Unk		Not Reported
	Hygroton			S	Unknown	Unk		Not Reported
	Mometahexal			S	Nasal	Unk		Novartis
	Doxycyclin - 1 A Pharma			S	Unknown	Unk		Not Reported
	Novaminsulfon			S	Unknown	Unk		Not Reported
	Ibu 1a Pharma			S	Unknown	Unk		Not Reported
	Roxithromycin			S	Unknown	Unk		Not Reported
	L-Thyroxhexal			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Cefpodoxime			S	Unknown	Unk		Not Reported
	Sulfamethoxazole+Trimethoprim			S	Unknown	Unk		Not Reported
	Sulfamethoxazole+Trimethoprim			S	Unknown	Unk		Not Reported
	Doxazosin 1a Pharma			S	Unknown	Unk		Not Reported
	Cefpodoxim Hexal			S	Unknown	Unk		Not Reported
	Clindahehexal			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valsartan 1 A Pharma Plus	S	Unknown	Unk	Not Reported
Valsartan Hexal	S	Unknown	Unk	Not Reported
Hct Hexal	S	Unknown	Unk	Not Reported
Fluconazole	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Not Reported
Cotrim Forte	S	Unknown	Unk	Not Reported
Nebivolol	S	Unknown	Unk	Not Reported
Valsartan Hexal Comp	S	Unknown	Unk	Not Reported
Fluconazol Puren	S	Unknown	Unk	Not Reported
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Not Reported
Lercanidipine Ratiopharm	S	Unknown	Unk	Not Reported
Azithromycin 1 A Pharma	S	Unknown	Unk	Not Reported
Moronal	S	Unknown	Unk	Not Reported
Ciprofloxacin Al	S	Unknown	Unk	Not Reported
Ibuflam [Ibuprofen]	S	Unknown	Unk	Not Reported
Linola H Fett N	S	Unknown	Unk	Not Reported
Decortin H	S	Unknown	Unk	Not Reported
Doxagamma	S	Unknown	Unk	Not Reported
Ampicillin Ratiopharm (Ampicillin Sodium)	S	Unknown	Unk	Not Reported
Valsartan Ratiopharm Comp	S	Unknown	Unk	Not Reported
Spironolacton Aristo	S	Unknown	Unk	Not Reported
Eferox	S	Unknown	Unk	Not Reported
Ciprofloxacin Aristo	S	Unknown	Unk	Not Reported
Ampho Moronal	S	Unknown	Unk	Not Reported
Alfason Crelo	S	Unknown	Unk	Not Reported
Clindasol (Clindamycin Hydrochloride)	S	Unknown	Unk	Not Reported
Valsacor Comp	S	Unknown	Unk	Not Reported
Clinda-Saar	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeintropfen Ct	S	Unknown	Unk	Not Reported
Nebivolol Actavis	S	Unknown	Unk	Not Reported
Monuril	S	Unknown	Unk	Not Reported
Lonolox	S	Unknown	Unk	Not Reported
Dolgit	S	Unknown	Unk	Not Reported
Locacorten Vioform	S	Unknown	Unk	Not Reported
Eutirox	S	Unknown	Unk	Not Reported
Clindamycin Al	S	Unknown	Unk	Not Reported
Cotrimox Forte	S	Unknown	Unk	Not Reported
Valsartan Comp	S	Unknown	Unk	Not Reported
Cotrimoxazol Al	S	Unknown	Unk	Not Reported
Cefpo	S	Unknown	Unk	Not Reported
Euthyrox	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16234663	EXPEDITED (15-DAY)	HO		IT-MYLANLABS-2019M1037722		16 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Intentional Self-Injury; Substance Abuse	Paracetamol			S	Oral	1000 Milligram, Once		Not Reported
	Nimesulide			S	Oral	1500 Milligram, Once		Not Reported
	Azithromycin			S	Oral	1500 Milligram, Once		Not Reported
	Amoxicillin/Clavulanic Acid			S	Oral	1 Gram, Once		Not Reported
	Oki			S		120 Milligram, Once		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16262655	EXPEDITED (15-DAY)	HO		IT-TEVA-2019-IT-1043159		6 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Ecchymosis; Petechiae	Azithromycin			S	Oral	300 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16264382	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1041416		87 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acidosis; Hypercapnia; Hypothermia; Hypoventilation; Impaired Gastric Emptying; Pneumonia; Pupillary Reflex Impaired; Respiratory Failure; Vomiting	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ceftazidime			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16264550	EXPEDITED (15-DAY)		HO, OT	CZ-MYLANLABS-2019M1042295		68 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatorenal Syndrome	Azithromycin			S	Unknown			Not Reported	
	Voriconazole			S	Unknown			Not Reported	
	Amiodarone			S	Intravenous drip	After 36 Hours The Dose Was Reduced To 600 Mg/24 Hours Continuously		Mylan	
	Amiodarone			S	Intravenous drip	600 Milligram		Mylan	
	Cotrimoxazole			S	Unknown			Mylan	
	Moxifloxacin			S	Unknown			Mylan	
	Meropenem			C	Unknown			Mylan	
	Gliclazide			C	Unknown			Mylan	
	Metformin			C	Unknown			Mylan	
	Nitrendipine			C	Unknown			Mylan	
	Metoprolol			C	Unknown			Mylan	
	Hydrochlorothiazide			C	Unknown			Mylan	
	Valsartan			C	Unknown			Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Atorvastatin	C	Unknown						Mylan
	Fenofibrate	C	Unknown						Mylan
	Acetylsalicylic Acid	C	Unknown						Mylan
	Ciprofloxacin	C	Unknown						Mylan
	Nitrous Oxide	C	Respiratory (inhalation)						Mylan
	Esmolol	C	Unknown						Mylan
	Noradrenaline /00127501/	C	Unknown			Low Dose			Mylan
	Piperacillin/Tazobactam	C	Unknown						Mylan
	Piperacillin/Tazobactam	C							Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16264747	NON-EXPEDITED			US-PFIZER INC-2019185560		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16264970	EXPEDITED (15-DAY)		HO	PHHY2019TH100315		20 YR	Female	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection; Mycobacterium Abscessus Infection; Product Use In Unapproved Indication	Prednisolone			S	Oral	30 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	15 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	10 Mg, Qd		Not Reported	
	Prednisolone			S	Oral	5 Mg, Qd		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	1000 Mg, Unk		Not Reported	
	Azithromycin			S	Oral			Novartis	
	Cyclophosphamide			S	Intravenous (not otherwise specified)	400 Mg, Q2w, 6 Cycles		Not Reported	
	Cyclophosphamide			S	Intravenous (not otherwise specified)	400 Mg, Every 4-6 Weeks,		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cyclophosphamide	S	otherwise specified)	3 Cycles	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	400 Mg, Every 8-12 Weeks, 3 Cycles	Not Reported
Imipenem	S	Intravenous (not otherwise specified)	400 Mg, Every 12 Weeks	Not Reported
Linezolid	S	Parenteral	3 Courses (Each Course Of 4 Weeks Duration	Not Reported
Doxycycline	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16266201	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK201905128		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure During Pregnancy; Foetal Growth Restriction; Gestational Hypertension	Methylprednisolone (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
	Methylprednisolone (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
	Vancomycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Cefepime (Manufacturer Unknown)			S	Unknown			Not Reported	
	Ceftriaxone For Injection (Manufacturer Unknown)			S	Unknown			Not Reported	
	Salbutamol Sulfate			S	Unknown			Not Reported	
	Salbutamol Sulfate			S	Unknown			Not Reported	
	Ipratropium			S	Unknown			Not Reported	
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Not Reported	
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2019	16266264	EXPEDITED (15-DAY)		OT	ES-CANTON LABORATORIES, LLC- 2066557		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza Like Illness; Stevens-Johnson Syndrome	Naprosyn			S	Unknown			Canton Laboratories	
	Etanercept			S	Unknown			Not Reported	
	Pantoprazole Sodium			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Neotigason			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	14355353	EXPEDITED (15-DAY)		HO, OT	ES-ASTELLAS- 2017US057172		65 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Pain; Fatigue; Flank Pain; Gait Disturbance; Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Prograf			S	Oral			Astellas	
	Prograf			S	Oral	4.5 Mg Before Breakfast And 4 Mg Before Dinner		Astellas	
	Prograf			S	Oral	5 Mg, 2x/Day (Bid) (1 In Morning And 1 Before Dinner)		Astellas	
	Valcyte			S	Oral	900 Mg, Once Daily (With Lunch)		Not Reported	
	Valcyte			S	Oral	450 Mg, Once Daily (With Lunch)		Not Reported	
	Cellcept /01275102/			S	Oral			Not Reported	
	Cellcept /01275102/			S	Oral	500 Mg, Every 6 Hours (2 At Breakfast And 2 At Dinner)		Not Reported	
	Cellcept /01275102/			S	Oral	2 Df Of 500 Mg 2 At Breakfast And 2 At Dinner		Not Reported	
	Zitromax			S	Oral	250 Mg, Every Other Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

				(1 Df On Lxv At Lunch/ Every 48 Hours)	
Zitromax	S	Oral		Unk Unk, Unknown Freq.	Not Reported
Septrin	S	Oral		1 Df (400 Mg/80 Mg), Once Daily	Not Reported
Septrin	S	Oral		1 Df, Once Daily (At Lunch Time)	Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Oral			Not Reported
Prednisone	S	Oral		60 Mg, Once Daily 30x2/Day At Breakfast	Not Reported
Paracetamol	C	Oral		2 Df, Thrice Daily (2 At Breakfast - 2 At Lunch - 2 At Dinner)	Not Reported
Paracetamol	C	Oral			Not Reported
Calcium + Vitamin D /00944201/	C	Oral		1 Df (500/400), Twice Daily (Every 12 Hours)	Not Reported
Dexketoprofen	C	Oral		25 Mg, As Needed (1 At Breakfast - 1 At Lunch - 1 At Dinner)	Not Reported
Abelcet	C	Respiratory (inhalation)		50 Mg (Half Vial Of 100mg), Once Weekly (On Mondays In The Afternoon)	Not Reported
Omeprazole	C	Oral		20 Mg, Once Daily At Breakfast	Not Reported
Lorazepam	C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	14518559	NON-EXPEDITED			US-PFIZER INC- 2018060198			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Cipro [Ciprofloxacin]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16063637	NON-EXPEDITED			US-PFIZER INC-2019102899		85 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, Daily		Pfizer	
	Lumigan			C	Ophthalmic	2 Gtt, 1x/Day (1 Drop In Both Eyes Once A Day At Night)		Not Reported	
	Timolol Maleate			C	Ophthalmic	2 Gtt, 1x/Day (Drop In Each Eye Once A Day In The Morning)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16270006	EXPEDITED (15-DAY)		HO	DE-TEVA-2019-DE-1044250		47 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiovascular Disorder; Coagulopathy; Dizziness; Hepatitis Toxic; Jaundice; Nausea; Subacute Hepatic Failure	Azithromycin-Ratiopharm 250mg			S	Oral			Not Reported	
	Candesartan 16 Mg			C				Not Reported	
	Bisodipin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16271869	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2019-DE-1044183		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatic Fibrosis; Hepatitis Acute; Jaundice	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2019	16414020	DIRECT	Y				76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease; Dysphonia; Dyspnoea	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2019	16107952	EXPEDITED (15-DAY)		HO	PHHY2019FR062764		26 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Paracetamol			S	Oral	1 G, Unk (Par Prise De Manière Ponctuelle)		Not Reported	
	Zithromax			S	Oral	750 Mg, Qw (1 Comprimé De 250 Mg 3 Fois Par Semaine)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2019	16274404	EXPEDITED (15-DAY)		LT, OT	ES-AUROBINDO-AUR-APL-2019-021415			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza Like Illness; Product Use In Unapproved Indication; Stevens-Johnson Syndrome	Pantoprazole			S	Unknown	Unk		Aurobindo	
	Naproxen Sodium			S	Unknown	Unk		Aurobindo	
	Azithromycin Film-Coated Tablets			S	Unknown	Unk		Aurobindo	
	Etanercept			S	Unknown	Unk		Not Reported	
	Neotigason			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2019	16275598	NON-EXPEDITED			PHEH2019US018483			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	11883374	NON-EXPEDITED			US-PFIZER INC-2015436929			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Septra			S		Unk		Pfizer	
	Phenergan With Codeine			S		Unk		Not Reported	
	Niacin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Symbicort			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	13622842	EXPEDITED (15-DAY)		HO, OT	PHHY2016CA134077		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris;	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported	
Arthralgia; Arthritis;	Xolair			S	Subcutaneous	Unk		Not Reported	
Asthenia; Atrial Fibrillation;	Xolair			S	Subcutaneous	Unk		Not Reported	
Back Pain; Blood	Xolair			S	Subcutaneous	Unk		Not Reported	
Disorder; Blood Pressure	Xolair			S	Subcutaneous	Unk		Not Reported	
Systolic Increased; Body	Xolair			S	Subcutaneous	Unk		Not Reported	
Temperature Decreased;	Xolair			S	Subcutaneous	Unk		Not Reported	
Diarrhoea; Dyspnoea;	Xolair			S	Subcutaneous	Unk		Not Reported	
Fatigue; Infection;	Xolair			S	Subcutaneous	Unk		Not Reported	
Injection Site Discomfort;	Xolair			S	Subcutaneous	Unk		Not Reported	
Injection Site Pain;	Xolair			S	Subcutaneous	Unk		Not Reported	
Osteoarthritis; Pain In	Xolair			S	Subcutaneous	Unk		Not Reported	
Extremity; Pneumonia	Xolair			S	Subcutaneous	Unk		Not Reported	
Pseudomonal; Pneumonia	Xolair			S	Subcutaneous	300 Mg, Every 4 Weeks		Not Reported	
Streptococcal; Pulmonary									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mass; Pulmonary Oedema; Wheezing	Xolair	S	Subcutaneous	300 Mg, Every 4 Weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 4 Weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 4 Weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 4 Weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 4 Weeks	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 4 Weeks (In 2019)	Not Reported
	Bisoprolol Sandoz	S	Unknown	Unk	Novartis
	Azithromycin	S	Unknown	250 Mg, Qd (For 1 Year)	Not Reported
	Spiriva	C	Unknown	1 Df, Qd	Not Reported
	Zenhale	C	Unknown	2 Df, Bid	Not Reported
	Qvar	C	Unknown	1 Df, Bid	Not Reported
	Singulair	C	Unknown	1 Df, Qd	Not Reported
	Claritin	C	Unknown	Unk, Bid	Not Reported
	Ventolin	C	Unknown	Unk Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	14485212	NON-EXPEDITED			US-PFIZER INC- 2018048253		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Varenicline Tartrate			S		Unk		Pfizer
	Amoxicillin			S		Unk		Not Reported
	Hydroxychloroquine			S		Unk		Not Reported
	Hydroxychloroquine Sulfate			S		Unk		Not Reported
	Tramadol			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16236305	EXPEDITED (15-DAY)		CA, OT	BR-CIPLA LTD.- 2019BR02176			Unknown	BRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Murmur; Cryptorchism; Foetal Exposure During Pregnancy	Lamivudine/Tenofovir			S	Transplacental	Unk		Cipla
	Atazanavir			S	Transplacental	Unk		Cipla
	Ritonavir			S	Transplacental	Unk		Cipla
	Isentress			S	Transplacental	Unk		Not Reported
	Folate			S	Transplacental	Unk		Not Reported
	Metronidazole			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Hydroxyzine			S	Transplacental	Unk		Not Reported
	Miconazole			S	Transplacental	Unk		Not Reported
	Fluconazole			S	Transplacental	Unk		Not Reported
	Hepatitis B Vaccine			S	Transplacental	Unk		Not Reported
	Diphtheria And Tetanus Toxoids And Pertussis			S	Transplacental	Unk		Not Reported
	Dt Vaccine			S	Transplacental	Unk		Not Reported
	Ferrous Sulfate			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16273402	EXPEDITED (15-DAY)		OT	PL-AUROBINDO-AUR- APL-2019-024580			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conjunctivitis; Drug Interaction; Pharyngeal Swelling	Azithromycin			S	Unknown	(Unk Unk, Unknown Freq.)		Aurobindo
	Unidox			S	Unknown	(Unk Unk, Twice Daily)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16275657	EXPEDITED (15-DAY)		OT	SI-MYLANLABS- 2019M1042488		29 YR	Female	SVN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Premature Delivery	Oxytocin			S	Intravenous (not otherwise specified)	5 Mu/Min		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vancomycin	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Mylan
Ceftriaxone	S	Unknown	Unk	Mylan
Betamethasone	S	Unknown	Unk	Mylan
Oseltamivir	S	Unknown	Unk	Mylan
Sevoflurane	S	Unknown	Unk	Mylan
Cefepim	S	Unknown	Unk	Mylan
Imipenem/Cilastatin	S	Unknown	Unk	Mylan
Amphotericin B	S	Unknown	Unk	Mylan
Protamine Sulfate	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16276649	NON-EXPEDITED			US-PFIZER INC-2019187499		12 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Chlorhexidine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16277116	NON-EXPEDITED			US-PFIZER INC-2019190363		72 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pruritus	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16278128	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1042450		79 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Lower Respiratory Tract Infection	Azithromycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abatacept	S	Subcutaneous	125 Mg, Qwk	Mylan
Amlodipine	C	Unknown		Mylan
Carbocisteine	C	Unknown	Unk	Mylan
Rivaroxaban	C	Unknown		Mylan
Dexamethasone	C	Oral	500 Milligram	Mylan
Furosemide	C	Unknown	Unk	Mylan
Atorvastatin	C	Unknown	Unk	Mylan
Digoxin	C	Unknown		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-May-2019	16278609	NON-EXPEDITED			US-009507513-1904USA010640		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Delivery	Celestone Soluspan			S		A Dose.		Merck
	Magnesium Sulfate			S				Not Reported
	Azithromycin			S				Not Reported
	Ampicillin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	15188730	NON-EXPEDITED			US-PFIZER INC-2018297738		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Benzonatate			S		Unk		Pfizer
	Loratadine			S		Unk		Pfizer
	Benzocaine		Y	S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Cefixime			S		Unk		Not Reported
	Ipratropium			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ranitidine			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-May-2019	15248909	NON-EXPEDITED			US-PFIZER INC-2018312978		62 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Alopecia; Hair Growth	Chantix			S	Oral	1 Mg, Twice A Day		Pfizer		
Abnormal; Hair Texture	Chantix			S	Oral	1 Mg, 2x/Day		Pfizer		
Abnormal;	Azithromycin			S		250 Mg, 1x/Day		Pfizer		
Hypersensitivity; Weight	Naproxen			S		4 Mg, 2x/Day		Not Reported		
Increased	Naproxen			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-May-2019	15518551	EXPEDITED (15-DAY)		DE, HO	US-ACTELION-A-US2018-179679		71 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abnormal Faeces; Death;	Uptravi			S	Oral	1600 Mcg, Qd		Actelion		
Drug Hypersensitivity;	Uptravi			S	Oral	1000 Mcg, Bid		Actelion		
Dyspnoea; Dyspnoea	Uptravi			S	Oral	800 Mcg, Bid		Actelion		
Exertional; Fatigue;	Uptravi			S	Oral	600 Mcg, Bid		Actelion		
Hospitalisation; Incorrect	Azithromycin			S	Unknown			Not Reported		
Dose Administered; Joint	Augmentin			S	Unknown			Not Reported		
Swelling; Mucous Stools;										
Oxygen Saturation										
Decreased; Pain In Jaw;										
Pneumonia; Secretion										
Discharge; Swelling										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
07-May-2019	16270941	NON-EXPEDITED			US-PFIZER INC-2019185322			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer		
Rash										

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16280256	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK078219		68 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cardiac Failure; Emphysema	Salbutamol			S		Unk		Glaxosmithkline	
	Fluticasone			S		2 Df, Bid		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Rabeprazole			S		Unk		Not Reported	
	Olodaterol Hydrochloride + Tiotropium Bromide			C		2 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16281524	NON-EXPEDITED			US-PFIZER INC-2019192856			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16281697	NON-EXPEDITED			US-PFIZER INC-2019192498			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16281810	NON-EXPEDITED			US-PFIZER INC-2019193004			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Erythromycin		S			Unk		Pfizer	
	Cipro [Ciprofloxacin Hydrochloride]		S			Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16281830	EXPEDITED (15-DAY)		HO	BR-PFIZER INC-2019191037		90 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Rash; Swelling	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Unk		Pfizer	
	Oseltamivir			C	Oral	75 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16282474	NON-EXPEDITED			US-PFIZER INC-2019191695			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16282484	NON-EXPEDITED			US-PFIZER INC-2019190014		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Somnolence	Azithromycin			S	Oral	2 Df, 1x/Day		Pfizer	
	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16282491	NON-EXPEDITED			US-PFIZER INC-2019194050			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16283225	EXPEDITED (15-DAY)		HO	PL-TEVA-2019-PL-1045421		24 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eczema Vesicular; Erythema; Skin Lesion	Bactrazol			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-May-2019	16283821	EXPEDITED (15-DAY)		OT	CA-CELGENEUS-CAN-20190409791		50 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Fatigue; Haemoglobin Decreased; Headache; Nausea	Otezla			S	Oral	30 Milligram		Celgene	
	Pms-Azithromycin			S	Unknown			Not Reported	
	Valtrex			S	Unknown			Not Reported	
	Imatinib Mesilate			C	Oral	400 Milligram		Not Reported	
	Pantoprazole Sodium Anhydrous			C	Oral	40 Milligram		Not Reported	
	Purinethol			C	Oral	50 Milligram		Not Reported	
	Zofran			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	14708072	NON-EXPEDITED			US-PFIZER INC-2018135179		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Prevnar 13			S		Single Dose		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Bupivacaine Hcl			S		Unk		Pfizer	
	Ciprofloxacin Hcl			S		Unk		Unknown	
	Clindamycin Hcl			S		Unk		Pfizer	
	Chlorthalidone			S		Unk		Not Reported	
	Trimethoprim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Torsemide		S		Unk		Not Reported		
	Moxifloxacin Hcl		S		Unk		Not Reported		
	Enoxaparin		S		Unk		Not Reported		
	Metolazone		S		Unk		Not Reported		
	Sulfamethoxazole		S		Unk		Not Reported		
	Cipro		S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16286120	NON-EXPEDITED			US-PFIZER INC-2019194798			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin				S		Unk		Pfizer
	Flagyl				S		Unk		Pfizer
	Levaquin				S		Unk		Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16288104	EXPEDITED (15-DAY)		OT	PHHY2019IT103709		47 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema; Laryngeal Oedema	Azithromycin				S	Oral	500 Mg, Qd		Novartis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-May-2019	16288106	EXPEDITED (15-DAY)		HO	PHHY2019DE105686			Female	DEU
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swollen Tongue	Azithromycin				S	Oral	Unk		Novartis
	Azithromycin				S				Novartis
	Cosentyx				S	Unknown	150 Mg, Once		Not Reported
	Cosentyx				S	Unknown	150 Mg, Once		Not Reported
	Methotrexate				C	Subcutaneous	15 Mg, Qw		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Folic Acid	C	Oral	5 Mg, Qw		Not Reported			
	Ramipril	C	Oral	5 Mg, Qd		Not Reported			
	Prednisolone	C	Oral	20 Mg, Qd		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16289156	NON-EXPEDITED			PHEH2019US019948			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16289584	NON-EXPEDITED			PHEH2019US019248			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure Via Breast Milk	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16289591	NON-EXPEDITED			PHEH2019US019693			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Exposure Via Breast Milk; Vomiting	Azithromycin			S	Transmammary			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16291109	NON-EXPEDITED			US-PFIZER INC- 2019194494			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16291511	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1046110		73 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Diarrhoea; Drug Ineffective; Gastrointestinal Pain; Hypersensitivity; Intestinal Ulcer; Product Formulation Issue	Azithromycin Dihydrate			S	Oral	750 Milligram For Every 1 Week		Not Reported	
	Beconase Aqueous Budesonide			C				Not Reported	
				C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-May-2019	16291727	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2019195760		70 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatic Fibrosis; Hepatitis Acute; Jaundice	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	14221356	NON-EXPEDITED			US-PFIZER INC-2017506994			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	14518597	NON-EXPEDITED			US-PFIZER INC-2018061262			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Pneumovax 23			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dilaudid			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	15549224	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018US-188952			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acquired Gene Mutation; Pathogen Resistance; Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16125738	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-016046			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hepatocellular Injury	Paracetamol			S	Oral	1 Gram, 1g Par Prise De Manière Ponctuelle		Aurobindo	
	Zithromax			S	Oral	750 Milligram, 1 Week, 1 Comprimé De 250 Mg 3 Fois Par Semaine		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16296545	NON-EXPEDITED			US-PFIZER INC- 2019198970			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16297041	EXPEDITED (15-DAY)		OT	PHHY2019US101988		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Growth Restriction; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Methylprednisolone	S	Intravenous (not otherwise specified)	60 Mg, Bid	Not Reported
	Methylprednisolone	S	Intravenous (not otherwise specified)	80 Mg, Q6h	Not Reported
	Vancomycin	S	Unknown		Novartis
	Vancomycin	S			Novartis
	Azithromycin	S	Unknown		Not Reported
	Ceftriaxone	S	Unknown		Not Reported
	Ceftriaxone	S			Not Reported
	Prednisone	S	Unknown		Not Reported
	Albuterol	S	Unknown	Unk Unk, Q2h	Not Reported
	Albuterol	S	Unknown	20 Mg, Qh	Not Reported
	Ipratropium	S	Unknown	Unk Unk, Q6h	Not Reported
	Cefepime	S	Unknown		Not Reported
	Oseltamivir	S	Unknown		Not Reported
	Oseltamivir	S			Not Reported
	Duoneb	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16297062	EXPEDITED (15-DAY)		OT	PHHY2019US101992			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Methylprednisolone			S	Transplacental	Maternal Dose: 60mg And 80 Mg Bid		Novartis	
	Vancomycin			S	Unknown	Maternal Dose: Unknown		Not Reported	
	Azithromycin			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Ceftriaxone			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Prednisone			S	Transplacental	Maternal Dose: Unknown		Not Reported	
	Albuterol			S	Transplacental	Maternal Dose: Every 2 Hours, 20 Mg/H		Not Reported	
	Ipratropium			S	Transplacental	Maternal Dose: Every 6 Hours		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefepime	S	Transplacental	Maternal Dose : Unknown	Not Reported
Duoneb	S	Transplacental	Maternal Dose: Unknown	Not Reported
Oseltamivir	S	Transplacental	Maternal Dose: Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16298101	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2019-CA-1046956		81 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Acute Kidney Injury; Adjustment Disorder; Anaemia; Angina Pectoris; Atrophy; Back Pain; Bundle Branch Block Left; Death; Drug Hypersensitivity; Drug Intolerance; Hepatic Steatosis; Hypercalcaemia; Hypertension; Monoclonal Gammopathy; Musculoskeletal Pain; Osteoarthritis; Palmar Erythema; Plasma Cell Myeloma; Sacroiliitis; Spinal Disorder; Toxicity To Various Agents	Codeine			S	Unknown			Not Reported
	Actonel			S	Unknown			Teva
	Aclasta			S	Intravenous drip			Not Reported
	Amoxil			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported
	Dilaudid			C				Not Reported
	Esomeprazole Sodium			C		40 Milligram Daily;		Not Reported
	Nitroglycerin			C	Oral			Not Reported
	Propranolol Hydrochloride			C		80 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16299119	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2019DE106810		49 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Acute Kidney Injury; Blister; Drug Interaction; Livedo Reticularis	Paracetamol			S	Unknown			Not Reported
	Azithromycin			S	Oral			Novartis
	Azithromycin			S				Novartis

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16299693	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1047790		52 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral			Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16300479	EXPEDITED (15-DAY)		OT	PL-PFIZER INC-2019197652		44 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Drug Interaction; Pharyngeal Swelling	Azithromycin			S		Unk		Pfizer	
	Unidox [Doxycycline Monohydrate] Solutab			S		Unk Unk, 2x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16300722	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019195844		73 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Gastrointestinal Pain; Hypersensitivity; Intestinal Ulcer; Product Formulation Issue	Azithromycin			S	Oral	750 Mg, Weekly		Pfizer	
	Beconase Aqueous			C		Unk		Not Reported	
	Budesonide			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16300951	NON-EXPEDITED			PHEH2019US020275			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Penicillin G Sodium			S	Unknown			Novartis	
	Azithromycin			S	Unknown			Not Reported	
	Erythromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-May-2019	16301301	EXPEDITED (15-DAY)		DE	FR-PFIZER INC-2019201659		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebral Haemorrhage	Novatrex			S	Oral	1 Df, Weekly		Pfizer	
	Previscan [Fluindione]			S	Oral	0.75 Df, 1x/Day		Not Reported	
	Speciafoldine			C	Oral	Unk		Not Reported	
	Metformine [Metformin]			C	Oral	1000 Mg, 1x/Day		Not Reported	
	Liptruzet			C	Oral	Unk		Not Reported	
	Cardensiel			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	13494780	NON-EXPEDITED			US-PFIZER INC-2017183634		71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16006204	EXPEDITED (15-DAY)		LT, OT	US-PFIZER INC-2019082776		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Heart Rate Increased; Hypertension; Near Death Experience; Palpitations	Azithromycin			S		2 For First Day		Pfizer	
	Azithromycin			S		One Daily For 4 Days		Pfizer	
	Synthroid			C		25 Mg, 1x/Day		Not Reported	
	Losartan Hctz			C		Unk, Unk [50-12 Mg]		Not Reported	
	Zegerid [Omeprazole]			C		Unk Unk, 1x/Day		Not Reported	
	Biotin			C		5000 Ug, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16180719	NON-EXPEDITED			US-PFIZER INC-2019153359		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16238455	EXPEDITED (15-DAY)		HO	GR-PFIZER INC-2019175502		49 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Resistance; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16304641	NON-EXPEDITED			US-PFIZER INC-2019201449			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16304678	NON-EXPEDITED			US-PFIZER INC-2019196789			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Glipizide			S		Unk		Pfizer	
	Cipro [Ciprofloxacin Hydrochloride Monohydrate]			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cephalexin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16304680	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019198618		29 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Pruritus	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16304696	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019198603		2 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cyanosis; Pyrexia; Vomiting	Sulperazon			S	Intravenous drip	0.55 G, 2x/Day		Pfizer	
	Azithromycin			S	Intravenous drip	0.11 G, 1x/Day		Pfizer	
	Azithromycin			S	Intravenous drip	0.11 G, 1x/Day		Pfizer	
	Sodium Chloride			S	Intravenous drip	50 MI, 2x/Day		Not Reported	
	Yi Nuo Shu (Ambroxol Hydrochloride)			S	Intravenous drip	7.5 Mg, 1x/Day		Not Reported	
	Glucose And Sodium Chloride			S	Intravenous drip	50 MI, 1x/Day		Not Reported	
	Glucose Injection			S	Intravenous drip	150 MI, 1x/Day		Not Reported	
	Glucose Injection			S	Intravenous drip	50 MI, 1x/Day		Not Reported	
	Calcium Gluconate			S	Intravenous drip	1 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16305627	NON-EXPEDITED			US-PFIZER INC-2019202393			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactrim	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16306540	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2019M1045871		33 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness	Azithromycin			S	Oral			Not Reported
	Azithromycin			S				Not Reported
	Linezolid			S	Oral			Not Reported
	Linezolid			S				Not Reported
	Moxifloxacin			S	Oral			Not Reported
	Moxifloxacin			S				Not Reported
	Cefoxitin			S	Intravenous (not otherwise specified)			Mylan
	Cefoxitin			S				Mylan
	Meropenem			S	Intravenous (not otherwise specified)			Mylan
	Meropenem			S				Mylan
	Amikacin			S	Intravenous (not otherwise specified)			Mylan
	Amikacin			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-May-2019	16306842	NON-EXPEDITED			PHEH2019US020182			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tremor	Azithromycin Sandoz			S	Oral	2 Df, Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	12944275	NON-EXPEDITED			US-PFIZER INC-2016528940			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Enalapril Maleate	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported
	Cipro [Ciprofloxacin]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	15952643	NON-EXPEDITED			US-PFIZER INC-2019053672		71 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; White Blood Cell Count Decreased	Zithromax			S	Oral	Four Times A Day And Tapered Down		Pfizer	
	Zithromax			S	Oral	Unk		Pfizer	
	Prednisone			S		10 Mg, 2x/Day		Not Reported	
	Prednisone			S		10 Mg, 1x/Day		Not Reported	
	Albuterol [Salbutamol]			C		2 Puff, 4x/Day		Not Reported	
	Advair			C		1 Puff , 2x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	15980439	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019072152		39 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	500 Mg, Total		Pfizer	
	Oki			C	Oral	2 Df, Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			C	Oral	3 Df, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-May-2019	16307212	EXPEDITED (15-DAY)		OT	MY-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-207476		39 YR	Male	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Delirium; Substance-Induced Psychotic Disorder	Azithromycin	S	Oral	Unk	Sun				
	Amoxicillin-Clavulanate	S	Intravenous (not otherwise specified)	Unk	Sun				
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16307676	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-025367			Unknown	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Erythema; Laryngeal Oedema	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16309100	NON-EXPEDITED			US-PFIZER INC-2019200070		74 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Neomycin Sulfate			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16309348	NON-EXPEDITED			US-PFIZER INC-2019205545			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
	Noroxin			S		Unk		Not Reported	
	Remicade			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-May-2019	16311214	EXPEDITED (15-DAY)		OT	BE-FRESENIUS KABI-FK201905418		21 YR	Female	BEL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Hepatotoxicity; Nausea; Vomiting	Tigecycline (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unknown		Not Reported	
	Imipenem (Manufacturer Unknown)			S	Intravenous (not otherwise specified)	Unknown		Not Reported	
	Azithromycin			S	Oral	Unknown		Not Reported	
	Bedaquiline			S	Oral	Unknown		Not Reported	
	Clofazimine			S	Oral	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	15727090	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2018-3746			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Xeljanz			S	Oral			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Demerol			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Arava			S	Unknown			Not Reported	
	Benadryl			S	Unknown			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Imuran			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Procytox	S	Intravenous (not otherwise specified)	Strength: 2000 Mg	Not Reported
Simponi	S	Subcutaneous		Not Reported
Enbrel	S	Unknown		Not Reported
Ezetrol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16313370	EXPEDITED (15-DAY)		OT	US-BAYER-2019-095572		32 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Avelox			S		400 Mg, Qd		Bayer	
	Avelox			S		Unk		Bayer	
	Azithromycin			S		500 Mg, Qd, Day 1		Not Reported	
	Azithromycin			S		250 Mg, Qd, Days 2-5		Not Reported	
	Doxycycline			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16313504	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1048192		47 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Laryngeal Oedema	Azithromycin			S	Oral	500 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16313632	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019203926		47 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Laryngeal Oedema	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16313791	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019199988		52 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16313935	NON-EXPEDITED			US-PFIZER INC-2019207580		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Augmentin [Amoxicillin Sodium;Clavulanate Potassium]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16313953	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2067012			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flushing; Swelling Face; Urticaria	Azithromycin			S	Oral			Wockhardt	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-May-2019	16473898	DIRECT	N	HO, OT			32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholecystectomy; Memory Impairment; Therapy Interrupted	Pulmozyme 2.5mg/2.5ml			S	Respiratory (inhalation)			Genentech	
	Cayston			C				Not Reported	
	Albuterrol			C				Not Reported	
	Azithromycin			S				Not Reported	
	Bd Pen Needle Mis			C				Not Reported	
	Budesonide			C				Not Reported	
	Creon			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Dulera	C	Not Reported
	Hypersal	C	Not Reported
	Lantus Solos	C	Not Reported
	Pantoprazole	C	Not Reported
	Spiriva	C	Not Reported
	Ursodiol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	13120543	NON-EXPEDITED			US-PFIZER INC-2017013737			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Tegretol			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	15168941	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2018-033006			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria; Myoclonus; Paraesthesia	Pantoprazole			S	Oral	Unk		Aurobindo	
	Terbutaline			S	Respiratory (inhalation)	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Aurobindo	
	Alprazolam			S	Oral	Unk		Aurobindo	
	Hizentra			S	Subcutaneous	Unk		Not Reported	
	Hydrocortisone			S	Oral	Unk		Not Reported	
	Oracilline			S	Oral	Non Communiquee		Not Reported	
	Neoral			S	Oral	Unk		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
	Seresta			S	Oral	Unk		Not Reported	
	Zelitrex			S	Oral	Unk		Not Reported	
	Vfend			S	Oral	Unk		Not Reported	
	Folinoral			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmicort	S	Respiratory (inhalation)	Unk	Not Reported
Ventoline	S	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16054133	EXPEDITED (15-DAY)		DE	US-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2019- BI-01			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Drug Hypersensitivity	Spiriva Respimat			S	Unknown			Boehringer Ingelheim	
	Azithromycin			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Avelox			S	Unknown			Not Reported	
	Fish Oil			S	Unknown			Not Reported	
	Fish Oil			S	Unknown			Not Reported	
	Fish Oil			S	Unknown			Not Reported	
	Fish Oil			S	Unknown			Not Reported	
	Fish Oil			S	Unknown			Not Reported	
	Fish Oil			S	Unknown			Not Reported	
	Hydrocodone			S	Unknown			Not Reported	
	Hydrocodone			S	Unknown			Not Reported	
	Hydrocodone			S	Unknown			Not Reported	
	Hydrocodone			S	Unknown			Not Reported	
	Hydrocodone			S	Unknown			Not Reported	
	Hydrocodone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paracetamol	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Paracetamol	S	Unknown	Not Reported
Aspirin (E.C.)	S	Unknown	Not Reported
Plavix	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16314370	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2019203315		69 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Infection; Malaise; Pancreatic Carcinoma	Zithromax			S		Unk		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16319798	EXPEDITED (15-DAY)		OT	PHHY2019US107368			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Seizure	Azithromycin			S	Oral			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16319803	EXPEDITED (15-DAY)		OT	PHHY2019US107295			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Oxygen Saturation Decreased	Azithromycin			S	Unknown			Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16319813	EXPEDITED (15-DAY)		OT	PHHY2019US107361			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Off Label Use; Skin Discolouration	Azithromycin			S	Oral			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16319816	EXPEDITED (15-DAY)		OT	PHHY2019US107362			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hepatomegaly; Off Label Use	Azithromycin			S	Oral			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16319822	EXPEDITED (15-DAY)		OT	PHHY2019US107366			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Nephrotic Syndrome; Off Label Use	Azithromycin			S	Unknown			Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16320432	NON-EXPEDITED			US-PFIZER INC-2019210558		57 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-May-2019	16321207	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019205851		60 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug-Induced Liver Injury; Hyperbilirubinaemia; Transaminases Increased	Azithromycin	S	Unk	Pfizer
	Bortezomib	C	Unk, Cyclic	Not Reported
	Lenalidomide	C	Unk Unk, Cyclic	Not Reported
	Doxorubicin	C	Unk Unk, Cyclic	Not Reported
	Pomalidomide	C	Unk Unk, Cyclic	Not Reported
	Entecavir	C	0.5 Mg, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321242	NON-EXPEDITED			US-AKRON, INC.- 2067084			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Swelling; Vision Blurred	Azasite			S				Akorn	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321258	NON-EXPEDITED			US-AKRON, INC.- 2067085			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Ocular Hyperaemia	Azasite			S				Akorn	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16321283	NON-EXPEDITED			US-AKRON, INC.- 2067088			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dark Circles Under Eyes	Azasite			S				Akorn	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-May-2019	16322339	NON-EXPEDITED			PHEH2019US020136			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Fatigue	Azithromycin			S	Oral	1 Df, Qd		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Magnesium	C	Oral	400 Mg, Qd	Not Reported
	Asa	C	Oral	81 Mg, Qd	Not Reported
	Mvi	C	Oral	Unk Unk, Qd	Not Reported
	Lipitor	C	Oral	40 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	15669769	EXPEDITED (15-DAY)		OT	US- GLAXOSMITHKLINE- US2018GSK213693		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atypical Pneumonia; Bronchitis; Inhalation Therapy; Intentional Product Use Issue; Malaise; Pneumonia	Ventolin Hfa			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Z-Pak			S				Not Reported	
	Prednisone			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	15707926	EXPEDITED (15-DAY)		OT	CA-AMGEN- CANSP2018175026			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen	
	Arava			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	250 Milligram, Qd		Not Reported	
	Benadryl			S	Unknown	Unk		Not Reported	
	Celebrex			S	Oral	Unk		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	
	Demerol			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Imuran			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Procytox	S	Unknown	2000 Milligram, Unk	Not Reported
Simponi	S	Unknown	Unk	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Xeljanz	S	Oral	5 Milligram, Bid	Not Reported
Pms Azithromycin	S	Unknown	250 Milligram, Qd	Not Reported
Ezetrol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16280278	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK076140			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchiectasis; Bronchomalacia; Cataract; Dyspnoea; Dyspnoea Exertional; Eosinophil Count Increased;	Fluticasone Propionate+Salmeterol Xinafoate Ventolin			S		Unk, 500		Glaxosmithkline
Gastrooesophageal Reflux Disease; Hypertension; Osteoporosis; Productive Cough; Spinal	Advair Zenhale Alvesco			S		Unk Unk, Prn		Glaxosmithkline
Osteoarthritis; Therapeutic Product Effect Incomplete; Tooth Disorder; Wheezing	Azithromycin Zantac Rhinocort Prednisone Aspirin Nexium Hydrochlorothiazide Pantoloc Ezetrol Actonel			S		Unk		Glaxosmithkline
				S		Unk		Glaxosmithkline
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Glaxosmithkline
				S		Unk		Glaxosmithkline
				S		Unk		Glaxosmithkline
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported
				S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quinapril			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-May-2019	16324028	EXPEDITED (15-DAY)		HO	GB-ACCORD-127862			Female	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Electrocardiogram Qt Prolonged	Amitriptyline			S	Oral	Once A Night		Accord		
	Azithromycin			S	Oral			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-May-2019	16324278	EXPEDITED (15-DAY)		DS, OT	GB-AUROBINDO-AUR-APL-2019-027394			Unknown	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Seizure	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Daily		Aurobindo		
	Epilim			C	Parenteral	2 Gram, Daily		Not Reported		
	Phenytoin Sodium			C	Unknown	100 Milligram		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-May-2019	16324282	EXPEDITED (15-DAY)		HO, LT, OT	DE-AUROBINDO-AUR-APL-2019-028125			Unknown	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Hepatic Failure;	Paracetamol			S	Unknown	Unk		Aurobindo		
Acute Kidney Injury;	Azithromycin			S	Oral	Unk		Not Reported		
Blister; Drug Interaction;	Azithromycin			S				Not Reported		
Livedo Reticularis										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
17-May-2019	16325005	EXPEDITED (15-DAY)		HO, LT, OT	DE-TEVA-2019-DE-1050051		49 YR	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acute Hepatic Failure;	Paracetamol			S	Unknown			Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Acute Kidney Injury; Blister; Drug Interaction; Livedo Reticularis	Azithromycin		S	Oral				Not Reported	
	Azithromycin		S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16325258	EXPEDITED (15-DAY)		OT	US-BAYER-2019-095542		31 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Avelox			S		400 Mg, Qd		Bayer	
	Azithromycin			S		1 G		Not Reported	
	Doxycycline			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16325449	EXPEDITED (15-DAY)		HO, LT, OT	DE-PFIZER INC-2019208505		49 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure; Acute Kidney Injury; Blister; Drug Interaction; Livedo Reticularis	Azithromycin			S	Oral	Tablets		Pfizer	
	Azithromycin			S				Pfizer	
	Paracetamol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16325456	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019207695		12 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Papule; Rash Erythematous	Zithromax			S	Oral	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-May-2019	16326176	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019203582		65 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Erythema Multiforme	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S			Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	15292126	EXPEDITED (15-DAY)		CA, DE, OT	FR-AUROBINDO-AUR- APL-2018-041924			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Induced; Foetal Exposure During Pregnancy; Foetal Malformation; Limb Deformity	Azithromycin			S	Transplacental	1 Gram, Daily		Aurobindo	
	Eviplera			S	Transplacental	1 Dosage Form, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	15341498	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2018-043792			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Pemphigoid; Pruritus; Pustule	Azithromycin			S	Oral	Unk		Aurobindo	
	Amoxicillin;Clavulanic Acid			S	Oral	Unk		Not Reported	
	Momenxsin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16328412	NON-EXPEDITED			US-TEVA-2019-US- 1049563		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Normal Newborn	Methylprednisolone			S	Intravenous (not otherwise specified)	120 Milligram Daily;		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	
	Prednisone			S	Unknown	Tapering Doses		Actavis	
	Azithromycin			S	Unknown			Not Reported	
	Albuterol			S	Unknown			Not Reported	
	Albuterol			S	Unknown	Continuous Salbutamol At 20 Mg/H		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ipratropium	S	Unknown	Not Reported
Vancomycin	S	Unknown	Not Reported
Cefepime	S	Unknown	Not Reported
Ceftriaxone	S	Unknown	Not Reported
Oseltamivir	S	Unknown	Not Reported
Duoneb	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-May-2019	16328628	EXPEDITED (15-DAY)		OT	PHHY2019GB091666			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Treatment Failure	Azithromycin			S	Oral	2 G, Single		Novartis	
	Ceftriaxone			S	Intramuscular	1 G, Single		Not Reported	
	Gentamicin			S	Intramuscular	240 Mg, Single		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	9866923	NON-EXPEDITED			US-PFIZER INC- 2014027476			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Ibuprofen			S		Unk		Pfizer	
	Tramadol			S		Unk		Not Reported	
	Cipro [Ciprofloxacin Hydrochloride Monohydrate]			S		Unk		Not Reported	
	Macrobid [Clarithromycin]			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Zithromycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	14482998	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2018-004554			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection; Hypokalaemia; Off Label Use; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days ()		Aurobindo
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Aurobindo
	Voriconazole			S	Other	8 Milligram/Kilogram		Aurobindo
	Azithromycin			S	Intravenous (not otherwise specified)	10 Unk		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported
	Prednisone			S	Unknown	()		Not Reported
	Amphotericin B, Liposome			S	Unknown	4 Milligram, Once A Day		Not Reported
	Amphotericin B, Liposome			S	Unknown	8 Mg/Kg, Qd, 28 Days		Not Reported
	Amphotericin B, Liposome			S	Unknown	5 Mg/Kg, Qd		Not Reported
	Amphotericin B, Liposome			S	Unknown	2.5 Mg/Kg, Qd		Not Reported
	Asparaginase			S	Unknown	()		Not Reported
	Dexamethasone			S	Unknown	10 Mg/M2 For 21 Days Then Tapering ()		Not Reported
	Dexamethasone			S	Unknown	10 Mg/M2 For 21 Days Then Tapering ()		Not Reported
	Sodium Chloride			S	Nasal	0.9% Nose Spray ()		Not Reported
	Pegaspargase			S	Intracardiac	()		Not Reported
	Vincristine			C	Unknown	()		Not Reported
	Vincristine			C	Unknown	()		Not Reported
	Daunorubicin			C	Unknown	()		Not Reported
	Daunorubicin			C	Unknown	()		Not Reported
	Methotrexate			C	Intrathecal	()		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Methotrexate			C		Intrathecal		Unk ()		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2019	15596028	NON-EXPEDITED			US-PFIZER INC-2018453103			Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2019	15710260	NON-EXPEDITED			US-PFIZER INC-2018508354		79 YR	Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2019	16330140	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-207890		47 YR	Male	ITA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Laryngeal Oedema	Azithromycin				S	Oral	500 Milligram, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-May-2019	16332460	NON-EXPEDITED			US-PFIZER INC-2019210937		52 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin				S		Unk		Pfizer	
	Demerol				S		Unk		Pfizer	
	Contrast				S		Unk		Not Reported	
	Keflex				S		Unk		Not Reported	
	Decadron				S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16332515	NON-EXPEDITED			US-PFIZER INC-2019209512		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
	Valium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16332688	NON-EXPEDITED			US-PFIZER INC-2019212017			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Headache	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16332830	NON-EXPEDITED			US-PFIZER INC-2019214577		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Lamisil			S		Unk		Not Reported	
	Montelukast			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16334387	EXPEDITED (15-DAY)		HO	PHHY2019IT111062		212 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Medication Error	Azithromycin			S	Oral	320 Mg, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-May-2019	16336795	DIRECT					53 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Palpitations	Zithromax Z-Pak			S				Not Reported	
	Adderall Xr			C				Not Reported	
	Ambien			C				Not Reported	
	Multi Vitamin			C				Not Reported	
	Calcium			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	15715581	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018511504			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Enbrel			S	Unknown	Unk		Pfizer	
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer	
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer	
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer	
	Xeljanz			S	Oral	5 Mg, Bid		Pfizer	
	Celebrex			S	Oral	Unk		Pfizer	
	Levofloxacin			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Demerol			S	Unknown	Unk		Pfizer	
	Azithromycin			S	Unknown	250 Mg, Qd		Pfizer	
	Azithromycin			S	Unknown	250 Milligram, Qd		Pfizer	
	Arava			S	Unknown	Unk		Not Reported	
	Benadryl			S	Unknown	Unk		Not Reported	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Imuran			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Procytox			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ezetrol			C		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-May-2019	15963573	NON-EXPEDITED			US-PFIZER INC-2019057953		66 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective; Infection	Zithromax			S		250 Mg, Unk		Pfizer		
	Zithromax			S				Pfizer		
	Guaifenesin			C		Unk		Not Reported		
	Ibrance			C	Oral	125 Mg, Unk		Not Reported		
	Codeine			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-May-2019	16338672	EXPEDITED (15-DAY)		HO, OT	GB-MYLANLABS-2019M1046708		30 YR	Male	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Facial Paralysis; Movement Disorder; Neurilemmoma Benign; Ototoxicity	Azithromycin			S		250 Milligram, Qd		Not Reported		
	Minocycline			S		200 Milligram, Qd		Not Reported		
	Clofazimine			S		100 Milligram, Qd		Mylan		
	Moxifloxacin			S		400 Milligram, Qd		Mylan		
	Amikacin			C		1000 Milligram, Qd		Mylan		
	Prednisolone			C		Unk		Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-May-2019	16338716	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1046780		61 YR	Female	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Asthma; Drug Ineffective; Respiratory Alkalosis	Azithromycin			S		Unk		Not Reported		
	Montelukast			S		Unk		Not Reported		
	Ipratropium Bromide W/Salbutamol			S		Unk Unk, Q8h (Every		Mylan		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Terbutaline	S	Eight Hours)	Mylan
Salmeterol/Fluticasone Cascan	S	Unk Unk, Qd 1500/150 Mcg Day	Mylan
Deflazacort	S	As Required	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-May-2019	16339674	NON-EXPEDITED			US-TEVA-2019-US-1047604			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Product Odour Abnormal; Product Taste Abnormal	Azithromycin			S	Oral	Form Strength: 200 Mg/5 ML.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	15690394	NON-EXPEDITED			US-PFIZER INC-2018502376			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S	Oral	Unk		Pfizer
	Biaxin			S	Oral	Unk		Not Reported
	Influenza Virus Vaccine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	15899464	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS- 2019-000711		8 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Gastritis; Infective Pulmonary Exacerbation Of Cystic	Orkambi			S	Oral	2 Tablets, Bid		Vertex
	Imipenem Cilastatin /00820501/			S	Intravenous (not otherwise specified)	600 Mg, Q8h		Not Reported
	Ceftazidime			S	Intravenous (not otherwise specified)	400 Mg, Q8h		Not Reported
	Ceftazidime			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fibrosis; Mycobacterium Abscessus Infection; Pneumonia	Amikacin	S	Intravenous (not otherwise specified)	700 Mg, Q24hr	Not Reported
	Azithromycin	S	Oral	250 Mg, Qd	Not Reported
	Azithromycin	S	Oral	Unk	Not Reported
	Cefoxitin	S	Intravenous (not otherwise specified)	Q8hr	Not Reported
	Creon	C			Not Reported
	Culturelle	C			Not Reported
	Flovent Hfa	C			Not Reported
	Ipratropium	C			Not Reported
	Loratadine	C			Not Reported
	Lidocaine W/Prilocaine	C			Not Reported
	Smz-Tmp	C			Not Reported
	Sodium Chloride	C			Not Reported
	Ventolin Hfa	C			Not Reported
	Vitamin D3	C			Not Reported
	Cyproheptadin	C			Not Reported
	Ranitidine	C			Not Reported
	Colistimethate /00013204/	C			Not Reported
	Fluticasone	C			Not Reported
	Sterile Water	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16007488	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019079035			Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoaesthesia; Subacute Combined Cord Degeneration; Taste Disorder	Zithromac			S	Oral	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16113352	NON-EXPEDITED			PR-PFIZER INC-2019123061		51 YR	Female	PRI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Hot Flush; Limb Injury; Mouth Injury;	Ibrance			S	Oral	100 Mg, Cyclic (1 Capsule,		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Platelet Count Decreased; White Blood Cell Count Decreased	Ibrance	S	Oral	Daily 21 Day On, 7 Days Off)	Pfizer
	Zithromax	S		100 Mg, Cyclic (21 Days On And 7 Days Off)	Pfizer
				Unk	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16269807	NON-EXPEDITED			US-PFIZER INC- 2019187523		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Promethazine Hcl			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16342666	EXPEDITED (15-DAY)		OT	BE-TEVA-2019-BE- 1053651		21 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Hepatotoxicity; Nausea; Vomiting	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported	
	Tigecycline			S				Not Reported	
	Imipenem			S	Intravenous (not otherwise specified)			Not Reported	
	Imipenem			S				Not Reported	
	Clofazimine			S	Oral			Not Reported	
	Clofazimine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16342901	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2013180282		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Basal Cell Carcinoma; Malignant Melanoma In Situ	Novatrex	S	Oral	10 Mg, Weekly	Pfizer
	Remicade	S	Intravenous (not otherwise specified)	4 Mg/Kg, Every 4 Weeks	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16343537	EXPEDITED (15-DAY)		HO	FR-BAUSCH-BL-2019-014662		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apraxia; Catatonia;	Venlafaxine			S	Oral			Not Reported	
Delirium; Hallucination,	Wellvone			S	Oral			Not Reported	
Auditory; Hallucination,	Cortancyl			S	Oral	Decreasing		Not Reported	
Visual; Persecutory	Cortancyl			S	Oral	Dose Reduced		Not Reported	
Delusion; Psychomotor	Novatrex			S	Oral			Not Reported	
Skills Impaired									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16343699	NON-EXPEDITED			US-PFIZER INC-2019214137		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Influenza	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-May-2019	16344616	EXPEDITED (15-DAY)		OT	PHHY2019HR111218		76 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Infectious	Azithromycin			S	Unknown			Novartis	
Pleural Effusion	Azithromycin			S				Novartis	
	Piperacillin+Tazobactam			S	Parenteral			Not Reported	
	Piperacillin+Tazobactam			S				Not Reported	
	Amoxicillin			C	Unknown			Not Reported	
	Nebivolol			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16083792	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK048162		60 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parainfluenzae Virus Infection; Pneumonia	Mepolizumab			S	Subcutaneous	100 Mg, Z (Monthly)		Glaxosmithkline	
	Mepolizumab			S	Subcutaneous	100 Mg, Z (Monthly)		Glaxosmithkline	
	Asa			S		Unk		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Symbicort			S				Not Reported	
	Spiriva			S				Not Reported	
	Combivent			S				Not Reported	
	Daxas			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16251919	NON-EXPEDITED			US-PFIZER INC-2019180472		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
	Enbrel			C		50 Mg, Weekly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346169	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027582			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo	
	Lamivudine			S	Transplacental	150 Milligram		Aurobindo	
	Zidovudine			S	Transplacental	300 Milligram		Aurobindo	
	Acyclovir			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactrim	S	Transplacental	Unk	Not Reported
Intelence	S	Transplacental	200 Milligram, Daily	Not Reported
Prezista	S	Transplacental	600 Milligram	Not Reported
Raltegravir Potassium	S	Transplacental	400 Milligram	Not Reported
Ritonavir	S	Transplacental	100 Milligram	Not Reported
Viread	S	Transdermal	300 Milligram	Not Reported
Abacavir	C	Transplacental	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346202	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR- APL-2019-027614			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Paraesthesia; Stress; Tinnitus	Azithromycin			S		200 Milligram, Daily		Aurobindo
	Azithromycin Oral Suspension			S	Unknown	90 Milligram, Daily		Aurobindo
	Azithromycin Oral Suspension			S	Unknown	180 Milligram, Daily		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346208	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027681			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo
	Lamivudine			S	Transplacental	150 Milligram		Aurobindo
	Zidovudine			S	Transplacental	300 Milligram		Aurobindo
	Acyclovir			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Milligram, Daily		Not Reported
	Prezista			S	Transplacental	600 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Raltegravir Potassium	S	Transplacental	400 Milligram	Not Reported
Ritonavir	S	Transplacental	100 Milligram	Not Reported
Viread	S	Transdermal	300 Milligram	Not Reported
Abacavir	C	Transplacental	300 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346212	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027875			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Aspirin			C	Oral	81 Milligram, Once A Day		Not Reported
	Folic Acid			C	Oral	1 Milligram, Once A Day		Not Reported
	Hydrochlorothiazide;Triamterene			C	Oral	25 Milligram, Once A Day		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	315 Milligram		Not Reported
	Methotrexate			C	Oral	20 Milligram		Not Reported
	Pantoprazole Sodium Anhydrous			C	Oral	40 Milligram		Not Reported
	Vitamin B12			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346213	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027630			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder;	Azithromycin			S	Oral	500.0 Dosage Form, Total		Aurobindo
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Dose Omission; Pruritus	Cefazolin	S	Unknown	Unk	Not Reported
	Docusate	C	Unknown	Unk	Not Reported
	Eprex	C	Unknown	Unk	Not Reported
	Ergocalciferol	C	Unknown	Unk	Not Reported
	Fluticasone	C	Unknown	Unk	Not Reported
	Megestrol	C	Unknown	Unk	Not Reported
	Nepafenac	C	Unknown	Unk	Not Reported
	One Alpha	C	Unknown	Unk	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Salbutamol	C	Unknown	Unk	Not Reported
	Sevelamer	C	Unknown	Unk	Not Reported
	Sodium Polystyrene Sulfonate	C	Unknown	Unk	Not Reported
	Amlodipine	C	Unknown	Unk	Not Reported
	Bisoprolol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346217	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027609			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo
	Lamivudine			S	Transplacental	150.0 Milligram		Aurobindo
	Zidovudine			S	Transplacental	300.0 Milligram		Aurobindo
	Abacavir			S	Transplacental	300.0 Milligram, Daily		Not Reported
	Acyclovir			S	Transplacental	Unk		Not Reported
	Bactrim			S	Unknown	Unk		Not Reported
	Intelence			S	Transplacental	200.0 Milligram, Daily		Not Reported
	Prezista			S	Transplacental	600.0 Milligram, Daily		Not Reported
	Raltegravir Potassium			S	Transplacental	400.0 Milligram		Not Reported
	Ritonavir			S	Transplacental	100.0 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Viread	S	Transdermal	300.0 Milligram, Daily	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346222	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027626			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Azithromycin			S	Unknown	Unk		Aurobindo
	Azathioprine			S	Unknown	Unk		Not Reported
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Naproxen			S	Unknown	Unk		Not Reported
	Plaquenil			S	Unknown	Unk		Not Reported
	Sulfasalazine			S	Unknown	Unk		Not Reported
	Xeljanz			S	Unknown	5.0 Milligram, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346234	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-027878			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Chest Discomfort; Cough; Dyspnoea; Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Spiriva			S		2 Dosage Form, Once A Day		Not Reported
	Budesonide;Formoterol Fumarate			S		2 Dosage Form, 3 Times A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zenhale			S		Unknown	Unk	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346559	NON-EXPEDITED			US-ZYDUS-034025		10 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Blister; Pruritus	Azithromycin			S	Oral			Zydus Pharm	
	Cetirizine			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16346814	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027619			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Daily		Aurobindo	
	Levofloxacin			S	Unknown	Unk		Aurobindo	
	Arava			S	Unknown	Unk		Not Reported	
	Benadryl			S	Unknown	Unk		Not Reported	
	Celebrex			S	Oral	Unk		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	
	Demerol			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Imuran			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Procytox			S	Unknown	Unk		Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported	
	Xeljanz			S	Oral	5 Milligram, Two Times A		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xeljanz	S	Oral	Day	Not Reported
	Xeljanz	S	Oral	5 Milligram, Two Times A Day	Not Reported
	Ezetrol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16347188	EXPEDITED (15-DAY)		LT, OT	US-PFIZER INC-2018130391		6 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Status Asthmaticus	Azithromycin			S		Unk		Pfizer
	Azithromycin			S		200 Mg, Unk (3 Times/Wk)		Pfizer
	Theophylline			S		Unk		Pfizer
	Theophylline			S		450 Mg, Daily		Pfizer
	Fluticasone-Salmeterol Disk			S		Unk		Not Reported
	Montelukast			S		Unk		Not Reported
	Montelukast			S		10 Mg, Daily		Not Reported
	Prednisolone			S		Unk		Not Reported
	Prednisolone			S		9 Mg, Unk (9 Mg Qod)		Not Reported
	Omeprazole			S		Unk		Not Reported
	Ivig			S	Intravenous (not otherwise specified)	Unk (1 G/Kg Q4wk)		Not Reported
	Ivig			S	Intravenous (not otherwise specified)	Unk (1 G/Kg Q2wk)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16349731	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK090063			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Bronchiectasis; Cardiac Murmur; Chronic Obstructive Pulmonary Disease; Chronic Obstructive Pulmonary Disease; Gastroesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps; Oedema Peripheral; Rhinitis Allergic; Sarcoidosis; Total Lung Capacity Increased; Wheezing	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg, Z (Monthly)	Glaxosmithkline
	Ventolin	S		400 Ug, Unk	Glaxosmithkline
	Advair	S		Unk	Glaxosmithkline
	Avamys	S		Unk	Glaxosmithkline
	Breo Ellipta	S		Unk	Glaxosmithkline
	Incruse Ellipta	S		Unk	Glaxosmithkline
	Anoro	S		Unk	Glaxosmithkline
	Avelox	S		Unk	Glaxosmithkline
	Azithromycine	S		Unk	Glaxosmithkline
	Cipro	S		Unk	Glaxosmithkline
	Atrovent	S		Unk	Not Reported
	Combivent	S		Unk	Not Reported
	Spiriva Respimat	S		18 Ug, Unk	Not Reported
	Seebri	S		Unk	Not Reported
	Tudorza	S		Unk	Not Reported
	Symbicort	S		Unk	Not Reported
	Zenhale	S		Unk	Not Reported
	Ultibro	S		Unk	Not Reported
	Inspirolo	S		Unk	Not Reported
	Duaklir	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Singulair	S		Unk	Glaxosmithkline
	Xolair	S			Not Reported
	Nasonex	S		Unk	Not Reported
	Omnaris	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-May-2019	16349791	EXPEDITED (15-DAY)		OT	PHEH2019US021595			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematochezia; Oropharyngeal Pain	Azithromycin			S	Unknown	250 Mg, Bid		Novartis	
	Amoxicillin			C	Unknown	500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	12765987	EXPEDITED (15-DAY)		HO, OT	FR- GLAXOSMITHKLINE- FR2016GSK136695		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apraxia; Catatonia; Delirium; Hallucination, Auditory; Hallucination, Visual; Persecutory Delusion; Psychomotor Retardation	Wellvone			S	Oral	Unk		Glaxosmithkline	
	Novatrex			S	Oral	2.5 Mg, Z		Glaxosmithkline	
	Cortancyl			S	Oral	Unk		Not Reported	
	Venlafaxine			S	Oral	75 Mg, 1d		Glaxosmithkline	
	Speciafoldine			C		Unk		Glaxosmithkline	
	Innovair Nexthaler			C		2 Puff(S), Bid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16120104	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT067313		64 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inflammation; Ischaemia; Pleural Effusion; Pyrexia; Spinal Cord Compression; Spinal Cord Injury	Ceftriaxone			S	Unknown			Novartis	
	Ceftriaxone			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16152733	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC- 2019143379		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Transitional Cell Carcinoma	Pantoprazole			S	Unknown	Unk		Pfizer	
	Fluconazole			S	Unknown	Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lonolox	S	Unknown	Unk	Pfizer
Ciprofloxacin	S	Unknown	Unk	Not Reported
Codeintropfen Ct	S	Unknown	Unk	Not Reported
Lercanidipin Omniapharm	S	Unknown	Unk	Not Reported
Moronal	S	Unknown	Unk	Not Reported
Ibu 1a Pharma	S	Unknown	Unk	Not Reported
Ciprofloxacin Al	S	Unknown	Unk	Not Reported
Valsartan Comp	S	Unknown	Unk	Not Reported
Azithromycin 1a Pharma	S	Unknown	Unk	Not Reported
[Azithromycin]				
Roxithromycin	S	Unknown	Unk	Not Reported
Ibuflam [Ibuprofen]	S	Unknown	Unk	Not Reported
Linola H Fett N	S	Unknown	Unk	Not Reported
Decortin H	S	Unknown	Unk	Not Reported
L-Thyrox Hexal	S	Unknown	Unk	Not Reported
Doxagamma	S	Unknown	Unk	Not Reported
Ampicillin Ratiopharm [Ampicillin Sodium]	S	Unknown	Unk	Not Reported
Valsartan Ratiopharm Comp	S	Unknown	Unk	Not Reported
Spironolacton Aristo	S	Unknown	Unk	Not Reported
Eferox	S	Unknown	Unk	Not Reported
Ciprofloxacin Aristo	S	Unknown	Unk	Not Reported
Euthyrox	S	Unknown	Unk	Not Reported
Ampho Moronal	S	Unknown	Unk	Not Reported
Alfason Crelo	S	Unknown	Unk	Not Reported
Mometahexal	S	Nasal	Unk	Not Reported
Hct Hexal	S	Unknown	Unk	Not Reported
Cotrim Forte	S	Unknown	Unk	Not Reported
Cotrimoxazol Al	S	Unknown	Unk	Not Reported
Clindamycin Al	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valsacor Comp	S	Unknown	Unk	Not Reported
Novaminsulfon	S	Unknown	Unk	Not Reported
Hygroton	S	Unknown	Unk	Not Reported
Locacorten Vioform	S	Unknown	Unk	Not Reported
Clindasol [Clindamycin Hydrochloride]	S	Unknown	Unk	Not Reported
Cefpo	S	Unknown	Unk	Not Reported
Valsartan Hexal Comp	S	Unknown	Unk	Not Reported
Clinda-Saar [Clindamycin Hydrochloride]	S	Unknown	Unk	Not Reported
Valsartan 1a Pharma Plus	S	Unknown	Unk	Not Reported
Doxazosin 1 A Pharma	S	Unknown	Unk	Not Reported
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Not Reported
Nebivolol	S	Unknown	Unk	Not Reported
Monuril	S	Unknown	Unk	Not Reported
Doxycyclin 1a Pharma	S	Unknown	Unk	Not Reported
Valsartan Hexal	S	Unknown	Unk	Not Reported
Dolgit	S	Unknown	Unk	Not Reported
Rasilez	S	Unknown	Unk	Not Reported
Clindahexal [Clindamycin Hydrochloride]	S	Unknown	Unk	Not Reported
Cefpodoxim Hexal	S	Unknown	Unk	Not Reported
Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16352356	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019221143		4 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use Issue; Rash; Tachypnoea	Zithromax			S	Intravenous drip	0.2 G, 1x/Day		Pfizer
	Sulperazon			C	Intravenous drip	1.5 G, 1x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16352357	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019221141		8 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use Issue; Pruritus; Rash; Tachypnoea	Zithromax			S	Intravenous drip	0.29 G, 1x/Day		Pfizer	
	Rocephin			C	Intravenous drip	1.5 G, 1x/Day		Not Reported	
	Solu-Medrol			C	Intravenous drip	40 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16354844	EXPEDITED (15-DAY)		OT	PHHY2019FR114980		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalopathy	Sandimmun			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zarzio			S	Intravenous (not otherwise specified)	Unk		Novartis	
	Vancomycin Sandoz			S	Intravenous (not otherwise specified)	2 G, Q24h		Not Reported	
	Alprazolam			S	Oral	2 Df, Qd		Not Reported	
	Difclir			S	Oral	2 Df, Qd		Not Reported	
	Smecta			S	Oral	Unk		Not Reported	
	Cellcept			S	Oral	Unk		Not Reported	
	Vfend			S	Oral	2 Df, Qd		Not Reported	
	Ondansetron Accord			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Azyter			S	Ophthalmic	Unk		Not Reported	
	Magne B6			S	Oral	Unk		Not Reported	
	Tranxene			S	Oral	2 Df, Qd		Not Reported	
	Pantoprazole Arrow			S	Intravenous (not otherwise specified)	40 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydroxyzine	S	Oral	1 Df, Qd	Not Reported
Celluvisc	S	Ophthalmic	Unk	Not Reported
Valaciclovir Arrow	S	Oral	1 Df, Qd	Not Reported
Zerbaxa	S	Intravenous (not otherwise specified)	Unk	Not Reported
Sulfarlem	S	Oral	Unk	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Unk	Not Reported
Furosemide Renaudin	S	Intravenous (not otherwise specified)	20 Mg, Q12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-May-2019	16376928	DIRECT		DS, LT			36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anger; Feeling Abnormal; Homicidal Ideation; Irritability; Product Formulation Issue	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Pfizer	
	Cbd Oil		Y	S	Sublingual	Quantity:1 Drop(S);		Herbal Products Manufacturer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	14705415	EXPEDITED (15-DAY)		HO, LT	US-009507513- 1803USA011878		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Singulair			S	Oral	Unk		Merck	
	Singulair			S	Oral	10 Milligram, Qd		Merck	
	Fluticasone Propionate (+) Salmeterol Xinafoate			S	Respiratory (inhalation)	Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Azithromycin			S		200 Milligram, 3 Times/Wk		Not Reported	
	Prednisolone			S		Unk, Qd		Not Reported	
	Prednisolone			S		9 Milligram, Qod		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Theophylline	S		Unk	Not Reported
	Theophylline	S		450 Milligram, Qd	Not Reported
	Globulin, Immune	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Globulin, Immune	S		1 Gram Per Kilogram, Q2wk	Not Reported
	Omeprazole	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	15778704	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-18S-163-2607360-00		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Colon Operation; Diverticulitis; Gastrointestinal Infection; Glaucoma; Vomiting	Creon			S	Oral	Two Capsules Orally Three Times Daily.		Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Topamax			C	Unknown			Not Reported	
	Lasix			C				Not Reported	
	Azopt			C	Unknown			Not Reported	
	Metenix			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16339103	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019212774		11 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Drug Interaction; Drug Level Increased; Pericarditis	Azithromycin			S		Unk		Pfizer	
	Chlorpheniramine;Hydrocodone			S		2 MI, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16342271	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019212302		6 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Interaction; Drug Level Increased; Respiratory Depression	Azithromycin	S	Unk	Pfizer
	Chlorpheniramine;Hydrocodone	S	Unk, 2x/Day (2-2.5 MI)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16357013	EXPEDITED (15-DAY)			US-ALKEM LABORATORIES LIMITED-US-ALKEM-2018-06808		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Constipation	Benzonatate			S	Unknown	Unknown		Alkem
	Azithromycin			S	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16358714	EXPEDITED (15-DAY)		OT	PHHY2019US117854		28 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Foetal Death; Maternal Exposure During Pregnancy; Oxygen Saturation Decreased; Upper Airway Obstruction; Vomiting	Fentanyl			S	Intravenous (not otherwise specified)	100-300 Ug, Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Novartis
	Doxycycline			S	Unknown	Unk		Not Reported
	Sodium Citrate/Citric Acid			S	Oral	15 MI, Unk		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	0.5-1 Mg/Kg, Unk		Not Reported
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	1-3 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16358722	EXPEDITED (15-DAY)		HO	PHHY2019US117858		40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anaesthetic Complication Pulmonary; Cough; Hypoxia; Maternal	Fentanyl			S	Intravenous (not otherwise specified)	100-300 Ug, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During	Azithromycin	S	Unknown		Novartis
Pregnancy; Oxygen	Doxycycline	S	Unknown		Not Reported
Saturation Decreased;	Sodium Citrate/Citric Acid	S	Oral	15 MI, Unk	Not Reported
Upper Airway Obstruction;	Propofol	S	Intravenous (not otherwise specified)	0.5-1 Mg/Kg, Unk	Not Reported
Wheezing	Midazolam Hydrochloride	S	Intravenous (not otherwise specified)	1-3 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-May-2019	16363197	DIRECT					36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Chest Discomfort; Heart Rate Decreased; Heart Rate Increased; Rash	Azithromycin 250mg Tablets, Usp			S	Oral	Quantity:1 Tablet(S);		Aurobindo	
	Vyvanse			C				Not Reported	
	Zanaflex			C				Not Reported	
	Gabapentin			C				Not Reported	
	Lexapro			C				Not Reported	
	Marinol			C				Not Reported	
	Ibuprofen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	14518584	NON-EXPEDITED			US-PFIZER INC-2018061279			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex [Cefalexin]			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Ultram [Tramadol Hydrochloride]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	14899767	NON-EXPEDITED		HO	US-STRIDES ARCOLAB LIMITED-2018SP000630		28 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Strides
	Vancomycin			S	Oral	Unk		Strides
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	14911729	NON-EXPEDITED		HO, LT, OT	US-STRIDES ARCOLAB LIMITED-2017SP012481		66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Strides
	Decadron /00016001/			S	Oral	4 Mg, Bid		Not Reported
	Bactrim			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Furosemide			S	Unknown	Unk		Not Reported
	Levetiracetam			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	15099628	NON-EXPEDITED			US-AMGEN-USASP2018088689		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance; Treatment Failure	Enbrel			S	Unknown	Unk		Amgen
	Lyrica			S	Unknown	225 Mg, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Medrol Dosepak	S	Unknown		Not Reported
Zithromax	S	Unknown		Not Reported
Effexor	S	Unknown		Not Reported
Neurontin	S	Oral	800 Mg, 1 To Three Times Daily	Not Reported
Skelaxin	S	Oral	800 Mg, 1 To Twice Daily	Not Reported
Percocet	C	Oral	5-325 Mg Prn	Not Reported
Tramadol Hcl	C	Oral	50 Mg, As Necessary	Not Reported
Imitrex	C	Oral	25 Mg, Bid As Needed	Not Reported
Zyrtec Allergy	C	Oral	10 Mg, Qd	Not Reported
Nabumetone	C	Oral	750 Mg, Bid	Not Reported
Zanaflex	C	Oral	4 Mg, 1 To Three Times Daily	Not Reported
Zonisamide	C	Oral	50 Mg, Bid	Not Reported
Aspir 81	C	Oral	81 Mg, Qd	Not Reported
Verapamil Hcl	C	Oral	240 Mg, Qd	Not Reported
Zofran	C	Oral	4 Mg, As Necessary 1 To Three Time Daily	Not Reported
Cosentyx	C	Subcutaneous	150 Mg, Qmo	Not Reported
Methotrexate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16168047	NON-EXPEDITED			US-PFIZER INC-2019145221		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Visual Impairment	Azithromycin			S	Oral	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16361171	EXPEDITED (15-DAY)		HO	PHHY2019US117860		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaesthetic Complication Pulmonary; Cough; Hypoxia; Maternal Exposure During Pregnancy; Oxygen Saturation Decreased; Vomiting	Fentanyl	S	Intravenous (not otherwise specified)	100-300 Ug, Unk	Not Reported
	Azithromycin	S	Unknown		Novartis
	Doxycycline	S	Unknown	Unk	Not Reported
	Propofol	S	Intravenous (not otherwise specified)	0.5-1 Mg/Kg, Unk	Not Reported
	Midazolam Hydrochloride	S	Intravenous (not otherwise specified)	1-3 Mg, Unk	Not Reported
	Cannabis	S	Unknown		Not Reported
	Sodium Citrate/Citric Acid	S	Oral	15 MI, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16361609	NON-EXPEDITED			US-PFIZER INC- 2019220774		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Cipro [Ciprofloxacin]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16361984	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019217242			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16362368	NON-EXPEDITED			US-PFIZER INC- 2019224079		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Arthrotec			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactrim	S	Unk	Not Reported
Prevacid	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16362922	EXPEDITED (15-DAY)	HO		PHHY2019US117852		22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Maternal Exposure During Pregnancy; Upper Airway Obstruction	Fentanyl			S	Intravenous (not otherwise specified)	100-300 Ug, Unk		Not Reported	
	Azithromycin			S	Unknown			Novartis	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Sodium Citrate/Citric Acid			S	Oral	15 ML, Unk		Not Reported	
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	1-3 Mg, Unk		Not Reported	
	Propofol			S	Intravenous (not otherwise specified)	0.5-1 Mg/Kg, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16362923	EXPEDITED (15-DAY)	OT		PHHY2019US117857		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Hypoxia; Maternal Exposure During Pregnancy; Oxygen Saturation Decreased; Upper Airway Obstruction	Fentanyl			S	Intravenous (not otherwise specified)	100-300 Ug, Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Sodium Citrate/Citric Acid			S	Oral	15 ML, Unk		Not Reported	
	Propofol			S	Intravenous (not otherwise specified)	0.5-1 Mg/Kg, Unk		Not Reported	
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	1-3 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16362933	EXPEDITED (15-DAY)		HO	PHHY2019US117856		29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Oxygen Saturation Decreased; Upper Airway Obstruction	Fentanyl			S	Intravenous (not otherwise specified)	100-300 Ug, Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	
	Doxycycline			S	Unknown	Unk		Not Reported	
	Sodium Citrate/Citric Acid			S	Oral	15 MI, Unk		Not Reported	
	Propofol			S	Intravenous (not otherwise specified)	0.5-1 Mg/Kg, Unk		Not Reported	
	Midazolam Hydrochloride			S	Intravenous (not otherwise specified)	1-3 Mg, Unk		Not Reported	
	Albuterol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-May-2019	16363359	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1048743		31 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Cefpodoxime			S	Oral	200 Milligram, Qd		Not Reported	
	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported	
	Naproxene /00256201/			S	Oral	Unk		Mylan	
	Mabthera			S	Intravenous drip	1000 Milligram,9 Month		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	6458131	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2007089617		45 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypocalcaemia	Zithromax (Adult Oral)			S	Oral	500 Mg, 1x/Day		Pfizer	
	Erythromycin			S	Oral	250 Mg, 4x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

One-Alpha	S		1 Ug, 3x/Day	Not Reported
Calcium W/Magnesium	C	Oral	Unk, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	12772844	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2016434875		68 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apraxia; Catatonia; Delirium; Hallucination, Auditory; Hallucination, Visual; Loss Of Personal Independence In Daily Activities; Persecutory Delusion; Postural Tremor; Psychomotor Skills Impaired	Novatrex			S	Oral	2.5 Mg, Weekly		Pfizer
	Novatrex			S	Oral	2.5 Mg, 3 Times A Week		Pfizer
	Novatrex			S	Oral	2.5 Mg, 4 Times A Week		Pfizer
	Venlafaxine Hcl			S	Oral	75 Mg, 1x/Day		Pfizer
	Cortancyl			S	Oral	35 Mg, 1x/Day In The Morning		Not Reported
	Wellvone			S	Oral	Unk		Not Reported
	Innovair			C		2 Puffs, 2x/Day In The Morning And In The Evening		Not Reported
	Speciafoldine			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	13459480	NON-EXPEDITED			US-PFIZER INC-2017170245			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Dilantin			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Celexa			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported
	Trileptal			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zomig		S		Unk		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	14479681	EXPEDITED (15-DAY)		HO, OT	DE-MACLEODS PHARMACEUTICALS US LTD- MAC2018009082			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Off Label Use; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Levofloxacin			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Macleods	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day Unk, 10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times Week, 6 Weeks		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg, Bid, 0.5 Day, 9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Not Reported	
	Voriconazole			S	Other	8 Mg/Kg, Bid		Not Reported	
	Sodium Chloride			S	Nasal	0.9 %, Unk		Not Reported	
	Amphotericin B			S	Unknown	4 Mg/Kg, Qd, 8 Mg/Kg/Days As A 3-H Infusion For28 Days Followed By 5 Mg/Kg/Day As A 2-H		Not Reported	
	Amphotericin B			S	Unknown	5 Mg/Kg Injection, 8 Mg/Kg/Days As A 3-H Infusion For28 Days		Not Reported	
	Amphotericin B			S	Unknown	8 Milligram/Kilogram, Qd, Injection, 8 Mg/Kg/Days As A 3-H Infusion For28 Days		Not Reported	
	Amphotericin B			S	Unknown	2.5 Milligram/Kilogram, Qd, Injection, 8 Mg/Kg/Days As A 3-H Infusion For28 Days		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexamethasone	S	Unknown	Unk, 10 Mg/M2 For 21 Days Then Tapering	Not Reported
Pegaspargase	S	Unknown	Unk	Not Reported
Vincristine	C	Unknown	Unk	Not Reported
Methotrexate	C	Intrathecal	Unk	Not Reported
Daunorubicin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	15368545	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2018- BI-04		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal;	Spiriva			S	Unknown			Boehringer Ingelheim
Blood Pressure Increased;	Zenhale			S	Unknown	Aerosol, Metered Dose		Not Reported
Body Temperature Increased; Cataract;	Zenhale			S	Unknown			Not Reported
Cough; Drug Dependence;	Salbutamol Sulfate			S	Unknown			Not Reported
Heart Rate Increased;	Advair			S	Unknown			Not Reported
Lung Diffusion Test Decreased; Nasal	Azithromycin			S	Oral			Not Reported
Disorder; Nasopharyngitis;	Prednisone			S	Oral			Not Reported
Obstructive Airways Disorder; Pyrexia;	Cetirizine			C	Unknown			Not Reported
Restrictive Pulmonary Disease; Therapeutic Response Decreased;	Pariet			C	Unknown	Form: Tablet (Enteric-Coated)		Not Reported
Type 2 Diabetes Mellitus	Rosuvastatin Calcium			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	15634382	NON-EXPEDITED			US-PFIZER INC- 2018476969			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Farxiga			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythromycin Ethylsuccinate			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	15698882	NON-EXPEDITED			US-PFIZER INC-2018502684		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16276902	NON-EXPEDITED			US-PFIZER INC-2019188459		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Clindagel			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-May-2019	16371335	DIRECT		LT			45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Chest Pain; Heart Rate Increased	Azithromycin Tablets, Usp	Y		S	Oral	Quantity:6 Tablet(S);		Aurobindo	
	Spiriva, Daliresp, Albuterol Rescue Inhaler, Gapapentin, Celexa, Hydroxyzine, Clonazepam, Omeprazole, Spiriva			C				Not Reported	
	Daliresp			C				Not Reported	
	Albuterol Rescue Inhaler			C				Not Reported	
	Gapapentine Arrow			C				Not Reported	
	Celexa			C				Not Reported	
	Hydroxyzine			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clonazepam	C	Not Reported
Omeprazole	C	Not Reported
Oxycodone	C	Not Reported
Aspirin	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	10031632	NON-EXPEDITED			US-PFIZER INC-2014079645			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Cipro			S		Unk		Not Reported
	Macrochantin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	14483823	EXPEDITED (15-DAY)		HO, OT	DE-AXELLIA-001341		1 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspergillus Infection; Hypokalaemia; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily 8mg/Kg Every 0.5 Days		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported
	Levofloxacin/Levofloxacin Mesylate			S	Intravenous (not otherwise specified)	20 Mg/Kg In 2 Single Doses For 21 Days		Not Reported
	Prednisone			S				Not Reported
	Sodium Chloride			S	Nasal	0.9% Nose Spray		Not Reported
	Amphotericin B			S		8 Mg/Kg/Days As A 3-H Infusion For28 Days Followed By 5 Mg/Kg/Day As A 2-H Infusion		Not Reported
	Dexamethasone			S		10 Mg/M2 For 21 Days Then Tapering		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pegaspargase	S			Not Reported
Methotrexate	C	Intrathecal		Not Reported
Daunorubicin	C		Unk	Not Reported
Vincristine	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	15706742	EXPEDITED (15-DAY)		HO	FR-LUNDBECK-DKLU2057891		2 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crohn'S Disease	Sabril (For Oral Solution)			S	Oral			Lundbeck	
	Epitomax			S	Oral			Not Reported	
	Circadin			S	Oral			Not Reported	
	Rivotril			S	Oral			Not Reported	
	Lioresal			S	Oral			Not Reported	
	Laroxyl			S	Oral			Not Reported	
	Oramorph			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Inexium			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16284033	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT103152		73 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cachexia; Chills;	Azithromycin			S	Unknown			Novartis	
Condition Aggravated;	Cefixime			S	Unknown			Not Reported	
Disseminated Bacillus									
Calmette-Guerin Infection;									
Hepatitis Cholestatic;									
Infection; Inflammation;									
Kidney Infection;									
Medication Error;									
Normochromic Anaemia;									
Normocytic Anaemia;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pyrexia; Respiratory Rate Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16369701	EXPEDITED (15-DAY)		HO, LT, OT	DE-BAXTER-2018BAX001552		1 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspergillus Infection; Hypokalaemia; Off Label Use; Pancreatitis Acute; Pneumonia Legionella; Product Contamination Microbial	Levofloxacin 5 Mg/ML Solution For Infusion			S	Intravenous (not otherwise specified)	20 Mg/Kg, In 2 Single Doses For 21 Days		Not Reported	
	Sodium Chloride			S	Nasal	0.9% Nose Spray		Not Reported	
	Dexamethasone			S	Unknown	10 Mg/M2 For 21 Days Then Tapering		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg Per Day For 5 Days Then 10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	10 Mg/Kg/Day Two Times A Week For 6 Weeks		Not Reported	
	Amphotericin B, Liposome			S	Unknown	8 Mg/Kg, Qd, 28 Days		Not Reported	
	Amphotericin B, Liposome			S	Unknown	5 Mg/Kg, Qd		Not Reported	
	Amphotericin B, Liposome			S	Unknown	2.5 Mg/Kg, Qd		Not Reported	
	Amphotericin B, Liposome			S	Unknown	4 Mg/Kg/Day		Not Reported	
	Voriconazole			S	Other	8 Mg/Kg, Unk		Not Reported	
	Voriconazole			S	Intravenous (not otherwise specified)	9 Mg/Kg On Day One Followed By 8 Mg/Kg Daily		Not Reported	
	Pegylated Asparaginase			S	Unknown			Not Reported	
	Daunorubicin			C	Unknown			Not Reported	
	Methotrexate			C	Intrathecal			Not Reported	
	Vincristine			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16370490	EXPEDITED (15-DAY)		HO, OT	US-AXELLIA-002487		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Renal Failure	Colistin			S	Intravenous (not otherwise specified)	For 4 Weeks Also Received Inhaled Colistin		Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Xellia Pharmaceuticals	
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	For 4 Weeks		Not Reported	
	Piperacillin/Tazobactam			S	Intravenous (not otherwise specified)	For The First 2 Weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16370715	NON-EXPEDITED			PHEH2019US021910			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16370793	EXPEDITED (15-DAY)		DE	PL-AUROBINDO-AUR- APL-2019-029740			Unknown	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo	
	Montelukast			S	Oral	Unk		Aurobindo	
	Amphotericinum B			C	Unknown	Unk		Not Reported	
	Azacididine			C	Unknown	Unk		Not Reported	
	Busulfan			C	Unknown	Unk		Not Reported	
	Cladribine			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Cyclophosphamide	C	Unknown	Unk	Not Reported
	Cytarabine	C	Unknown	Unk	Not Reported
	Daunorubicin	C	Unknown	Unk	Not Reported
	Fluconazole	C	Unknown	Unk	Not Reported
	Fludarabine	C	Unknown	Unk	Not Reported
	Methylprednisolone	C	Unknown	Unk	Not Reported
	Mitoxantrone	C	Unknown	Unk	Not Reported
	Posaconazole	C	Unknown	Unk	Not Reported
	Tacrolimus	C	Unknown	Unk	Not Reported
	Treosulfan	C	Unknown	Unk	Not Reported
	Voriconazole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16371451	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC-2019226028		35 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Eructation; Faeces Discoloured; Gastrooesophageal Reflux Disease; Henoch- Schonlein Purpura; Melaena; Off Label Use; Petechiae; Petechiae; Product Use In Unapproved Indication; Product Use Issue; Upper Gastrointestinal Haemorrhage	Zithromax Compound Paracetamol And Amantadine Hydrochloride [Amantadine Hydrochl			S	Oral	0.5 G, 1x/Day		Pfizer
				S	Oral	1 Df, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16371769	NON-EXPEDITED			US-PFIZER INC-2019232438		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-May-2019	16371866	NON-EXPEDITED			US-VERTEX PHARMACEUTICALS- 2019-004898			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Chest Discomfort; Dyspnoea	Orkambi			S	Oral	2 Dosage Form, Bid		Vertex	
	Aztreonam Lysine			S	Respiratory (inhalation)	1 Dosage Form, Tid, 28 Days On And 28 Days Off		Not Reported	
	Pulmozyme			S	Respiratory (inhalation)	2.5 Mg, Qd		Not Reported	
	Ventolin /00139501/			S	Respiratory (inhalation)	2 Dosage Form, Qid		Not Reported	
	Ventolin /00139501/			S				Not Reported	
	Omeprazole			S	Oral	1 Dosage Form, Qd		Not Reported	
	Loratadine			S	Oral	1 Dosage Form, Qd		Not Reported	
	Tobramycin			S	Respiratory (inhalation)	5 Milliliter, Bid, 28 Days On And 28 Days Off		Not Reported	
	Creon			S	Oral	5 Caps With Meals And 2 Caps With Snacks		Not Reported	
	Azithromycin			S	Oral	1 Dosage Form, Every M, W And F		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	13726489	NON-EXPEDITED			US-PFIZER INC- 2017290724		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S				Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Sulfamethoxazole/Trimethoprim			S		160 Mg, Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
	Opana			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Tizanidine		S			Unk			Not Reported
	Linzezz		S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	15283467	NON-EXPEDITED			US-PFIZER INC-2018329186		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	15678790	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2018SF56026		2 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crohn'S Disease	Inexium			S	Oral			Astrazeneca	
	Epitomax			S	Oral			Not Reported	
	Rivotril			S	Oral			Not Reported	
	Sabril			S	Oral			Not Reported	
	Oramorph			S	Oral			Not Reported	
	Melatonin			S	Oral			Not Reported	
	Lioresal			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Laroxyl			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	15725156	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD-2018R1-193644			Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia	Amiodarone			S	Unknown	Unknown		Taro	
	Azithromycin			S	Unknown	Unknown		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fluconazole	S	Unknown	Unknown	Sun
Moxifloxacin	S	Unknown	Unknown	Not Reported
Sotalol	S	Unknown	Unknown	Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	15725158	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2018R1-193649			Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arrhythmia	Amiodarone			S	Unknown	Unknown		Taro
	Azithromycin			S	Unknown	Unknown		Sun
	Fluconazole			S	Unknown	Unknown		Sun
	Moxifloxacin			S	Unknown	Unknown		Not Reported
	Sotalol			S	Unknown	Unknown		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16317954	EXPEDITED (15-DAY)		HO, OT	US-BIOGEN- 2019BI00737846		27 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aspiration; Cardio- Respiratory Arrest; Chest Pain; Choking; Drug Hypersensitivity; Dyspnoea; Feeling Abnormal; Loss Of Consciousness; Nasopharyngitis; Productive Cough; Pulmonary Pain	Spinraza			S	Unknown			Biogen
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16376872	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019233268		83 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Recurrence; Pain; Pneumonia; Therapy Non-Responder	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16377032	NON-EXPEDITED			US-PFIZER INC-2019232474		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16377573	EXPEDITED (15-DAY)		OT	SE-MYLANLABS-2019M1049975		77 YR	Female	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anal Haemorrhage; Vaginal Haemorrhage	Azithromycin Mylan 250 Mg Filmdragerade Tabletter			S		Dag 1: 2 Tabletter, Dag 2-5: 1 Tablett Dagligen		Mylan	
	Bisostad /00802602/			C		Unk		Mylan	
	Eliquis			C		Unk		Mylan	
	Candesartan			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-May-2019	16379575	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1050822		60 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Urticaria	Azithromycin			S		500 Milligram, Qd		Not Reported	
	Levofloxacin			S	Oral	500 Milligram, Qd		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	2 Gram, Qd		Mylan	
	Clenil /00212602/			C		Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Brevia			C			Unk			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
31-May-2019	16379673	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1050694		43 YR	Male	PRT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Arthralgia; Purpura; Rash; Pruritic	Azithromycin			S	Oral	500 Milligram, Qd			Not Reported	
	Amoxicillin/Clavulanic Acid			S	Oral	2000 Milligram, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
31-May-2019	16573490	DIRECT	Y	RI			61 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Blister; Pruritus; Rash; Urticaria	Azithromycin			S					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
01-Jun-2019	15169775	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2018-032189			Unknown	PRT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Coagulopathy; Conjunctival Hyperaemia; Enanthema; Eye Discharge; General Physical Health Deterioration; Genital Ulceration; Lip Erythema; Lip Oedema; Lip Ulceration; Lung Infiltration; Mouth Swelling; Mucosal Inflammation; Nasal Mucosal Disorder; Oedema Mucosal; Oral Discomfort; Oral Disorder;	Azithromycin			S	Unknown	Unk			Aurobindo	
	Azithromycin			S					Aurobindo	
	Clarithromycin			S	Unknown	Unk			Aurobindo	
	Clarithromycin			S					Aurobindo	
	Nimesulide			S	Unknown	Unk			Not Reported	
	Nimesulide			S					Not Reported	
	Bilastine			S	Unknown	Unk			Not Reported	
	Bilastine			S					Not Reported	
	Brivudine			S	Unknown	Unk			Not Reported	
									Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oral Mucosa Erosion;
Pyrexia; Rash; Rash
Maculovesicular; Rash
Papular; Retinal Exudates;
Skin Lesion; Stevens-
Johnson Syndrome;
Stomatitis; Vulval Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jun-2019	15369128	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2018AP020143		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Mg, Qd		Apotex
	Prednisone			S	Oral	45 Mg, Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Apotex
	Theophylline			S	Oral	450 Mg, Qd		Apotex
	Atrovent			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Unknown	1 Df, Qd		Not Reported
	Ipratropium Bromide And Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Seebri Breezhaler			S	Unknown	1 Df, Qd		Not Reported
	Singulair			S	Oral	10 Mg, Qd		Not Reported
	Xolair			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Omalizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	14551970	NON-EXPEDITED			US-PFIZER INC- 2018071077		87 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Vomiting	Azithromycin			S	Oral	500 Mg, Unk (250mg 2 Tablets Once By Mouth)		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16270940	NON-EXPEDITED			US-PFIZER INC-2019187340		66 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
White Blood Cell Count Decreased	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16332705	NON-EXPEDITED			US-PFIZER INC-2019210793		67 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Reaction To Excipient	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16367521	NON-EXPEDITED			US-PFIZER INC-2019227418			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Procardia [Nifedipine]			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
03-Jun-2019	16377030	NON-EXPEDITED			US-PFIZER INC-2019227980			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Hydromorphone Hydrochloride			S		Unk		Unknown	
	Nifedipine			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Acetazolamide			S		Unk		Not Reported	
	Cefdinir			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fluticasone	S	Unk	Not Reported
Hydrocodone	S	Unk	Not Reported
Mometasone	S	Unk	Not Reported
Rifaximin	S	Unk	Not Reported
Salmeterol	S	Unk	Not Reported
Topiramate	S	Unk	Not Reported
Warfarin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16384480	NON-EXPEDITED			PHEH2019US023011			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16385276	NON-EXPEDITED			US-PFIZER INC-2019237153			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Zithromax			S		Unk; (Twice Yearly)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16385277	NON-EXPEDITED			US-PFIZER INC-2019231959		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2019	16385305	NON-EXPEDITED			US-AKRON, INC.-2067738			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16388235	EXPEDITED (15-DAY)		HO		PHHY2019GB125530	67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Confusional State; Delirium	Azithromycin			S	Oral	750 Mg, Qw (Monday, Wednesday, Friday)		Novartis	
	Avamys			C	Nasal	55 Ug, Qd (In Each Nostril)		Not Reported	
	Carbocisteine			C	Unknown	1500 Mg, Qd		Not Reported	
	Fostair			C	Respiratory (inhalation)	4 Df, Qd (200micrograms/Dose / 6micrograms/Dose)		Not Reported	
	Salbutamol			C	Respiratory (inhalation)	2 Df, Qid (1-2 Puffs, 4 Times A Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16388337	NON-EXPEDITED			US-PFIZER INC-2019237558		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16388546	EXPEDITED (15-DAY)		OT		BE-AUROBINDO-AUR-APL-2019-030573		Unknown	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Pyrexia; Toxicity To Various Agents	Moxifloxacin			S	Oral	Unk		Aurobindo	
	Moxifloxacin			S				Aurobindo	
	Moxifloxacin			S				Aurobindo	
	Moxifloxacin			S				Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Moxifloxacin	S				Aurobindo
Moxifloxacin	S				Aurobindo
Meropenem	S	Intravenous (not otherwise specified)	Unk		Aurobindo
Meropenem	S				Aurobindo
Meropenem	S				Aurobindo
Meropenem	S				Aurobindo
Meropenem	S				Aurobindo
Azithromycin	S	Oral	Unk		Aurobindo
Azithromycin	S				Aurobindo
Azithromycin	S				Aurobindo
Azithromycin	S				Aurobindo
Azithromycin	S				Aurobindo
Cefoxitin	S	Intravenous (not otherwise specified)	Unk		Not Reported
Cefoxitin	S				Not Reported
Cefoxitin	S				Not Reported
Cefoxitin	S				Not Reported
Cefoxitin	S				Not Reported
Amikacin	S	Intravenous (not otherwise specified)	Unk		Not Reported
Amikacin	S				Not Reported
Amikacin	S				Not Reported
Amikacin	S				Not Reported
Amikacin	S				Not Reported
Linezolid	S	Oral	Unk		Not Reported
Linezolid	S				Not Reported
Linezolid	S				Not Reported
Linezolid	S				Not Reported
Linezolid	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16390374	NON-EXPEDITED			US-AKRON, INC.-2067779			Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azasite Ophthalmic Solution			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16390392	NON-EXPEDITED			US-AKRON, INC.- 2067781			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Blepharitis; Dry Eye; Eye Irritation	Azasite			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16390534	NON-EXPEDITED			US-AKRON, INC.- 2067782			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abnormal Sensation In Eye; Eye Pruritus; Ocular Hyperaemia	Azasite			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16390574	NON-EXPEDITED			US-AKRON, INC.- 2067783			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Erythema; Erythema Of Eyelid; Eyelid Irritation; Rash Erythematous	Azasite			S	Ophthalmic			Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Jun-2019	16390697	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019233216			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Maternal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Pfizer	
	Amoxicillin			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Enoxaparin Sodium	S	Transplacental	30 Mg, 2x/Day			Not Reported	
		Cholecalciferol	S	Transplacental	Unk			Not Reported	
		Calcium Acetate	S	Transplacental	Unk			Not Reported	
		Betamethasone	S	Transplacental	12 Mg, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16391205	NON-EXPEDITED			US-AKRON, INC.- 2067789			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vision Blurred	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16391211	NON-EXPEDITED			US-AKRON, INC.- 2067790			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Product Administration Error	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16391213	NON-EXPEDITED			US-AKRON, INC.- 2067791			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Of Eyelid	Azasite Ophthalmic Solution			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jun-2019	16391216	NON-EXPEDITED			US-AKRON, INC.- 2067792			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication	Azasite Ophthalmic Solution			S				Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16223590	NON-EXPEDITED			US-PFIZER INC-2019164297		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fall; Nightmare; Pain	Azithromycin			S	Oral	500 Mg, Daily (Two Pills The First Day And Then Every Day You Take One More Pill)		Pfizer	
	Azithromycin			S	Oral	250 Mg, Daily (Two Pills The First Day And Then Every Day You Take One More Pill)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16315609	EXPEDITED (15-DAY)		DS, HO	US-WOCKHARDT USA, LLC-2067034		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Paralysis	Azithromycin			S	Oral			Wockhardt	
	Non-Prescription Nsaids			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16373419	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC-2019228755		69 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Liver Injury	Azithromycin			S		0.25 G, 1x/Day		Pfizer	
	Simvastatin			S	Oral	40 Mg, 1x/Day (At Night)		Not Reported	
	Simvastatin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16393130	EXPEDITED (15-DAY)		LT	US-NAPPMUNDI-GBR-2018-0054515		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Drug Ineffective	Theophylline	S	Unknown	450 Mg, Daily	Purdue
	Montelukast	S	Unknown	10 Mg, Daily	Not Reported
	Prednisolone	S	Unknown	9 Mg, Qod	Not Reported
	Azithromycin	S	Unknown	200 Mg, 3/Week	Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)	1 G/Kg Q2wk	Not Reported
	Immunoglobulin Iv	S	Intravenous (not otherwise specified)	Unk (1 G/Kg Q4wk)	Not Reported
	Budesonide W/Formoterol Fumarate	S	Unknown	2 Puff, Bid (160-4.5 Mcg)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16394993	EXPEDITED (15-DAY)		HO, LT, OT	CN-PFIZER INC-2019228749		59 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Sinus Bradycardia; Syncope; Ventricular Arrhythmia; Ventricular Fibrillation	Azithromycin			S	Intravenous drip	0.5 G, Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jun-2019	16395932	NON-EXPEDITED			US-PFIZER INC-2019241795			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	
	Buspirone			S		Unk		Not Reported	
	Fenofibrate			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	15891093	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1008035		72 YR	Unknown	PRT

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	15893038	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1008062		65 YR	Unknown	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16063660	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019GSK043586		71 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Respiratory Disorder; Upper Respiratory Tract Infection; White Blood Cell Count Decreased	Advair Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Bid		Not Reported	
	Zithromax			S				Not Reported	
	Prednisone			S				Not Reported	
	Albuterol Inhalation Powder			S	Respiratory (inhalation)	2 Puff(S), Qid		Glaxosmithkline	
	Nebulizer (Name Unknown)			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-Jun-2019	16352153	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2019-029159			Unknown	BEL
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Deafness; Hepatotoxicity; Nausea; Off Label Use; Product Use In Unapproved Indication;	Azithromycin			S	Oral	Dosage Form: Unspecified		Aurobindo	
	Azithromycin			S				Aurobindo	
	Clofazimine			S	Oral	Dosage Form: Unspecified		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting	Clofazimine	S						Not Reported
	Clofazimine	S						Not Reported
	Imipenem	S	Intravenous (not otherwise specified)	Dosage Form: Unspecified				Not Reported
	Imipenem	S						Not Reported
	Imipenem	S						Not Reported
	Bedaquiline	S	Oral	Unk				Not Reported
	Bedaquiline	S						Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)	Dosage Form: Unspecified				Not Reported
	Tigecycline	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16367597	NON-EXPEDITED			US-PFIZER INC-2019225014		5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Poor Quality Sleep; Pruritus	Azithromycin			S	Oral	5 MI, 1x/Day		Pfizer	
	Azithromycin			S	Oral	2.5 MI, 1x/Day		Pfizer	
	Motrin			C	Oral	Unk Unk, As Needed (100 Mg/5 MI Every 6 To 8 Hours By Mouth)/(5 MI Every 6 Or 7 Hours As Needed)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16397315	EXPEDITED (15-DAY)		HO	GB-AUROBINDO-AUR-APL-2019-031350			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Azithromycin			S	Oral	150 Milligram, Daily (For 3 Days)		Aurobindo	
	Co-Amoxiclav			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16398772	NON-EXPEDITED		OT	US-PFIZER INC-2019240459			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ampicillin Trihydrate			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Tramadol Hcl			S		Unk		Not Reported	
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported	
	Erythromycin Base			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
	Sodium Iodide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16398933	NON-EXPEDITED			US-PFIZER INC- 2019243136		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399195	NON-EXPEDITED			US-AKRON, INC.- 2067867			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399243	NON-EXPEDITED			US-AKRON, INC.- 2067869			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain	Azasite			S	Ophthalmic			Akorn	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399267	NON-EXPEDITED			US-AKRON, INC.- 2067870			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Pain; Ocular Hyperaemia	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399338	NON-EXPEDITED			US-AKRON, INC.- 2067875			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399352	NON-EXPEDITED			US-AKRON, INC.- 2067876			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399381	EXPEDITED (15-DAY)		LT	FR-PFIZER INC- 2019239982		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Novatrex			S	Oral	3 Df, 1x/Day		Pfizer	
Diarrhoea; Incorrect	Seresta			C		Unk		Not Reported	
Dosage Administered;	Tahor			C		Unk		Not Reported	
Mucosal Ulceration;	Metformine [Metformin]			C		Unk		Not Reported	
Pancytopenia	Apixaban			C		Unk		Not Reported	
	Chronadalate			C		Unk		Not Reported	
	Atenolol			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novonorm	C	Unk	Not Reported
Perindopril	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399943	NON-EXPEDITED			US-AKRON, INC.- 2067884			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation; Vision Blurred	Azasite			S	Ophthalmic			Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399977	NON-EXPEDITED			US-AKRON, INC.- 2067886			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azasite			S	Ophthalmic			Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16399995	NON-EXPEDITED			US-AKRON, INC.- 2067887			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lacrimation Increased	Azasite			S	Ophthalmic			Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400332	NON-EXPEDITED			US-AKRON, INC.- 2067888			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Throat; Eye Pain; Pharyngeal Swelling	Azasite			S	Ophthalmic			Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400409	NON-EXPEDITED			US-PFIZER INC- 2019241243			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Influenza Virus Vaccine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400456	NON-EXPEDITED			US-AKRON, INC.- 2067889			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400504	NON-EXPEDITED			US-AKRON, INC.- 2067890			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pruritus	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2019	16400559	NON-EXPEDITED			US-AKRON, INC.- 2067891			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apraxia; Eye Irritation; Eye Pain; Vision Blurred	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16249619	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1040280		90 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilia; Rash Maculo-Papular	Azithromycin			S	Oral	Unk		Not Reported	
	Extovyl			S	Oral	Unk		Mylan	
	Extovyl			S				Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Solupred /00016201/			S	Oral	Unk	Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16401859	EXPEDITED (15-DAY)		OT	GB-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-055537			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous;	Efavirenz			S	Unknown	Unk		Bristol Myers Squibb	
Maternal Exposure During	Abacavir + Lamivudin			S	Unknown	Unk		Not Reported	
Pregnancy	Azithromycin			S	Unknown	1 Gram, 3 Times/Wk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16403307	EXPEDITED (15-DAY)		HO	SK-TEVA-2019-SK- 1059472		59 YR	Male	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme	Sumamed			S		500 Milligram		Not Reported	
Increased; Liver Disorder	Fraxiparine			S		0.6 MI		Not Reported	
	Sorvasta			C		10 Milligram Daily;		Not Reported	
	Urapidil Stragen			C		30 Milligram, 1-0-1		Not Reported	
	Triplixam			C		1 Dosage Forms Daily;		Not Reported	
	Concor			C		5 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2019	16405011	EXPEDITED (15-DAY)		HO	GB-TEVA-2019-GB- 1058102		4 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Azithromycin Dihydrate			S	Oral	150 Milligram For Every 1 Days For 3 Days		Not Reported	
	Co-Amoxiclav			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	14706045	NON-EXPEDITED			US-PFIZER INC-2018131954			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
	Fentanyl Citrate			S		Unk		Unknown	
	Diclofenac Potassium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	15597767	EXPEDITED (15-DAY)		DE	CA-PFIZER INC-2018456440		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S				Pfizer	
	Tigecycline			S				Pfizer	
	Cilastatin/Imipenem			S				Unknown	
	Rifampin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16395371	EXPEDITED (15-DAY)		DE	IT-MYLANLABS-2019M1053379		90 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Toxic Epidermal Necrolysis	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Qd		Not Reported	
	Lercanidipine			C	Oral	5 Milligram		Mylan	
	Valsartan			C	Oral	80 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16409590	EXPEDITED (15-DAY)		OT	FR-ZYDUS-037431		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ageusia; Hypoaesthesia	Potassium	S	Oral		Not Reported
	Azithromycin	S	Oral		Zydus Pharm
	Acetazolamide	S	Oral	250 Mg, Scored Tablet	Not Reported
	Dorzolamide	S	Ophthalmic		Not Reported
	Hydrochloride/Timolol Maleate				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16411226	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1053668		63 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Face	Azithromycin			S		500 Milligram		Not Reported	
	Femoston			C		As Directed By Doctor		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16412219	EXPEDITED (15-DAY)		HO	FR-ALLERGAN-1924003US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Meningitis Aseptic	Ocufen (Flurbiprofen Sodium)			S	Intraocular	6 Gtt, Qd		Allergan	
	Azyter			S	Intraocular	2 Gtt, Qd		Not Reported	
	Dexafree /00016001/			S	Intraocular	4 Gtt, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jun-2019	16412245	EXPEDITED (15-DAY)		HO	PHHY2018CA014989		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Asthma; Blood Cholesterol Increased; Blood Immunoglobulin E Increased; Blood Urine Present; Bronchitis; Chest Discomfort; Chest Pain; Cough; Drug Ineffective; Dyspepsia; Dyspnoea;	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fatigue; Ill-Defined Disorder; Influenza; Malaise; Mite Allergy; Nasal Congestion; Nasopharyngitis; Nausea; Pneumonitis; Productive Cough; Upper Respiratory Tract Infection; Vomiting; Wheezing	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Azithromycin	S	Unknown	Unk	Novartis
	Vitamin D	C	Oral	1 Df, Qd	Not Reported
	Pantoprazole	C	Oral	1 Df, Qd	Not Reported
	Calcium	C	Oral	1 Df, Qd	Not Reported
	Ventolin	C	Respiratory (inhalation)	200 Ug, Prn	Not Reported
	Spiriva	C	Respiratory (inhalation)	1 Df, Qd	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Df, Bid	Not Reported
	Estrogel	C	Topical	2 Df, Unk	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Cortisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	15948088	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019039711		1 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus; Rash	Methylprednisolone Sodium Succinate			S	Intravenous drip	20 Mg, 1x/Day		Pfizer	
	Qi Xian			S	Intravenous drip	0.11 G, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16071313	NON-EXPEDITED			US-PFIZER INC-2019106240			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16177648	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-018944			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inflammation; Ischaemia; Pleural Effusion; Pyrexia; Spinal Cord Compression; Spinal Cord Injury	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ceftriaxone			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16312104	EXPEDITED (15-DAY)		HO	CZ-TEVA-2019-CZ-1049507		68 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatorenal Syndrome	Azithromycin			S	Unknown			Not Reported	
	Voriconazole			S	Unknown			Teva	
	Cotrimoxazole			S	Unknown			Teva	
	Moxifloxacin			S	Unknown			Teva	
	Amiodarone			S	Intravenous drip	After 36h, The Dose Of Amiodarone Was Reduced To 600 Mg/24h		Teva	
	Amiodarone			S	Intravenous drip			Teva	
	Meropenem			C	Unknown			Not Reported	
	Gliclazide			C	Unknown			Not Reported	
	Metformin			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Nitrendipine	C	Unknown		Not Reported
	Metoprolol	C	Unknown		Not Reported
	Hydrochlorothiazide	C	Unknown		Not Reported
	Valsartan	C	Unknown		Not Reported
	Atorvastatin	C	Unknown		Not Reported
	Fenofibrate	C	Unknown		Not Reported
	Acetylsalicylic Acid	C	Unknown		Not Reported
	Ciprofloxacin	C	Unknown		Not Reported
	Nitrous Oxide	C	Respiratory (inhalation)		Not Reported
	Esmolol	C	Unknown		Not Reported
	Noradrenaline	C	Unknown	Low Dose	Not Reported
	Piperacillin/Tazobactam	C	Unknown		Not Reported
	Piperacillin/Tazobactam	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16412637	EXPEDITED (15-DAY)		OT	CZ-PROVELL PHARMACEUTICALS- 2068054			Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Chronic Gastritis; Diarrhoea; Flatulence; Haemorrhoids; Helicobacter Infection; Irritable Bowel Syndrome; Menorrhagia; Stress	Euthyrox			S				Provell Pharmaceuticals	Not Reported
	Sumamed			S					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16412991	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2019-032741			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Hypoaesthesia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Diffu K			S	Oral	2 Dosage Form		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Diamox		S	Oral	3 Dosage Form, Once A Day			Not Reported	
	Cosopt		S	Ophthalmic	2 Gtt Drops, Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16414494	EXPEDITED (15-DAY)		HO	PHHY2019CZ129220		50 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Erythema; Erythema Nodosum; Inflammation; Oedema Peripheral; Rheumatoid Arthritis; Urinary Tract Infection; Viral Infection	Azithromycin			S	Unknown	Unk		Novartis	
	Klacid			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Mg, Q2w		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16415228	NON-EXPEDITED			US-PFIZER INC- 2019246685			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Pfizer	
	Demerol			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jun-2019	16416695	EXPEDITED (15-DAY)		DE, HO, LT	FR-PFIZER INC- 2019244364		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia	Novatrex			S	Oral	2.5 Mg, Weekly		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16418787	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-032134			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia; Rash Pustular; Staphylococcal Infection; Syncope	Fluoxetine Azithromycin Xolair Avamys Intuniv Prozac Quetiapine	S S S C C C C	Unknown Oral Subcutaneous Unknown Unknown Unknown Unknown	Unk 1 Dosage Form, Once A Day 300 Milligram Unk Unk Unk Unk	Aurobindo Aurobindo Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16418791	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR-APL-2019-032600			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Confusional State; Delirium	Azithromycin Film-Coated Tablets			S	Oral	750 Milligram, Every Week, Monday, Wednesday, Friday		Aurobindo
	Avamys			C	Nasal	55 Microgram, Daily, In Each Nostril		Not Reported
	Fostair			C	Respiratory (inhalation)	4 Dosage Form, Daily, 200micrograms/Dose / 6micrograms/Dose		Not Reported
	Salbutamol			C	Respiratory (inhalation)	Unk, As Necessary, Unk, 1-2 Puffs 4 Times A Day		Not Reported
	Carbocisteine			C	Unknown	1500 Milligram, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16420481	NON-EXPEDITED			US-PFIZER INC-2019247353		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16420483	NON-EXPEDITED			US-PFIZER INC-2019246777		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Cefdinir			S		Unk		Pfizer	
	Darvocet			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16422032	EXPEDITED (15-DAY)		OT	CA-VIIV HEALTHCARE LIMITED-CA2019GSK096371		19 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Acyclovir			S		Unk		Glaxosmithkline	
	Abacavir			S		300 Mg, Bid		Viiv	
	Azithromycin			S		2 Df, Qd		Glaxosmithkline	
	Lamivudine			S		150 Mg, Bid		Viiv	
	Tenofovir Alafenmide Fumarate			S		300 Mg, Qd		Not Reported	
	Zidovudine			S		300 Mg, Bid		Viiv	
	Bactrim (Sulfamethoxazole+Trimethopri me)			S		40 Mg, Bid		Glaxosmithkline	
	Intelence			S		200 Mg, Bid		Not Reported	
	Isentress			S	Oral	400 Mg, Bid		Not Reported	
	Prezista			S	Oral	60 Mg, Bid		Not Reported	
	Ritonavir			S		100 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	C	Unk	Glaxosmithkline
Iron	C	Unk	Not Reported
Magnesium Gluconate	C	Unk	Not Reported
Vitamin (Nos)	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16422061	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK096371		19 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Acyclovir			S		Unk		Glaxosmithkline
	Abacavir			S		300 Mg, Bid		Viiv
	Azithromycin			S		2 Df, Qd		Glaxosmithkline
	Lamivudine			S		150 Mg, Bid		Viiv
	Tenofovir Alafenmide Fumarate			S		300 Mg, Qd		Not Reported
	Zidovudine			S		300 Mg, Bid		Viiv
	Bactrim (Sulfamethoxazole+Trimethopri me)			S		40 Mg, Bid		Glaxosmithkline
	Intelence			S		200 Mg, Bid		Not Reported
	Isentress			S	Oral	400 Mg, Bid		Not Reported
	Prezista			S	Oral	60 Mg, Bid		Not Reported
	Ritonavir			S		100 Mg, Bid		Not Reported
	Folic Acid			C		Unk		Glaxosmithkline
	Iron			C		Unk		Not Reported
	Magnesium Gluconate			C		Unk		Not Reported
	Vitamin (Nos)			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jun-2019	16422245	EXPEDITED (15-DAY)		OT	PHHY2019FR133648		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Burn Oesophageal; Cough	Doxycycline	S	Oral	200 Mg, Qd	Novartis
	Zithromax	S	Oral	250 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	14139924	EXPEDITED (15-DAY)		OT	US-ROCHE-2014584		81 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Babesiosis; Drug Resistance	Rituximab			S	Unknown			Not Reported
	Atovaquone			S	Unknown			Not Reported
	Atovaquone			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Bendamustine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16326227	EXPEDITED (15-DAY)		HO, OT	US-ABBVIE-19K-163-2786352-00		58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Biliary Dilatation; Cholecystectomy; Chronic Obstructive Pulmonary Disease; Electrocardiogram Qt Prolonged; Intervertebral Disc Degeneration; Lung Hypoinflation; Polyuria; Rhinovirus Infection; White Blood Cell Count Increased	Mavyret			S	Oral	100-40 Mg		Not Reported
	Azithro			S	Unknown			Not Reported
	Marijuana			S	Respiratory (inhalation)			Not Reported
	Cocaine			S	Respiratory (inhalation)			Not Reported
	Lasix			C	Intravenous (not otherwise specified)			Not Reported
	Lasix			C	Oral			Not Reported
	Synthroid			C				Not Reported
	Dolophine			C				Not Reported
	Senokot			C				Not Reported
	Flomax			C				Not Reported
	Spiriva			C				Not Reported
	Melatonin			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Theragra	C		Not Reported
Vibramycin	C		Not Reported
Prednisone	C	For 5 Days	Not Reported
Prednisone	C		Not Reported
Albuterol Hfa	C		Not Reported
Amlodipine	C		Not Reported
Breo Ellipta	C		Not Reported
Neurontin	C		Not Reported
Duoneb	C		Not Reported
Albuterol	C	For 5 Days	Not Reported
Albuterol	C		Not Reported
Famotidine	C	For 5 Days	Not Reported
Famotidine	C		Not Reported
Fluticasone	C	For 5 Days	Not Reported
Fluticasone	C		Not Reported
Vilanterol	C	For 5 Days	Not Reported
Vilanterol	C		Not Reported
Furosemide	C	For 5 Days	Not Reported
Furosemide	C		Not Reported
Gabapentin	C	For 5 Days	Not Reported
Gabapentin	C		Not Reported
Ipratropium	C	For 5 Days	Not Reported
Ipratropium	C		Not Reported
Levothyroxine	C	For 5 Days	Not Reported
Levothyroxine	C		Not Reported
Methadone	C	For 5 Days	Not Reported
Methadone	C		Not Reported
Sennoside	C	For 5 Days	Not Reported
Sennoside	C		Not Reported
Tamsulosin	C	For 5 Days	Not Reported
Tamsulosin	C		Not Reported
Tiotropium	C	For 5 Days	Not Reported
Tiotropium	C		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16380519	NON-EXPEDITED			US-CELGENEUS-USA-20190510072		18 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Otezla			S	Oral	Taper Pack		Celgene
	Otezla			S	Oral	60 Milligram		Celgene
	Azithromycin			S	Unknown	500 Milligram		Not Reported
	Azithromycin			S	Unknown	500 Milligram		Not Reported
	Augmentin			S	Unknown	875/125		Not Reported
	Adderall			C	Unknown			Not Reported
	Bicillin L-A			C	Unknown			Not Reported
	Buspirone			C	Unknown			Not Reported
	Duloxetine			C	Unknown			Not Reported
	Fluticasone			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Methotrexate			C	Unknown			Not Reported
	Topiramate			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16423555	EXPEDITED (15-DAY)		HO	CA-ROCHE-2335579		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Asthma; Blood Cholesterol Increased; Blood Immunoglobulin E Increased; Blood Urine Present; Bronchitis; Chest Discomfort; Chest Pain; Cough; Drug Ineffective; Dyspepsia; Dyspnoea; Fatigue; Ill-Defined	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Influenza;	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Malaise; Mite Allergy;	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Nasal Congestion;	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Nasopharyngitis; Nausea;	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Pneumonitis; Sputum	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Increased; Upper	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Respiratory Tract	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Infection; Vomiting;	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
Wheezing	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Biw	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Pantoprazole	C	Oral	1 Df, Qd	Not Reported
	Calcium	C	Oral	1 Df, Qd	Not Reported
	Ventolin [Salbutamol]	C	Respiratory (inhalation)	200 Ug, Prn	Not Reported
	Spiriva	C	Respiratory (inhalation)	1 Df, Qd	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Df, Bid	Not Reported
	Estrogel	C	Topical	2 Df, Unk	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Cortisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16423668	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-032859			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Gastrointestinal Pain	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16423758	EXPEDITED (15-DAY)		HO	GB-TEVA-2019-GB-1061567		67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Agitation; Confusional State; Delirium	Azithromycin	S	Oral	Monday, Wednesday, Friday	Not Reported
	Avamys	C	Nasal	In Each Nostril	Not Reported
	Carbocisteine	C			Not Reported
	Fostair	C	Respiratory (inhalation)	200micrograms/Dose / 6micrograms/Dose	Not Reported
	Salbutamol	C	Respiratory (inhalation)	1-2 Puffs 4 Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16423798	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1061059		53 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin Dihydrate			S	Oral	500 Milligram Daily;			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16424537	NON-EXPEDITED			US-TAKEDA-2013TEU003136			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Pantoprazole			S					Not Reported
	Lansoprazole			S					Takeda
	Azithromycin			S					Not Reported
	Doxycycline Hyclate			S					Not Reported
	Sertraline Hcl			S					Not Reported
	Clindamycin Hcl			S					Not Reported
	Metaxalone			S					Not Reported
	Metronidazole			S					Not Reported
	Oxycodone Hydrochloride			S					Not Reported
	Cefixime			S					Not Reported
	E-Mycin /00020901/			S					Not Reported
	Fentanyl			S					Not Reported
	Cipro /00697201/			S					Not Reported
	Cephalexin /00145501/			S					Not Reported
	Hydrocodone			S					Not Reported
	Tramadol			S					Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16424769	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019246198		54 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Hypoaesthesia	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
	Diamox			S	Oral	3 Df, 1x/Day		Pfizer	
	Diffu K			S	Oral	2 Df, Unk		Not Reported	
	Cosopt			S	Ophthalmic	2 Drops, Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16425233	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1061043		54 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ageusia; Hypoaesthesia	Azithromycine Anhydre			S	Oral			Not Reported	
	Diffu K			S	Oral			Not Reported	
	Diamox 250 Mg, Comprimé			S	Oral			Not Reported	
	Sécable								
	Cosopt			S	Ophthalmic			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16425713	NON-EXPEDITED			US-PFIZER INC-2019250075			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Oral Discomfort; Tongue Discomfort	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jun-2019	16427901	NON-EXPEDITED			US-PFIZER INC-2019254017			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort; Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jun-2019	16428196	EXPEDITED (15-DAY)		OT	PT-MYLANLABS- 2019M1055456		19 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Respiratory Distress	Azithromycin			S	Oral	Unk		Not Reported	
	Lepicortinolo /00016201/			S	Oral	Unk		Mylan	
	Maxilase			S	Oral	Unk		Mylan	
	Lergonix			S	Oral	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	15645767	EXPEDITED (15-DAY)		OT	PHHY2018GB155019		39 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication	Azithromycin			S	Unknown	1 G, Q3w		Novartis	
	Pyrimethamine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16351262	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-028908			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cachexia; Chills; Condition Aggravated; Disseminated Bacillus Calmette-Guerin Infection; Hepatitis Cholestatic; Infection; Inflammation; Kidney Infection; Medication Error; Normochromic Anaemia; Normocytic Anaemia;	Azithromycin			S	Unknown	Unk		Aurobindo	
	Cefixime			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pyrexia; Respiratory Rate Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16430660	EXPEDITED (15-DAY)		HO	PHHY2019FR135828		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis;	Paracetamol			S	Oral	4 G, Qd		Not Reported	
Hepatocellular Injury	Azithromycine			S	Oral	500 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16431565	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019237931			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aspartate	Halcion			S	Oral			Pfizer	
Aminotransferase	Zithromac			S	Oral			Pfizer	
Increased; Blood Creatine	Myslee			S		Unk		Not Reported	
Phosphokinase Increased;	Carbocisteine			S		Unk		Not Reported	
Blood Lactate	Loxoprofen [Loxoprofen Sodium]			S		Unk		Not Reported	
Dehydrogenase Increased									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16431601	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019248567		20 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Malaise;	Zitromax			S		500 Mg, Unk		Pfizer	
Paraesthesia; Tremor;									
Vomiting									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jun-2019	16436741	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1062496		33 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper; Gastrointestinal Pain	Azithromycin Dihydrate	S	Oral	500mg Per Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jun-2019	16437496	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR- APL-2019-033793			Unknown	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Azithromycin			S	Unknown	Unk		Aurobindo
Erythema; Erythema	Humira			S	Subcutaneous	40 Milligram, 2 Weeks		Not Reported
Nodosum; Inflammation;	Klacid			S	Unknown	Unk		Not Reported
Oedema Peripheral;								
Rheumatoid Arthritis;								
Urinary Tract Infection;								
Viral Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	11910090	NON-EXPEDITED			US-PFIZER INC- 2015450706			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	15880462	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019031562		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Zithromax			S	Oral	500 Mg, Unk (2 Tablets First Day)		Pfizer
Coeliac Disease;	Zithromax			S	Oral	250 Mg, Unk (1 Tablet The Remaining 4 Days)		Pfizer
Condition Aggravated;	Flonase [Fluticasone Propionate]			C	Respiratory (inhalation)	Unk		Not Reported
Drug Ineffective; Eating Disorder; Gastritis;	Mucinex			C		600 Mg, 2x/Day		Not Reported
Incorrect Product								
Administration Duration;								
Malaise; Reaction To								
Excipient; Weight Decreased								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Mucinex		C	Oral		Unk, As Needed		Not Reported	
	Mucinex		C					Not Reported	
	Mucinex		C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16250979	NON-EXPEDITED			US-PFIZER INC-2019176745		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Oral	Unk		Pfizer	
	Sulfamethoxazole			S	Oral	Unk		Not Reported	
	Cephalexin [Cefalexin]			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16402921	EXPEDITED (15-DAY)		OT	CA-VIIV HEALTHCARE LIMITED-CA2019GSK098225			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Acyclovir			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycin			S	Transplacental	Unk Mg, (300 Mg)		Glaxosmithkline	
	Bactrim (Sulfamethoxazole+Trimethopri me)			S	Transplacental	Unk		Glaxosmithkline	
	Lamivudine			S	Transplacental	Unk Mg, (150 Mg)		Viiv	
	Viread			S	Transdermal	300 Mg (Tablet)		Glaxosmithkline	
	Zidovudine			S	Transplacental	Unk (300 Mg)		Viiv	
	Intelence			S	Transplacental	1 Df, Qd (Tablet)		Not Reported	
	Prezista			S	Transplacental	600 Mg, Unk (Tablet)		Not Reported	
	Raltegravir Potassium			S	Transplacental	400 Mg, Unk (Tablet)		Not Reported	
	Ritonavir			S	Transplacental	Unk Mg, (100 Mg)		Not Reported	
	Folic Acid			C		Unk		Glaxosmithkline	
	Magnesium Gluconate			C		Unk		Not Reported	
	Abacavir			C	Transplacental	300 Mg, Unk (Capsule)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Iron			C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16402923	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK098225			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Acyclovir			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycin			S	Transplacental	Unk Mg, (300 Mg)		Glaxosmithkline	
	Bactrim (Sulfamethoxazole+Trimethopri me)			S	Transplacental	Unk		Glaxosmithkline	
	Lamivudine			S	Transplacental	Unk Mg, (150 Mg)		Viiv	
	Viread			S	Transdermal	300 Mg (Tablet)		Glaxosmithkline	
	Zidovudine			S	Transplacental	Unk (300 Mg)		Viiv	
	Intelence			S	Transplacental	1 Df, Qd (Tablet)		Not Reported	
	Prezista			S	Transplacental	600 Mg, Unk (Tablet)		Not Reported	
	Raltegravir Potassium			S	Transplacental	400 Mg, Unk (Tablet)		Not Reported	
	Ritonavir			S	Transplacental	Unk Mg, (100 Mg)		Not Reported	
	Folic Acid			C		Unk		Glaxosmithkline	
	Magnesium Gluconate			C		Unk		Not Reported	
	Abacavir			C	Transplacental	300 Mg, Unk (Capsule)		Not Reported	
	Iron			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16438414	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-033214			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Haematochezia; Product Use In Unapproved Indication	Amoxicillin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Eliquis			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz C Oral 10 Milligram, 2 Every One Day Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16438430	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-033226			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Amoxicillin			S	Unknown	Unk		Aurobindo
Cerebrovascular Disorder;	Azithromycin			S	Unknown	Unk		Aurobindo
Chest X-Ray Abnormal;	Levofloxacin			S	Unknown	Unk		Aurobindo
Gastrointestinal	Vancomycin Hydrochloride			S	Intravenous (not otherwise specified)	1 Gram, Two Times A Day		Aurobindo
Haemorrhage; Hypoxia;	Betamethasone			S	Unknown	Unk		Not Reported
Infection; Influenza Like	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk		Not Reported
Illness; Neuropathy	Heparin Sodium			S	Intravenous (not otherwise specified)	Unk		Not Reported
Peripheral; Pancreatitis;	Oseltamivir Phosphate			S	Oral	75 Milligram, Two Times A Day		Not Reported
Polyneuropathy;								
Premature Labour;								
Respiratory Acidosis;								
Respiratory Distress;								
Respiratory Failure;								
Tachypnoea								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16438546	EXPEDITED (15-DAY)			US- ELI_LILLY_AND_COMP ANY-US201906003156			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Depression; Drug	Cymbalta			S	Unknown	Unk, Unknown		Eli Lilly And Co
Hypersensitivity; Tinnitus	Azithromycin			S	Unknown	Unk, Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16439545	NON-EXPEDITED			US-PFIZER INC- 2019253467		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Morphine Sulfate	S	Unk	Unknown
	Minocycline	S	Unk	Pfizer
	Hydrocodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16441286	NON-EXPEDITED			US-PFIZER INC-2019258875			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jun-2019	16442999	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	PHHY2019CA138409		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Metoprolol			S	Intravenous (not otherwise specified)	5 Mg, Q6h		Novartis
	Metoprolol			S	Intravenous (not otherwise specified)	2.5 Mg, Q6h		Novartis
	Morphine Sulfate Inj Usp			S	Intravenous (not otherwise specified)	1 Df, Every 10 Minutes		Not Reported
	Amiodarone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	10 Mg, Qh		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Mg, Q4h		Not Reported
	Diltiazem			S	Oral	180 Mg, Unk		Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Mg, Q4h		Not Reported
	Furosemide			S	Oral	40 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Q6h	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Every 14 Days	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Qh	Not Reported
Procytos	S	Intravenous (not otherwise specified)	1060 Mg, Qd	Not Reported
Trastuzumab	S	Unknown		Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q4h	Not Reported
Hydromorphone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, Qd	Not Reported
Adriamycin	S	Intravenous (not otherwise specified)	106 Mg, Every 14 Days	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Emend	C	Unknown	Unk	Not Reported
Filgrastim	C	Unknown	Unk	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Metoclopramide	C	Unknown	Unk	Not Reported
Ondansetron	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	13513958	NON-EXPEDITED			US-PFIZER INC-2017188371			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Neosporin			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Benadryl			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	14346774	NON-EXPEDITED			US-PFIZER INC-2018000440		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Azithromycin			S				Pfizer	
	Vicodin			S		Unk		Not Reported	
	Percocet			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
	Coq 10			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Fenofibrate			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Cephalexin Hcl			S		Unk		Not Reported	
	Coenzyme			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16426669	EXPEDITED (15-DAY)		DE	PHHY2019UA134766		40 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia	Amoksiklav			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	Novartis
Cefaxon [Ceftriaxone Sodium]	S	Unknown	Not Reported
Amoxil	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16427312	EXPEDITED (15-DAY)		DE, OT	PHHY2019UA135873		60 YR	Male	UKR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia; Pulmonary Necrosis	Amoksiklav			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Cefaxon [Ceftriaxone Sodium]			S	Unknown	Unk		Not Reported
	Amoxil			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16443666	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-210733		54 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Hypoaesthesia	Azithromycin			S	Oral	250 Milligram, Daily		Sun
	Diffu K			S	Oral	2 Dosage Form, Unk		Not Reported
	Diamox 250 Mg, Comprime			S	Oral	3 Dosage Form, Daily		Not Reported
	Secable Cosopt			S	Ophthalmic	2 Gtt, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16443878	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-033228			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug Level Above Therapeutic; Drug Interaction; Peripheral Swelling	Azithromycin			S	Unknown	Unk		Aurobindo
	Cefuroxime			S	Unknown	Unk		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Warfarin			S		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16443887	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033230			Unknown	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anticoagulation Drug Level Above Therapeutic; Drug Interaction	Cefuroxime			S	Unknown	Unk		Aurobindo		
	Azithromycin			S	Unknown	Unk		Aurobindo		
	Warfarin			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16443919	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034845			Unknown	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Asthma; Cardiac Failure; Emphysema	Azithromycin			S	Unknown	Unk		Aurobindo		
	Fluticasone			S	Unknown	2 Dosage Form, Two Times A Day		Not Reported		
	Rabeprazole			S	Unknown	Unk		Not Reported		
	Salbutamol			S	Unknown	Unk		Not Reported		
	Tiotropium Bromide			C	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16443924	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034708			Unknown	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Feeling Of Body Temperature Change; Nausea; Vertigo	Azithromycin			S	Oral	2 Gram, Once		Aurobindo		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Jun-2019	16444143	NON-EXPEDITED			US-PFIZER INC-2019256121		54 YR	Female	USA	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Bactrim			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16444196	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-033697			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Death; Decreased Appetite; Drug Ineffective; Fatigue; Malignant Neoplasm Progression; Pancreatic Neuroendocrine Tumour; Platelet Count Decreased; Rash; Somnolence; Weight Decreased	Azithromycin			S	Unknown	Unk		Aurobindo
	Ciprofloxacin			S	Unknown	Unk		Aurobindo
	Afinitor			S	Oral	5 Milligram, Daily		Not Reported
	Octreotide			S	Subcutaneous	Unk		Not Reported
	Sandostatin			S	Unknown	60 Milligram		Not Reported
	Trimethoprim			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16445292	EXPEDITED (15-DAY)		OT	AT-MYLANLABS-2019M1055678			Female	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Adrenal Insufficiency; Adverse Food Reaction; Agonal Rhythm; Alopecia; Arthralgia; Asthenia; Constipation; Depression; Diarrhoea; Dry Eye; Dysgeusia; Fatigue; Flatulence; Gait Disturbance; Gastrointestinal Pain; Headache; Hormone Level	Azithromycin			S		Unk, 1x Per Day		Not Reported
	Diflucan			S	Unknown	Unk Unk, Qod		Mylan
	Diflucan			S				Mylan
	Itraconazole			S	Unknown	200 Mg		Mylan
	Itraconazole			S	Unknown	200 Mg, 2x Per Day		Mylan
	Avelox			S	Unknown	Unk		Mylan
	Ivermec			S	Unknown	Unk Unk, Qod		Mylan
	Ivermec			S	Unknown	Unk Unk, Qod		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Hypoaesthesia;	Prohance /01180901/	S	Unknown	Unk	Mylan
Incontinence; Injection	Prohance /01180901/	S	Unknown	Unk	Mylan
Site Pain; Joint Ankylosis;	Cortisone	S		1 Df, Per Day	Mylan
Joint Swelling;	Moxifloxacin Krka	S		1 Df, 1x Per Day	Mylan
Menstruation Irregular;	Anaerobex	S		Unk, 2x Per Day	Mylan
Metabolic Disorder;	Pantelmin	C		Unk, 2x Per Day	Mylan
Mitochondrial Toxicity;	Pantoloc /01263201/	C		Unk	Mylan
Mucosal Dryness; Muscle	Pantoloc /01263201/	C		40 Milligram, Qd	Mylan
Injury; Muscle Spasticity;					
Muscular Weakness;					
Musculoskeletal Pain;					
Musculoskeletal Stiffness;					
Nausea; Nervous System					
Disorder; Neuralgia;					
Neuropathy Peripheral;					
Pain; Pain In Extremity;					
Panic Attack;					
Paraesthesia; Photopsia;					
Skin Irritation; Suicidal					
Ideation; Suicide Attempt;					
Swelling; Temperature					
Intolerance; Tendon Injury;					
Vein Rupture; Vertigo;					
Vision Blurred; Visual					
Impairment; Vomiting;					
Weight Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16445567	NON-EXPEDITED			US-PFIZER INC-2019258103		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Z-Pak			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16446150	EXPEDITED (15-DAY)		OT	CA-VIIV HEALTHCARE LIMITED-CA2019GSK074256		56 DAY	Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia Neonatal; Foetal Exposure During Pregnancy	Lamivudine			S	Transplacental	150 Mg, Unk		Viiv
	Acyclovir			S	Transplacental	Unk		Glaxosmithkline
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline
	Bactrim			S	Transplacental	Unk		Glaxosmithkline
	Zidovudine			S	Transplacental	300 Mg, Unk		Viiv
	Isentress			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Mg, Unk		Not Reported
	Prezista			S	Transplacental	600 Mg, Unk		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Mg, Unk		Not Reported
	Ritonavir			S	Transplacental	100 Mg, Unk		Not Reported
	Tenofovir			S	Transplacental	300 Mg, Unk		Not Reported
	Abacavir			C	Transplacental	300 Mg, Unk		Not Reported
	Vitamin B12			C		Unk		Glaxosmithkline
	Vitamin C			C		Unk		Glaxosmithkline
	Folic Acid			C		Unk		Glaxosmithkline
	Calcium D			C		Unk		Glaxosmithkline
	Ergocalciferol			C		Unk		Glaxosmithkline
	Nicotinamide			C		Unk		Glaxosmithkline
	Pyridoxine Hydrochloride			C		Unk		Glaxosmithkline
	Calcium Carbonate			C		Unk		Glaxosmithkline
	Ferrous Fumarate			C		Unk		Glaxosmithkline
	Iron			C		Unk		Not Reported
	Magnesium Gluconate			C		Unk		Not Reported
	Retinol Palmitate			C		Unk		Not Reported
	Riboflavin			C		Unk		Not Reported
	Thiamine Mononitrate			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16446178	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK074256		56 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia Neonatal; Foetal Exposure During Pregnancy	Lamivudine			S	Transplacental	150 Mg, Unk		Viiv	
	Acyclovir			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline	
	Bactrim			S	Transplacental	Unk		Glaxosmithkline	
	Zidovudine			S	Transplacental	300 Mg, Unk		Viiv	
	Isentress			S	Transplacental	Unk		Not Reported	
	Intelence			S	Transplacental	200 Mg, Unk		Not Reported	
	Prezista			S	Transplacental	600 Mg, Unk		Not Reported	
	Raltegravir Potassium			S	Transplacental	400 Mg, Unk		Not Reported	
	Ritonavir			S	Transplacental	100 Mg, Unk		Not Reported	
	Tenofovir			S	Transplacental	300 Mg, Unk		Not Reported	
	Abacavir			C	Transplacental	300 Mg, Unk		Not Reported	
	Vitamin B12			C		Unk		Glaxosmithkline	
	Vitamin C			C		Unk		Glaxosmithkline	
	Folic Acid			C		Unk		Glaxosmithkline	
	Calcium D			C		Unk		Glaxosmithkline	
	Ergocalciferol			C		Unk		Glaxosmithkline	
	Nicotinamide			C		Unk		Glaxosmithkline	
	Pyridoxine Hydrochloride			C		Unk		Glaxosmithkline	
	Calcium Carbonate			C		Unk		Glaxosmithkline	
	Ferrous Fumarate			C		Unk		Glaxosmithkline	
	Iron			C		Unk		Not Reported	
	Magnesium Gluconate			C		Unk		Not Reported	
	Retinol Palmitate			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Riboflavin		C			Unk		Not Reported	
	Thiamine Mononitrate		C			Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16446573	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1057217		40 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hyperaemia; Periorbital Swelling	Brufen 600 Mg Granulato Effervescente			S	Oral	600 Milligram, Qd		Mylan	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Gentalyn			S	Topical	1 Dosage Form, Prn		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16446762	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019252936		89 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia Macrocytic; Thrombocytopenia	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jun-2019	16447116	EXPEDITED (15-DAY)		HO	PHHY2019FR135890		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cheilitis; Dermatitis Exfoliative Generalised; Mouth Ulceration	Pantoprazole			S	Oral	20 Mg, Qd		Novartis	
	Levofloxacin			S	Intravenous (not otherwise specified)			Not Reported	
	Lasilix			S	Respiratory (inhalation)	40 Mg, Qd		Not Reported	
	Rocephine			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zithromax			S	Oral	Unk		Not Reported	
	Flagyl			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	12454932	NON-EXPEDITED			US-PFIZER INC-2016267363			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Darvocet			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Ultracet			S		Unk		Not Reported	
	Amoxicillin/Clavulanate Potassium			S		Unk		Not Reported	
	Acetaminophen;Propoxyphene			S		Unk		Not Reported	
	Cephalexin [Cefalexin]			S		Unk		Not Reported	
	Tramadol And Acetaminophen			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	14266977	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2017-06498		81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Gene Mutation; Treatment Failure	Azithromycin			S	Unknown	500 Mg, Qd		Lupin	
	Azithromycin			S	Unknown	1000 Mg, Qd		Lupin	
	Atovaquone			S	Unknown	750 Mg, Bid		Lupin	
	Atovaquone			S	Unknown	1750 Mg, Qd		Lupin	
	Proguanil			C	Unknown	400 Mg, Qd		Not Reported	
	Doxycycline			C	Unknown	100 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	15700927	EXPEDITED (15-DAY)		OT	PHEH2018US050827		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Dyspnoea; Fatigue; Headache; Migraine; Neck Pain; Palpitations; Vision Blurred	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Gilenya			S	Oral	0.5 Mg, Qd		Novartis
	Z-Pak			S	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Modafinil			C	Unknown			Not Reported
	Lipitor			C	Unknown			Not Reported
	Probiotic			C	Unknown			Not Reported
	Nexum			C	Unknown	Unk		Not Reported
	Losartan			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16081158	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR- APL-2019-012920			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Mental Status Changes; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Imipenem And Cilastatin			S	Unknown	Unk		Not Reported
	Imipenem And Cilastatin			S				Not Reported
	Rifampin			S	Unknown	Unk		Not Reported
	Rifampin			S				Not Reported
	Tigecycline			S	Unknown	Unk		Not Reported
	Tigecycline			S				Not Reported
	Minocycline			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16081388	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012925			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Gait Disturbance; Headache; Influenza Like Illness; Malaise; Musculoskeletal Pain; Nasopharyngitis; Neck Pain; Pneumonia; Pyrexia; Seasonal Allergy	Azithromycin			S	Oral	250 Milligram		Aurobindo
	Xolair			S	Subcutaneous	300 Milligram, 1 Every 2 Weeks		Not Reported
	Advair			C		1 Dosage Form, Two Times A Day		Not Reported
	Atrovent			C	Unknown	1 Dosage Form		Not Reported
	Clarithromycin			C	Oral	500 Milligram		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Spiriva			C		1 Dosage Form, Two Times A Day		Not Reported
	Symbicort			C		Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported
	Ventolin			C		2 Dosage Form		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16216311	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-021116			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastroenteritis Viral; Influenza; Oral Candidiasis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	250 Milligram, Two Times A Day		Aurobindo
	Azithromycin			S	Unknown	250 Milligram, Two Times A Day		Aurobindo
	Remicade			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 8 Weeks		Not Reported
	Betahistine			C	Oral	24 Milligram, Once A Day		Not Reported
	Denosumab			C	Unknown	60 Milligram, 1 Every 6		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ergocalciferol	C	Oral	Weeks 3000 International Unit, Once A Day	Not Reported
Folic Acid	C	Oral	5 Milligram, 6 Every 1 Week	Not Reported
Methotrexate	C	Oral	15 Milligram, 1 Every 7 Days	Not Reported
Ranitidine	C	Oral	150 Milligram, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16224743	NON-EXPEDITED			US-CELGENEUS-USA- 20190405971			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Bronchitis; Diarrhoea; Inflammation	Otezla			S	Oral	60 Milligram		Celgene
	Otezla			S				Celgene
	Z-Pak			S	Unknown			Not Reported
	Azithromycin			C	Unknown			Not Reported
	Diltiazem			C	Unknown			Not Reported
	Doxycycline Hyclate			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Ketorolac			C	Unknown			Not Reported
	Levothyroxine			C	Unknown			Not Reported
	Raloxifene			C	Unknown			Not Reported
	Sertraline			C	Unknown			Not Reported
	Soolantra			C	Unknown			Not Reported
	Wellbutrin			C	Unknown			Not Reported
	Xiidra			C	Unknown			Not Reported
	Zolpidem			C	Unknown			Not Reported
	Cartia			C	Unknown			Not Reported
	Mucinex			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16328072	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027316			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Above Therapeutic; Drug Interaction; Peripheral Swelling	Azithromycin			S	Unknown	Unk		Aurobindo	
	Cefuroxime			S	Unknown	Unk		Aurobindo	
	Warfarin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16427319	EXPEDITED (15-DAY)		DE	PHHY2019UA135184		53 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Pulmonary Oedema	Amoksiklav			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Cefaxon [Ceftriaxone Sodium]			S	Unknown	Unk		Not Reported	
	Amoxil			S	Unknown	Unk		Not Reported	
	Alfa-Tocoferol			S	Unknown	Unk		Not Reported	
	Dihydroquercetin			S	Unknown	Unk		Not Reported	
	Mexidol			S	Unknown	Unk		Not Reported	
	Meldonium			S	Unknown	Unk		Not Reported	
	Probucolum			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16447453	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033673			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo	
	Zidovudine			S	Transplacental	300 Milligram		Aurobindo	
	Tenofovir			S	Transplacental	Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tenofovir	S	Transdermal	300 Milligram	Aurobindo
Lamivudine	S	Transplacental	150 Milligram	Aurobindo
Isentress	S	Transplacental	Unk	Not Reported
Prezista	S	Transplacental	600 Milligram	Not Reported
Ritonavir	S	Transplacental	100 Milligram	Not Reported
Acyclovir	S	Transplacental	Unk	Not Reported
Raltegravir Potassium	S	Transplacental	400 Milligram	Not Reported
Intelence	S	Transplacental	200 Milligram	Not Reported
Bactrim	S	Transplacental	Unk	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Abacavir	C	Transplacental	300 Milligram	Not Reported
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448024	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP016390		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Blood Bilirubin Increased; Drug Hypersensitivity; Transaminases Increased	Allopurinol			S	Oral	300 Mg, Qd		Apotex
	Azithromycin			S	Oral	250 Mg, Qd		Apotex
	Pms Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Cholestyramine			C	Unknown	Unk		Not Reported
	Diphenhydramine			C	Unknown	Unk		Not Reported
	Hydroxyzine			C	Unknown	Unk		Not Reported
	Lispro Insulin			C	Unknown	Unk		Not Reported
	Valsartan			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448889	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034838			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Increased; Off Label Use; Stress	Azithromycin			S	Oral	250 Milligram, 1 Every 3 Weeks		Aurobindo	
	Xolair			S	Subcutaneous	300 Milligram, 1 Every 2 Weeks		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Spiriva			C	Unknown	Unk		Not Reported	
	Symbicort			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448897	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-034793			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Pruritus	Azithromycin			S	Oral	500 Milligram, Unk		Aurobindo	
	Cefazolin			S	Intraperitoneal	1500 Milligram, Once A Day		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Asa			C	Unknown	Unk		Not Reported	
	Bisoprolol			C	Unknown	Unk		Not Reported	
	Docusate Sodium			C	Unknown	Unk		Not Reported	
	Eprex			C	Unknown	Unk		Not Reported	
	Fluticasone			C	Unknown	Unk		Not Reported	
	Kayexalate			C	Unknown	Unk		Not Reported	
	Megestrol			C	Unknown	Unk		Not Reported	
	One Alpha			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Sevelamer			C	Unknown	Unk		Not Reported	
	Vitamin D			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nepafenac			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448918	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034702			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gonorrhoea	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ceftriaxone Sodium			S	Unknown	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	640 Milligram, 1 Every 5 Week		Not Reported	
	Keppra			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Ventolin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448923	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034686			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchospasm;	Azithromycin			S	Unknown			Aurobindo	
Candida Infection;	Potassium Acetate			S	Unknown	Unk		Not Reported	
Cerebrovascular Accident;	Xolair			S	Subcutaneous	375 Milligram, One Every Two Weeks		Not Reported	
Dyspnoea; Heart Rate Increased; Hemiplegia; Inappropriate Schedule Of Product Administration;	Xolair			S	Subcutaneous	Unk		Not Reported	
Oxygen Saturation Decreased; Peritonsillar Abscess; Pharyngeal Inflammation; Pilonidal Cyst; Postoperative Wound Complication;	Levaquin			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Singulair			C	Unknown	Unk		Not Reported	
	Spiriva			C	Unknown	Unk		Not Reported	
Productive Cough;	Ventolin			C	Unknown	Unk		Not Reported	
Pulmonary Pain;	Zenhale			C	Unknown	Unk		Not Reported	
Respiratory Rate Increased; Rhonchi;									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Therapy Partial
Responder; Wheezing

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16448933	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR- APL-2019-034683			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Atrial Flutter; Cardiac Arrest; Cardioversion; Hyperbaric Oxygen Therapy; Resuscitation; Torsade De Pointes	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Atorvastatin Calcium			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Ferrous Gluconate			C	Unknown	Unk		Not Reported
	Ipratropium;Salbutamol			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Thyroxine Sodium			C	Unknown	Unk		Not Reported
	Zopiclone			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449018	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR- 1065367		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burn Oesophageal; Cough	Doxycycline			S	Oral	200 Milligram Daily;		Actavis
	Zithromax			S	Oral	250 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449222	EXPEDITED (15-DAY)		DE, HO, OT	CA-AUROBINDO-AUR- APL-2019-034182			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Azithromycin			S	Oral	1 Dosage Form, Once A		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Blood Pressure Increased; Death; Decreased Appetite; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Heart Rate Increased; Inappropriate Schedule Of Product Administration; Influenza; Malaise; Obstructive Airways Disorder; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication	Xolair	S	Subcutaneous	Day 15 Milligram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449257	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033889			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Cardiac Failure; Emphysema	Azithromycin			S	Unknown	Unk		Aurobindo
	Fluticasone			S	Unknown	2.0 Dosage Form, Two Times A Day		Not Reported
	Rabeprazole			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Olodaterol + Tiotropium			C	Unknown	2 Dosage Form, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449261	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033866			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Contact; Diabetes Mellitus; Hypertension;	Azithromycin			S	Oral	250.0 Milligram, Daily		Aurobindo
	Atrovent			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Staphylococcus Test Positive	Breo Ellipta	S	Unknown	1 Dosage Form	Not Reported
	Ipratropium;Salbutamol	S	Unknown	Unk	Not Reported
	Prednisone	S	Oral	45.0 Milligram	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Seebri Breezhaler	S	Unknown	1.0 Dosage Form, Daily	Not Reported
	Singulair	S	Oral	10.0 Milligram, Daily	Not Reported
	Theophylline	S	Oral	450.0 Milligram, Daily	Not Reported
	Xolair	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449264	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033869			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Azithromycin			S	Unknown	Unk		Aurobindo
Abdominal Pain; Asthenia;	Codeine			S	Unknown	Unk		Not Reported
Blood Pressure Decreased; Blood	Sandostatin			S	Intramuscular	30 Milligram, Every Month		Not Reported
Pressure Diastolic Decreased; Blood	Zithromax			C	Unknown	Unk		Not Reported
Pressure Systolic Increased; Body								
Temperature Decreased;								
Cellulitis; Cerebrovascular								
Accident; Cholelithiasis;								
Contusion; Decreased								
Appetite; Diarrhoea;								
Discomfort; Erythema;								
Fall; Furuncle; Heart Rate								
Decreased; Heart Rate								
Irregular; Hyperhidrosis;								
Hypotension; Injection Site								
Pain; Malaise; Needle								
Issue; Pain In Extremity;								
Peripheral Swelling;								
Productive Cough;								
Pruritus; Pulmonary								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Congestion; Septic Rash;
Skin Laceration; Skin
Ulcer; Yellow Skin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449291	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034290			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product; Chapped Lips; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder; Stomatitis; Urticaria	Azithromycin			S	Unknown	250 Milligram		Aurobindo
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	300 Milligram		Not Reported
	Benadryl			C	Oral	1 Dosage Form		Not Reported
	Prednisone			C	Oral	1 Dosage Form		Not Reported
	Singular			C	Oral	10 Milligram, Once A Day		Not Reported
	Cetirizine Hydrochloride			C	Oral	1 Dosage Form, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449319	EXPEDITED (15-DAY)		DE, HO, OT	CA-AUROBINDO-AUR- APL-2019-034387			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Cough; Death; Decreased Appetite; Diarrhoea; Drug Interaction; Dry Mouth; Dysphonia; Dyspnoea; Eye Colour Change; Feeling Abnormal; Intercepted Product Prescribing Error; Labelled Drug-Drug Interaction Medication Error; Myocardial Infarction; Nasopharyngitis; Oral Fungal Infection; Oxygen	Azithromycin			S	Unknown	250 Milligram, 3 Times In A Week		Aurobindo
	Ofev			S	Oral	100 Milligram, Two Times A Day		Not Reported
	Ofev			S	Oral	150 Milligram, Two Times A Day		Not Reported
	Ofev			S	Oral	150 Milligram, Two Times A Day		Not Reported
	Ofev			S	Oral	100 Milligram, Two Times A Day		Not Reported
	Loperamide			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Therapy; Pneumonia; Productive Cough; Stent Placement; Tremor	Ultram	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449326	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034417			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dactylitis; Drug Ineffective; Incorrect Dosage Administered; Joint Swelling; Malaise; Musculoskeletal Stiffness; Psoriatic Arthropathy	Azithromycin			S	Unknown	Unk		Aurobindo
	Cosentyx			S	Subcutaneous	300 Milligram,1 Every 1 Weeks		Not Reported
	Cosentyx			S	Unknown	150 Milligram		Not Reported
	Cosentyx			S	Subcutaneous	450 Milligram,1 Every 1 Months		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Methotrexate			S	Subcutaneous	25 Milligram,1 Every 1 Weeks		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
Simponi			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449341	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-034443			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Gastrointestinal Haemorrhage; Haematemesis	Azithromycin			S	Unknown	Unk		Aurobindo
	Eliquis			S	Oral	5 Milliequivalent, Once A Day		Not Reported
	Acetaminophen			C	Unknown	Unk		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Finasteride			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Metoprolol	C	Unknown	Unk	Not Reported
	Pregabalin	C	Unknown	Unk	Not Reported
	Vitamin D	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449350	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034444			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Increased; Stress	Azithromycin			S	Oral	250 Milligram, 1 Every 3 Weeks		Aurobindo	
	Omalizumab			S	Subcutaneous	300 Milligram, Unk		Not Reported	
	Omalizumab			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	300 Milligram, Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
	Salbutamol Sulfate			C		Unk		Not Reported	
	Spiriva			C		1 Dosage Form, 1 Every 24 Hours		Not Reported	
	Symbicort			C		3 Dosage Form, Two Times A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16449725	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034302			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Atrovent			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	1 Dosage Form, Once A Day		Not Reported	
	Ipratropium Bromide;Salbutamol Sulfate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Omalizumab		S	Intravenous (not otherwise specified)	Unk			Not Reported
	Prednisone		S	Oral	45 Milligram, Once A Day			Not Reported
	Salbutamol Sulfate		S	Unknown	Unk			Not Reported
	Seebri Breezhaler		S	Unknown	1 Dosage Form, Once A Day			Not Reported
	Singulair		S	Oral	10 Milligram, Once A Day			Not Reported
	Theophylline		S	Oral	45 Milligram, Once A Day			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16450997	NON-EXPEDITED			US-PFIZER INC-2019261483			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Phenothiazine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16454105	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019257307		58 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burn Oesophageal; Cough	Doxycycline Monohydrate			S	Oral	200 Mg, 1x/Day		Pfizer
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jun-2019	16454174	NON-EXPEDITED			US-PFIZER INC-2019263405		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	12663242	EXPEDITED (15-DAY)		OT	CA-APOTEX-2016AP010374		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Apo-Azithromycin			S	Oral	Unk		Apotex
	Apo-Azithromycin			S	Unknown	Unk		Apotex
	Apo-Ciproflox			S	Oral	Unk, Cyclical		Apotex
	Apo-Montelukast			S	Oral	Unk		Apotex
	Apo-Mycophenolate			S	Oral	Unk		Apotex
	Apo-Sulfatrim			S	Oral	Unk		Apotex
	Apo-Voriconazole			S	Oral	Unk		Not Reported
	Apo-Voriconazole			S	Oral	Unk		Not Reported
	Nifedipine			S	Oral	Unk		Apotex
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Apotex
	Pantoprazole			S	Oral	Unk		Apotex
	Prednisone			S	Oral	Unk		Apotex
	Tacrolimus			S	Oral	Unk		Not Reported
	Candidas			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Caspofungin Acetate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Caspofungin Acetate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Caspofungin Acetate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	15179691	EXPEDITED (15-DAY)		DS, OT	CA-APOTEX-2018AP017278		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Apo-Quetiapine	S	Oral	100 Mg, Qd	Apotex
	Azithromycin	S	Unknown	Unk	Apotex
	Ciprofloxacin	S	Oral	500 Mg, Qd	Apotex
	Ciprofloxacin	S	Unknown	Unk	Apotex
	Quetiapine	S	Oral	25 Mg, Bid	Apotex
	Quetiapine	S	Oral	100 Mg, Qd	Apotex
	Cipro /00697201/	S	Oral	500 Mg, Qd	Not Reported
	Cipro /00697201/	S	Unknown	Unk	Not Reported
	Sandoz Azithromycin	S	Unknown	Unk	Not Reported
	Sandoz Ciprofloxacin	S	Oral	500 Mg, Qd	Not Reported
	Sandoz Ciprofloxacin	S			Not Reported
	Teva Quetiapine	S	Oral	25 Mg, Bid	Not Reported
	Zyprexa	C	Unknown	Unk	Not Reported
	Risperidone	C	Unknown	Unk	Not Reported
	Epival /00017001/	C	Unknown	Unk	Not Reported
	Amoxicillin	C	Unknown	Unk	Not Reported
	Valproate Semisodium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16454098	EXPEDITED (15-DAY)		HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-034474			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acid Fast Bacilli Infection; Respiratory Failure	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo	
	Tobramycin			S		250 Milligram		Not Reported	
	Adalat XL			C	Unknown	Unk		Not Reported	
	Primidone			C	Unknown	Unk		Not Reported	
	Synthroid			C	Unknown	Unk		Not Reported	
	Ventolin			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16455547	EXPEDITED (15-DAY)		DE, HO, OT	CA-APOTEX-2019AP016529		19 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bipolar Disorder; Metabolic Acidosis; Overdose; Toxicity To Various Agents	Ciprofloxacin			S	Oral	Unk		Apotex
	Amitriptyline			S	Oral	Unk		Apotex
	Azithromycin			S	Oral	Unk		Apotex
	Acetaminophen W/Codeine Phosphate			S	Oral	Unk		Not Reported
	Aerius /01009701/			S	Oral	Unk		Not Reported
	Caffeine			S	Oral	Unk		Not Reported
	Caffeine			S	Oral	Unk		Not Reported
	Codeine			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16455836	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034329			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Gonorrhoea	Azithromycin			S	Unknown	Unk		Aurobindo
	Ceftriaxone Sodium			S	Unknown	Unk		Not Reported
	Remicade			S	Intravenous (not otherwise specified)	640 Milligram		Not Reported
	Flovent			C	Unknown	Unk		Not Reported
	Keppra			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	10 Milligram, Once A Day		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16455839	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034309			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Serum Sickness; Therapeutic Product Effect Incomplete	Azithromycin			S		Unk		Aurobindo	
	Arnuity Ellipta			S		Unk		Not Reported	
	Flovent			S		Unk		Not Reported	
	Fluticasone Furoate;Vilanterol Trifenatate			S		Unk		Not Reported	
	Omalizumab			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Singulair			S	Unknown	10 Milligram, Once A Day		Not Reported	
	Ventolin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16456789	NON-EXPEDITED			US-TEVA-2019-US-1062673			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	250mg, 2 Tablets By Mouth On Day 1, Then 1 Tablet By Mouth Every Day For 5 Days For A Total 5 Days		Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16457876	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019262584		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cheilitis; Dermatitis Exfoliative Generalised; Mouth Ulceration	Pantoprazole			S	Oral	20 Milligram, Qd		Pfizer	
	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Zithromax			S	Oral	Unk		Pfizer	
	Flagyl [Metronidazole]			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lasilix [Furosemide]	S	otherwise specified)	Respiratory (inhalation)	40 Milligram, Qd	Not Reported
Rocephine	S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jun-2019	16460350	NON-EXPEDITED			US-PFIZER INC-2019262619			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	11882914	EXPEDITED (15-DAY)		HO, LT, OT	US-INDIVIOR LIMITED-INDV-086674-2015		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cyanosis; Drug Interaction; Hypoxia; Mental Impairment; Pneumonia; Respiratory Distress; Respiratory Failure; Respiratory Symptom; Transaminases Increased	Suboxone			S	Unknown	Unknown		Reckitt Benckiser	
	Lorazepam			S	Unknown	Unknown		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16425524	NON-EXPEDITED			US-PFIZER INC-2019249557		45 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Keflex [Cefalexin]			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16427322	EXPEDITED (15-DAY)		DE, OT	PHHY2019UA135192		52 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Pulmonary Necrosis	Amoksiklav			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Cefaxon [Ceftriaxone Sodium]			S	Unknown	Unk		Not Reported	
	Amoxil			S	Unknown	Unk		Not Reported	
	Alfa-Tocoferol			S	Unknown	Unk		Not Reported	
	Dihydroquercetin			S	Unknown	Unk		Not Reported	
	Mexidol			S	Unknown	Unk		Not Reported	
	Meldonium			S	Unknown	Unk		Not Reported	
	Probucolum			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16461659	EXPEDITED (15-DAY)		OT	TR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-211095		39 YR	Female	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Dyspnoea; Nausea; Skin Reaction; Vomiting	Azithromycin			S	Unknown	500 Milligram, Daily		Sun	
	Ofloxacin			S	Unknown	400 Milligram, Daily		Ranbaxy	
	Gentamicin			S	Unknown	4 Microgram/Kilogram, Daily, On Days 8-12		Taro	
	Doxycycline			S	Unknown	200 Milligram, Daily, On Days 1-7		Sun	
	Sulphamethoxazole + Trimethoprim			S	Unknown	800/160 Mg/Day		Mutual	
	Rifampicin			S	Unknown	600 Milligram, Daily		Not Reported	
	Ceftriaxone			C	Unknown	2 Gram, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rifabutin			C	Unknown	600 Milligram, Daily			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16461728	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034438			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Atrovent			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	1 Dosage Form, Once A Day		Not Reported	
	Ipratropium Bromide;Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Omalizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			S	Oral	45 Milligram		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Seebri Breezhaler			S	Unknown	1 Dosage Form, Once A Day		Not Reported	
	Singulair			S	Oral	10 Milligram, Once A Day		Not Reported	
	Theophylline			S	Oral	450 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16461744	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034475			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Pruritus	Azithromycin			S	Oral	500 Units Once		Aurobindo	
	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported	
	Cefazolin			S	Intraperitoneal	1500 Milligram, Daily		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Bisoprolol			C	Unknown	Unk		Not Reported	
	Docusate			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eprex	C	Unknown	Unk	Not Reported
Ergocalciferol	C	Unknown	Unk	Not Reported
Fluticasone	C	Unknown	Unk	Not Reported
Megestrol	C	Unknown	Unk	Not Reported
Nepafenac	C	Unknown	Unk	Not Reported
One Alpha	C	Unknown	Unk	Not Reported
Pantoprazole	C	Unknown	Unk	Not Reported
Salbutamol	C	Unknown	Unk	Not Reported
Sevelamer	C	Unknown	Unk	Not Reported
Sodium Polystyrene Sulfonate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16461995	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034297			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Foetal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo
	Lamivudine			S	Transplacental	150 Milligram		Aurobindo
	Tenofovir			S	Transdermal	300 Milligram		Aurobindo
	Zidovudine			S	Transplacental	Unk		Aurobindo
	Abacavir			S	Transplacental	300 Milligram		Not Reported
	Acyclovir			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Milligram		Not Reported
	Prezista			S	Transplacental	600 Milligram		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Milligram		Not Reported
	Ritonavir			S	Transplacental	100 Milligram		Not Reported
	Magnesium Gluconate			C	Unknown	Unk		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16462011	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034421			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Back Pain; Headache; Herpes Zoster; Lung Cancer Metastatic; Lymphoma; Nasal Congestion; Nasopharyngitis; Poor Quality Sleep; Productive Cough; Skin Lesion	Azithromycin			S	Oral	1 Dosage Form		Aurobindo	
	Diltiazem			S	Oral	1 Dosage Form, Once A Day		Not Reported	
	Esomeprazole			S	Oral	1 Dosage Form, Two Times A Day		Not Reported	
	Xolair			S	Subcutaneous	375 Milligram, 1 Every 2 Weeks		Not Reported	
	Xolair			S	Subcutaneous	375 Milligram, 1 Every 2 Weeks		Not Reported	
	Xolair			S	Subcutaneous	375 Milligram, 1 Every 2 Weeks		Not Reported	
	Xolair			S	Subcutaneous	375 Milligram, 1 Every 2 Weeks		Not Reported	
	Xolair			S	Subcutaneous	375 Milligram, 1 Every 2 Weeks		Not Reported	
	Asa			C	Oral	1 Dosage Form, Once A Day		Not Reported	
	Rhinocort			C	Nasal	4 Dosage Form, Two Times A Day		Not Reported	
	Rhinocort Singulair			C	Oral	1 Dosage Form, Once A Day		Not Reported	
				C				Not Reported	
	Spiriva			C		2 Dosage Form, Once A Day		Not Reported	
	Symbicort			C		2 Dosage Form, 3 Times A Day		Not Reported	
	Synthroid			C	Oral	1 Dosage Form, Once A Day		Not Reported	
	Ventolin			C		2 Dosage Form		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16462385	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2019254098		23 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Lip Swelling; Pharyngitis; Rash; Rash Papular	Rebamipide			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Pfizer	
	Transamin			S	Oral	Unk		Not Reported	
	Loxonin			S	Oral	Unk		Not Reported	
	Meiact			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16464446	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1058028		152 DAY	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Medication Error; Vomiting	Azithromycin			S	Oral	7.5 Milliliter, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16465443	EXPEDITED (15-DAY)		DE, HO, LT, OT	GB-MYLANLABS-2019M1057807		66 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Drug Ineffective; Lung Opacity; Lymphopenia; Off Label Use; Pneumocystis Jirovecii Pneumonia; Pneumomediastinum; Respiratory Failure; Sepsis; Syncope	Vancomycin			S	Unknown	Unk		Not Reported	
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported	
	Folinic Acid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Temozolomide			S	Oral	150 Milligram/Sq. Meter, Qd (On Days 7-11)		Not Reported	
	Temozolomide			S				Not Reported	
	Dexamethasone			S	Unknown	Tapered Dose		Mylan	
	Dexamethasone			S	Unknown	Trade Name: Decadron		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexamethasone	S	Unknown	Trade Name: Decadron	Mylan
Dexamethasone	S	Unknown	Tapered Dose	Mylan
Dexamethasone	S	Oral	4 Milligram, Qd	Mylan
Dexamethasone	S	Oral	4 Milligram, Qd	Mylan
Dexamethasone	S	Oral	4 Milligram, Qd	Mylan
Dexamethasone	S	Oral	4 Milligram, Qd	Mylan
Rituximab	S	Intravenous (not otherwise specified)	On Days 3, 10, 17, 24	Mylan
Rituximab	S			Mylan
Furosemide	S	Unknown	Unk	Mylan
Methotrexate	S	Intravenous (not otherwise specified)	On Day 1 And 15	Mylan
Bactrim	S	Intravenous (not otherwise specified)	Unk	Mylan
Coumadin	C	Unknown	Unk	Mylan
Levetiracetam	C	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2019	16469287	DIRECT	Y				48 YR	Female	PRI

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Rash Pruritic	Azithromycin			S	Intravenous drip			Fresenius Kabi

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	12356903	NON-EXPEDITED			US-PFIZER INC-2016252232		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Premarin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Biaxin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Endocet		S		Unk			Not Reported	
	Motrin		S		Unk			Not Reported	
	Bactrim		S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	15535739	NON-EXPEDITED		OT	US-PFIZER INC-2018424369		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Tinnitus	Zithromax			S	Oral	Unk		Pfizer	
	Celebrex			C		Unk		Not Reported	
	Amitriptyline			C		Unk		Not Reported	
	Duloxetine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	15952468	NON-EXPEDITED			US-PFIZER INC-2019050837		95 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Height Decreased	Zithromax			S		Unk, 1x/Day		Pfizer	
	Eliquis			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16244798	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019176670		77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Taste Disorder; Weight Decreased	Azithromycin			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16466893	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-034451			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Maternal Exposure During Pregnancy	Abacavir+Lamivudine	S	Unknown	Unk	Aurobindo
	Efavirenz	S	Unknown	Unk	Aurobindo
	Azithromycin	S	Unknown	1 Gram, 3 Times/Wk	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468221	EXPEDITED (15-DAY)	LT		PHHY2019IT144134		20 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Hypoglycaemia; Respiratory Failure	Tegretol			S	Oral	8 G, Total		Novartis
	Paroxetine			S	Oral	20 Mg, Total		Not Reported
	Quetiapine Fumarate			S	Oral	1 G, Total		Not Reported
	Azithromycin			S	Oral	1500 Mg, Total		Not Reported
	Novorapid			S	Subcutaneous	2 Df, Total		Not Reported
	Lobivon			S	Oral	140 Mg, Total		Not Reported
	Amisulpride			S	Oral	600 Mg, Total		Not Reported
	En			S	Oral	20 Mg, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468664	EXPEDITED (15-DAY)	HO		MY-PFIZER INC- 2019265597		11 YR	Female	MYS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Bilirubin Increased; Coagulation Test Abnormal; Hepatic Enzyme Increased	Zithromax			S	Intravenous (not otherwise specified)	200 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16468845	NON-EXPEDITED			US-PFIZER INC- 2019267335			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azithromycin	S						Pfizer
	Azithromycin	S						Pfizer
	Mucinex D	S			Unk			Not Reported
	Mucinex D	S						Not Reported
	Mucinex D	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jun-2019	16469166	EXPEDITED (15-DAY)		OT	PHHY2019HR143001			Unknown	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apathy; Asthenia; Blood Pressure Increased; Circulatory Collapse; Constipation; Crying; Dizziness; Dyschezia; Gastrointestinal Pain; Hot Flush; Muscle Contracture; Muscle Spasticity; Myalgia; Nervousness; Night Sweats; Pain In Extremity; Palpitations; Panic Attack; Personality Change; Restlessness; Tendon Pain	Levofloxacin			S	Unknown	Unk		Novartis
	Sumamed			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	15535668	NON-EXPEDITED			US-PFIZER INC-2018424401		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use; Weight Increased	Zithromax			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Zithromax			S		Unk (7 Day Pack)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16252624	NON-EXPEDITED			US-PFIZER INC-		53 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2019177684

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lip Swelling	Zithromax			S		Unk		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16337120	NON-EXPEDITED			US-PFIZER INC-2019208477		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Dextromethorphan Hbr		Y	S		Unk		Unknown
	Furosemide			S		Unk		Unknown
	Gabapentin			S		Unk		Pfizer
	Spironolactone			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Methotrexate Sodium			S		Unk		Pfizer
	Diconazol			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Sulfur Dioxide			S		Unk		Not Reported
	Warfarin			S		Unk		Not Reported
	Coreg			S		Unk		Not Reported
	Leflunomide			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16472808	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-03918		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Reaction With Eosinophilia And Systemic Symptoms	Vancomycin	S		Unk	Lupin
	Azithromycin	S	Unknown	Unk	Lupin
	Meropenem	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Lupin
	Clindamycin	S	Unknown	Unk	Not Reported
	Gentamicin	S	Unknown	Unk	Not Reported
	Piperacillin And Tazobactam	S	Unknown	Unk	Not Reported
	Amoxicillin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16473377	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-035921			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cheilitis; Dermatitis Exfoliative Generalised; Mouth Ulceration	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Pantoprazole			S	Oral	20 Milligram, Daily		Aurobindo
	Lasilix			S	Respiratory (inhalation)	40 Milligram, Daily		Not Reported
	Rocephine			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Zithromax			S	Oral	Unk		Not Reported
	Flagyl			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16473389	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1068027		61 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Hepatocellular Injury	Paracetamol			S	Oral	4 Gram Daily;		Not Reported
	Azithromycine Anhydre			S	Oral	500 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16473450	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019271913		50 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Pneumonia	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16473917	EXPEDITED (15-DAY)		HO	US-ROCHE-2342063		19 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Bacterial Infection; Pulmonary Haemorrhage	Pulmozyme			S	Unknown			Not Reported	
	Cayston			S	Respiratory (inhalation)	Ongoing: Yes		Not Reported	
	Symdeko			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16474186	NON-EXPEDITED			US-PFIZER INC-2019264787		48 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16474281	NON-EXPEDITED			US-PFIZER INC-2019271290			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rhinorrhoea	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16474285	NON-EXPEDITED			US-PFIZER INC-2019265083			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16474501	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP016842		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia; Rash Pustular; Staphylococcal Infection; Syncope	Fluoxetine			S	Unknown	Unk		Apotex	
	Azithromycin			S	Oral	1 Df, Qd, 1 Every 1 Day		Apotex	
	Xolair			S	Unknown	300 Mg, Unk		Not Reported	
	Avamys			C	Unknown	Unk		Not Reported	
	Intuniv			C	Unknown	Unk		Not Reported	
	Prozac			C	Unknown	Unk		Not Reported	
	Quetiapine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jun-2019	16474959	EXPEDITED (15-DAY)		HO	ES-TEVA-2019-ES-1068114		61 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Unknown	500 Mg Day		Not Reported	
	Cisatracurio (2738a)			S	Intravenous (not otherwise specified)	120 Mmg Every 6 Hours		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxona (501a)

S

Intravenous (not
otherwise specified)

2 Gr Day

Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Jun-2019	16475082	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1059193		28 YR	Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Insomnia	Azithromycin			S	Oral	250 Dosage Form			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16477396	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1067299		68 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cheilitis; Dermatitis Exfoliative Generalised; Mouth Ulceration	Levofloxacin			S	Intravenous (not otherwise specified)				Teva
	Pantoprazole			S	Oral				Teva
	Lasilix			S	Respiratory (inhalation)				Not Reported
	Rocephine			S	Intravenous (not otherwise specified)				Not Reported
	Zithromax			S	Oral				Not Reported
	Flagyl			S	Intravenous (not otherwise specified)				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Jun-2019	16478036	EXPEDITED (15-DAY)		LT	IT-ASTRAZENECA-2019SE91254		20 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Quetiapine Fumarate			S	Oral	1.0g Once/Single Administration			Zeneca
	Novorapid Flexpen			S	Subcutaneous	2.0df Once/Single Administration			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paroxetine	S	Oral	20.0mg Once/Single Administration	Not Reported
Tegretol	S	Oral	8.0g Once/Single Administration	Not Reported
Lobivon	S	Oral	140.0mg Once/Single Administration	Not Reported
Amisulpride	S	Oral	600.0mg Once/Single Administration	Not Reported
Azithromycin	S	Oral	1500.0mg Once/Single Administration	Not Reported
En	S	Oral	20.0mg Once/Single Administration	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16479305	EXPEDITED (15-DAY)		HO, OT	US-VERTEX PHARMACEUTICALS- 2019-005851		19 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Pulmonary Haemorrhage	Symdeko			S	Oral			Vertex	
	Cayston			S	Respiratory (inhalation)	75 Mg, Qd		Not Reported	
	Pulmozyme			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16479353	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS- 2019M1058012		23 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Condition Aggravated; Granulomatosis With Polyangiitis; Haemoptysis	Azithromycin			S		Unk		Not Reported	
	Ceftriaxone /00672201/			S		Unk		Mylan	
	Oseltamivir			S		Unk		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jun-2019	16479955	EXPEDITED (15-DAY)		HO	FR-FRESENIUS KABI-FK201906735		68 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cheilitis; Dermatitis Exfoliative Generalised; Mouth Ulceration	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported	
	Furosemide			S	Respiratory (inhalation)			Not Reported	
	Pantoprazole			S	Oral			Not Reported	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Metronidazole Benzoate			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	15784110	NON-EXPEDITED		HO	PHEH2018US055370		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nasopharyngitis; Pruritus; Psoriasis; Rash; Urticaria; Urticaria	Cosentyx			S	Subcutaneous	300 Mg, Qmo (Every 4 Weeks)		Novartis	
	Prednisone			S	Unknown			Not Reported	
	Z-Pak			S	Unknown			Not Reported	
	Metformin			C	Unknown			Not Reported	
	Synthroid			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	15999347	NON-EXPEDITED			US-PFIZER INC-2019078247		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S	Oral	Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16459130	EXPEDITED (15-DAY)		HO	PHHY2019DK141563		80 YR	Female	DNK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatine Increased; Hypercalcaemia	Azithromycin Sandoz			S	Oral	750 Mg, Qw		Novartis	
	Simvastatin Actavis			C	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16483151	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019267805			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cellulitis; Off Label Use; Product Use In Unapproved Indication	Zithromac 250mg			S		250 Mg, 1x/Day		Pfizer	
	Cefazolin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16483223	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2019268248		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Paracetamol			S	Oral	4 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16483893	NON-EXPEDITED			US-TEVA-2019-US- 1058205		7 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16485077	EXPEDITED (15-DAY)		OT	PHEH2019US026453			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Mycobacterium Abscessus Infection	Azithromycin			S	Oral	Unk		Novartis	
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16486610	EXPEDITED (15-DAY)		OT	HR-TEVA-2019-HR- 1070044		43 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apathy; Asthenia; Blood Pressure Increased; Circulatory Collapse; Constipation; Crying; Dizziness; Dyschezia; Gastrointestinal Pain; Hot Flush; Muscle Contracture; Muscle Spasticity; Myalgia; Nervousness; Night Sweats; Pain In Extremity; Palpitations; Panic Attack; Personality Change; Restlessness; Tendon Pain	Sumamed			S	Unknown			Not Reported	
	Levofloxacinum			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16487684	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2019M1059873		74 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Diarrhoea; Rectal Haemorrhage	Azithromycin	S	Oral	Unk	Not Reported
	Flagyl /00012501/	S	Oral	Unk	Mylan
	Deroxat	S		Unk	Mylan
	Candesartan Cilexetil	C		8 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16487977	EXPEDITED (15-DAY)		DE, OT	PT-MYLANLABS- 2019M1059452		56 YR	Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Failure; Multiple Organ Dysfunction Syndrome	Azithromycin			S	Unknown	Unk		Not Reported
	Rifampicin			S	Unknown	Unk		Mylan
	Ethambutol			S	Unknown	Unk		Mylan
	Piperacillin/Tazobactam			C	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2019	16701934	DIRECT	Y				67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Constipation; Gingival Operation; Impaired Healing	Azithromycin 250mg 6 Tab Pack			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	15551291	EXPEDITED (15-DAY)		OT	GB-MYLANLABS- 2018M1079856		27 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Condition Aggravated; Drug Resistance; Malaise; Pain In Extremity; Urethritis Mycoplasmal; Urinary Tract Infection	Doxycycline			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	1 G, Unk		Not Reported
	Azithromycin			S	Unknown	250 Mg, Qd (4 Days)		Not Reported
	Azithromycin			S	Unknown	1 G, Unk		Not Reported
	Azithromycin			S	Unknown	500 Ot, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Moxifloxacin	S	Unknown	1 Dosage Form, Total	Not Reported
Pristinamycin	S	Unknown	1 G, Qd	Mylan
Pristinamycin	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16116037	EXPEDITED (15-DAY)		OT	JP-GLAXOSMITHKLINE-A20016226		54 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cellulitis;	Lamivudine.			S	Oral	150 Mg, Bid		Viiv
Erectile Dysfunction;	Epzicom			S	Oral	1 Df, 1d		Viiv
Folliculitis; Gastric Polyps;	Crixivan			S	Oral	2.4 G, 1d		Not Reported
Gastrooesophageal Reflux Disease; Haemophilic	Crixivan			S	Oral	2.4 G, 1d		Not Reported
Arthropathy; Hepatic Function Abnormal;	Zithromac			S	Oral	600 Mg, Qd		Not Reported
Hepatitis C; Hiatus Hernia;	Zithromac			S	Oral	600 Mg, Qd		Not Reported
Hyperkalaemia;	Zithromac			S	Oral	600 Mg, Qd		Not Reported
Hypertriglyceridaemia;	Zithromac			S	Oral	600 Mg, Qd		Not Reported
Hyperuricaemia;	Zithromac			S	Oral	Unk Unk, Qd		Not Reported
Hypoproteinaemia;	Cycloserine			S	Oral	250 Mg, Bid		Not Reported
Oesophageal Candidiasis;	Prezcobix			S	Oral	1 Df, 1d		Not Reported
Panniculitis; Protein Urine;	Prezistanaive			S	Oral	800 Mg, 1d		Not Reported
Tinea Pedis	Prezistanaive			S	Oral	1 Df, 1d		Not Reported
	Norvir			S	Oral	100 Mg, 1d		Not Reported
	Retrovir			C	Oral	400 Mg, 1d		Not Reported
	Baktar			C	Oral	2 G, Bid		Not Reported
	Kogenate			C	Subcutaneous	1000 Iu, Four To Eight Times Per Month		Not Reported
	Cross Eight M			C	Subcutaneous	1000 Iu, Four To Eight Times Per Month		Not Reported
	Cross Eight M			C		Unk		Not Reported
	Reyataz			C	Oral	300 Mg, 1d		Not Reported
	Truvada			C	Oral	1 Df, 1d		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cilnidipine	C	Unk	Not Reported
Calonal	C	Unk	Not Reported
Lyrica	C	Unk	Not Reported
Furosemide	C	Unk	Not Reported
Diart	C	Unk	Not Reported
Samsca	C	Unk	Not Reported
Blopress	C	Unk	Not Reported
Amlodipine Besilate	C	Unk	Not Reported
Harnal	C	Unk	Not Reported
Vesicare	C	Unk	Not Reported
Gentacin Ointment	C	Unk	Not Reported
Azunol Ointment	C	Unk	Not Reported
Alfacalcidol Capsule	C	Unk	Not Reported
Esanbutol	C	Unk	Not Reported
Feiba	C	Unk	Not Reported
Picosulfate Na Oral Solution	C	Unk	Not Reported
Miya Bm	C	Unk	Not Reported
Teprenone Capsules	C	Unk	Not Reported
Nexium	C	Unk	Not Reported
Magnesium Oxide	C	Unk	Not Reported
Pursennid (Sennoside A+B Calcium)	C	Unk	Not Reported
Amitiza	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16116046	EXPEDITED (15-DAY)		OT	JP-VIIV HEALTHCARE LIMITED-A20016226		54 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Cellulitis;	Lamivudine.			S	Oral	150 Mg, Bid		Viiv
Erectile Dysfunction;	Epzicom			S	Oral	1 Df, 1d		Viiv
Folliculitis; Gastric Polyps;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastroesophageal Reflux Disease; Haemophilic Arthropathy; Hepatic Function Abnormal;	Crixivan	S	Oral	2.4 G, 1d	Not Reported
Hepatitis C; Hiatus Hernia; Hyperkalaemia;	Crixivan	S	Oral	2.4 G, 1d	Not Reported
Hypertriglyceridaemia; Hyperuricaemia;	Zithromac	S	Oral	600 Mg, Qd	Not Reported
Hypoproteinaemia; Oesophageal Candidiasis;	Zithromac	S	Oral	600 Mg, Qd	Not Reported
Panniculitis; Protein Urine; Tinea Pedis	Zithromac	S	Oral	600 Mg, Qd	Not Reported
	Zithromac	S	Oral	600 Mg, Qd	Not Reported
	Zithromac	S	Oral	Unk Unk, Qd	Not Reported
	Cycloserine	S	Oral	250 Mg, Bid	Not Reported
	Prezcobix	S	Oral	1 Df, 1d	Not Reported
	Prezista	S	Oral	800 Mg, 1d	Not Reported
	Prezista	S	Oral	1 Df, 1d	Not Reported
	Norvir	S	Oral	100 Mg, 1d	Not Reported
	Retrovir	C	Oral	400 Mg, 1d	Not Reported
	Baktar	C	Oral	2 G, Bid	Not Reported
	Kogenate	C	Subcutaneous	1000 Iu, Four To Eight Times Per Month	Not Reported
	Cross Eight M	C	Subcutaneous	1000 Iu, Four To Eight Times Per Month	Not Reported
	Cross Eight M	C		Unk	Not Reported
	Reyataz	C	Oral	300 Mg, 1d	Not Reported
	Truvada	C	Oral	1 Df, 1d	Not Reported
	Cilnidipine	C		Unk	Not Reported
	Calonal	C		Unk	Not Reported
	Lyrica	C		Unk	Not Reported
	Furosemide	C		Unk	Not Reported
	Diart	C		Unk	Not Reported
	Samsca	C		Unk	Not Reported
	Blopress	C		Unk	Not Reported
	Amlodipine Besilate	C		Unk	Not Reported
	Harnal	C		Unk	Not Reported
	Vesicare	C		Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gentacin Ointment	C	Unk	Not Reported
Azunol Ointment	C	Unk	Not Reported
Alfacalcidol Capsule	C	Unk	Not Reported
Esanbutol	C	Unk	Not Reported
Feiba	C	Unk	Not Reported
Picosulfate Na Oral Solution	C	Unk	Not Reported
Miya Bm	C	Unk	Not Reported
Teprenone Capsules	C	Unk	Not Reported
Nexium	C	Unk	Not Reported
Magnesium Oxide	C	Unk	Not Reported
Pursennid (Sennoside A+B Calcium)	C	Unk	Not Reported
Amitiza	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16362386	NON-EXPEDITED			US-PFIZER INC-2019227388			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cephalexine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16450903	EXPEDITED (15-DAY)		OT	JP-TEVA-2019-JP-1064171		66 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Prednisolone			S	Oral			Actavis
Mycobacterium Chelonae Infection; Pathogen Resistance; Skin Ulcer; Subcutaneous Abscess	Clarithromycin			S	Unknown			Actavis
	Clarithromycin			S				Actavis
	Methotrexate			S	Oral			Not Reported
	Levofloxacin			S	Oral			Not Reported
	Levofloxacin			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levofloxacin	S		Not Reported
Rifampicin	S	Unknown	Not Reported
Rifampicin	S		Not Reported
Azithromycin	S	Unknown	Not Reported
Azithromycin	S		Not Reported
Aspirin	C	Oral	Not Reported
Itraconazole	C	Unknown	Not Reported
Minocycline	C	Oral	Not Reported
Erythromycin	C	Unknown	Not Reported
Erythromycin	C		Not Reported
Streptomycin	C	Unknown	Not Reported
Streptomycin	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16489378	NON-EXPEDITED			US-PFIZER INC-2019265643			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper	Azithromycin			S	Oral	1000 Mg, Unk (Four 250mg Pills At Once For First Dose)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16489636	NON-EXPEDITED			US-PFIZER INC-2019276586		71 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16493817	NON-EXPEDITED			PHEH2019US027164			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Incorrect Dosage Administered	Azithromycin	S	Unknown	Unk				Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16495103	EXPEDITED (15-DAY)		LT	IT-NOVOPROD-669136		20 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Hypoglycaemia; Respiratory Failure	Novorapid Flexpen			S	Subcutaneous	2 Df		Novo Nordisk
	Paroxetine			S	Oral	20 Mg		Not Reported
	Tegretol			S	Oral	8 G		Not Reported
	Lobivon			S	Oral	140 Mg		Not Reported
	Quetiapine Fumarate			S	Oral	1 G		Not Reported
	Amisulpride			S	Oral	600 Mg		Not Reported
	En			S	Oral	20 Mg		Not Reported
	Azithromycin			S	Oral	1500 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16495622	NON-EXPEDITED			US-PFIZER INC-2019276831			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16495639	NON-EXPEDITED			US-PFIZER INC-2019277207		61 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2019	16497775	EXPEDITED (15-DAY)		OT	CA-			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

GLAXOSMITHKLINE-
CA2019AMR109328

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline
	Breo Ellipta			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Spiriva			S		Unk		Not Reported
	Prednisone			S		Unk Unk, Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	12754251	NON-EXPEDITED			US-PFIZER INC- 2016430643		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Erythromycin			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Ondansetron			S		Unk		Pfizer
	Prednisolone			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Asprin			S		Unk		Not Reported
	Cefalexin			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Cipro [Ciprofloxacin]			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	15270159	NON-EXPEDITED			US-PFIZER INC-2018321771		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16500645	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019268173		38 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Eruption	Coughcode-N			S		Unk		Not Reported	
	Zithromac 250mg			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2019	16500854	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019273192		61 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Cisatracurium Besilate			S	Intravenous (not otherwise specified)	120 Mg, 4x/Day (Every 6 Weeks)		Pfizer	
	Azithromycin			S		500 Mg, Daily (24 Hours)		Pfizer	
	Ceftriaxon			S	Intravenous (not otherwise specified)	2 G, Daily (Every 24 Hours)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	14927424	NON-EXPEDITED			US-PFIZER INC-2018211220		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Novocaine			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16474081	NON-EXPEDITED			US-PFIZER INC-2019269624			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
	Cefdinir			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16507234	NON-EXPEDITED			US-PFIZER INC-2019278225			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Metoprolol Tartrate			S		Unk		Unknown	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16507782	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-212091		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Paracetamol		Y	S	Oral	4 Gram, Daily		Ohm Lab	
	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16510845	EXPEDITED (15-DAY)		LT	IT-ACCORD-135923		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Abuse; Hypoglycaemia; Respiratory Failure	Quetiapine	S	Oral		Not Reported
	Azithromycin	S	Oral		Not Reported
	Novorapid Flexpen	S	Subcutaneous	Strength:100 Units / ML, Solution For Injection In Pre-Filled Perfusion	Not Reported
	Paroxetine	S	Oral		Not Reported
	Tegretol	S	Oral	Strength: 400 Mg	Not Reported
	Lobivon	S	Oral	Strength: 5 Mg	Not Reported
	Amisulpride	S	Oral		Not Reported
	En	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16514308	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-212253		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective	Azithromycin			S	Oral	500 Milligram, Daily		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16514589	EXPEDITED (15-DAY)		DS	FR-MYLANLABS- 2019M1060504		54 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Visual Impairment	Azithromycin			S	Oral	250 Milligram, Qd (Total Daily Dose: 250 Mg Unit Dose: 250 Mg)		Not Reported
	Izilox			S	Oral	400 Milligram, Qd (Total Daily Dose: 400 Mg Unit Dose: 400 Mg)		Mylan
	Myambutol			S	Oral	800 Milligram, Qd (Total Daily Dose: 800 Mg Unit Dose: 800 Mg)		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16514624	NON-EXPEDITED			US-TEVA-2019-US-1068001			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Onychomycosis	Azithromycin Tablets			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16514954	NON-EXPEDITED			US-JNJFOC-20190632577			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis	Imbruvica			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16517427	EXPEDITED (15-DAY)		OT	GR-PFIZER INC-2019277187			Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Growth Abnormality; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Pfizer	
	Cefoxitin			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16517801	NON-EXPEDITED			US-TEVA-2019-US-1061891			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Vomiting	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16518343	NON-EXPEDITED			US-PFIZER INC-2019280420		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16518347	NON-EXPEDITED			US-PFIZER INC-2019280843		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Entuss			S		Unk		Not Reported	
	Dilaudid			S		Unk		Not Reported	
	Nubain			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16518382	NON-EXPEDITED			US-PFIZER INC-2019281505		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16520520	EXPEDITED (15-DAY)		LT	IT-TEVA-2019-IT-1071019		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Azithromycin			S	Oral			Not Reported	
	Paroxetine			S	Oral			Teva	
	Quetiapine			S	Oral			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novorapid Flexpen 100 Units/ML Solution For Injection In Pre- Filled Pe	S	Subcutaneous	Not Reported
Tegretol 400 Mg Compresse A Rilascio Modificato	S	Oral	Not Reported
Lobivon 5 Mg Compresse	S	Oral	Not Reported
Amisulpride	S	Oral	Not Reported
En	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jul-2019	16524648	NON-EXPEDITED			US-BAUSCH-BL-2019- 018502			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Metronidazole			S	Unknown			Not Reported
	Doxycycline Hyclate			S	Unknown			Not Reported
	E-Mycin			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Oxycodone Hydrochloride			S	Unknown			Not Reported
	Cefixime			S	Unknown			Not Reported
	Fentanyl			S	Unknown			Not Reported
	Cipro			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Sertraline Hydrochloride			S	Unknown			Not Reported
	Clindamycin Hydrochloride			S	Unknown			Not Reported
	Cefalexin			S	Unknown			Not Reported
	Metaxalone			S	Unknown			Not Reported
	Hydrocodone			S	Unknown			Not Reported
	Tramadol			S	Unknown			Not Reported
	Lansoprazol			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	14288948	EXPEDITED (15-DAY)		DE, HO, OT	GB-MYLANLABS-2017M1078822			Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Azithromycin			S	Unknown	Unk		Not Reported
Abdominal Pain Upper;	Esbriet			S	Oral	2403 Mg, Unk		Mylan
Alopecia; Anxiety;	Esbriet			S	Oral	2403 Mg, Unk		Mylan
Asthenia; Breast Pain;	Esbriet			S	Oral	801 Milligram, Qd		Mylan
Cataract; Cellulitis; Chest Pain; Condition	Esbriet			S	Oral	801 Milligram, Qd		Mylan
Aggravated; Cough;	Esbriet			S	Oral	Full Dose		Mylan
Death; Depressed Mood;	Pirfenidone			S	Oral	2403 Milligram, Qd		Mylan
Depression; Drug	Pirfenidone			S	Oral	2403 Milligram, Qd		Mylan
Ineffective; Dyspnoea;								
Erythema; Fatigue;								
Flushing; Frequent Bowel Movements;								
Gastrointestinal Disorder;								
Gastrointestinal Pain;								
Gastrooesophageal Reflux Disease; General Physical Health Deterioration;								
Haemoptysis; Headache;								
Heart Rate Increased;								
Hiatus Hernia;								
Hypotension; Increased Upper Airway Secretion;								
Inguinal Hernia; Insomnia;								
Jaw Cyst; Lethargy; Lower Respiratory Tract Infection; Malaise;								
Musculoskeletal Stiffness;								
Nasopharyngitis;								
Osteomyelitis; Oxygen Saturation Decreased;								
Panic Attack; Pneumonia;								
Pneumonia; Productive Cough; Pruritus;								
Pulmonary Function Test Decreased; Pulmonary								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oedema; Pulmonary Pain;
Rash; Seasonal Allergy;
Seborrhoea; Skin Irritation;
Skin Ulcer; Sunburn;
Swelling; Tearfulness;
Therapeutic Product Effect
Decreased; Tinnitus;
Tooth Injury; Total Lung
Capacity Decreased;
Tremor; Ulcer; Upper-
Airway Cough Syndrome;
Vertigo; Viral Infection;
Weight Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	15427251	EXPEDITED (15-DAY)		HO, LT, OT	PHHY2018GB103990		9 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Reaction With Eosinophilia And Systemic Symptoms; Eosinophilia; Leukocytosis; Myalgia; Purpura; Pyrexia; Rash Erythematous; Rash Maculo-Papular; Thrombocytopenia; Transaminases Increased	Amikacin Sulfate			S	Unknown	Nebulised		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Novartis
	Azithromycin			S	Oral	Unk		Novartis
	Teicoplanin			S	Intravenous (not otherwise specified)			Not Reported
	Teicoplanin			S				Not Reported
	Co-Trimoxazole			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Co-Trimoxazole			S	Oral	Unk		Not Reported
	Moxifloxacin Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Moxifloxacin Hydrochloride			S	Oral	Unk		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefoxitin	S	Unknown	Not Reported
Chlorphenamine	C	Oral	Not Reported
Prednisolone	C	Oral	Unk
SulfametoXazol/Trimetoprim	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16521414	EXPEDITED (15-DAY)	HO		ES-ACCORD-136208		61 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Cisatracurium/Cisatracurium Besilate			S	Intravenous (not otherwise specified)	120 Mg Every 6 Hours		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gr Day		Not Reported
	Azithromycin			S	Unknown	500 Mg Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16526057	EXPEDITED (15-DAY)	HO		FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-212078		68 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cheilitis; Dermatitis	Pantoprazole			S	Oral	20 Milligram, Daily		Sun
Exfoliative Generalised; Mouth Ulceration	Levofloxacin			S	Intravenous (not otherwise specified)	()		Ranbaxy
	Lasilix			S	Respiratory (inhalation)	40 Milligram, Daily		Not Reported
	Rocephine			S	Intravenous (not otherwise specified)	()		Not Reported
	Zithromax			S	Oral	()		Not Reported
	Flagyl			S	Intravenous (not otherwise specified)	()		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16526592	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1062024		47 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Gonorrhoea; Rash Maculo-Papular	Azithromycin			S		Unk		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk Unk, Qw		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16527067	NON-EXPEDITED			US-PFIZER INC-2019274082		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Cefaclor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16527073	NON-EXPEDITED			US-PFIZER INC-2019283276		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16527807	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1071859			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis;	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported	
	Levofloxacin			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Arava			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment Failure	Benadryl	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Cimzia Single-Use Prefilled	S	Unknown		Not Reported
	Demerol	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Unknown		Not Reported
	Imuran	S	Unknown		Not Reported
	Plaquenil	S	Unknown		Not Reported
	Procytox	S	Unknown		Not Reported
	Simponi	S	Unknown		Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Xeljanz	S	Oral	10 Milligram Daily;	Not Reported
	Ezetrol	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16527818	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019279989			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Premature Baby	Novatrex			S	Transplacental			Pfizer
	Cimzia			S	Transplacental	400 Mg, Single		Not Reported
	Cortancyl			C	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16528589	EXPEDITED (15-DAY)		OT	PHHY2019US148646		38 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Chills;	Azithromycin			S	Unknown			Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eosinophilia; Erythema;
Leukocytosis;
Neutrophilia; Oedema
Peripheral; Product Use In
Unapproved Indication;
Pruritus; Rash; Rash
Morbilloform; Rash
Pustular; Skin Exfoliation;
Weight Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jul-2019	16528681	NON-EXPEDITED			US-TEVA-2019-US-1065942			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysuria	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	15888416	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1006025			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Levofloxacin			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Arava			S	Unknown			Not Reported	
	Benadryl			S	Unknown			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Cimzia			S	Unknown			Not Reported	
	Demerol			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Unknown			Not Reported	
	Imuran			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Pms-Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Procytox 2000mg/Vial	S	Unknown	Not Reported
	Simponi	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Azithromycin	S	Unknown	250 Milligram Daily; Not Reported
	Procytox	S	Unknown	Not Reported
	Ezetrol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16529776	EXPEDITED (15-DAY)		LT, OT	IT-AUROBINDO-AUR- APL-2019-036956			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Paroxetine			S	Oral	20 Milligram, Total		Aurobindo	
	Quetiapine			S	Oral	1 Gram, Total		Aurobindo	
	Amisulpride			S	Oral	600 Milligram, Total		Not Reported	
	Azithromycin			S	Oral	1500 Milligram, Total		Aurobindo	
	Novorapid			S	Subcutaneous	2 Dosage Form, Total		Not Reported	
	Tegretol			S	Oral	8 Gram, Total		Not Reported	
	Lobivon			S	Oral	140 Milligram, Total		Not Reported	
	En			S	Oral	20 Milligram, Total		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16530664	EXPEDITED (15-DAY)		LT, OT	IT-LUPIN PHARMACEUTICALS INC.-2019-04118		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Paroxetine			S	Oral	20 Milligram, Single		Lupin	
	Quetiapine Fumarate			S	Oral	1 Gram, Single		Lupin	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	1500 Milligram, Single	Lupin
Novorapid	S	Subcutaneous	2 Dosage Form, Single	Not Reported
Tegretol	S	Oral	8 Gram, Single	Not Reported
Lobivon	S	Oral	140 Milligram, Single	Not Reported
Amisulpride	S	Oral	600 Milligram, Single	Not Reported
En (Delorazepam)	S	Oral	20 Milligram, Single	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16532364	EXPEDITED (15-DAY)		LT	IT-PFIZER INC-2019281923		20 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse; Hypoglycaemia; Respiratory Failure	Azithromycin			S	Oral	1500 Mg, Total		Pfizer
	Novorapid			S	Subcutaneous	2 Df, Total		Not Reported
	Paroxetine			S	Oral	20 Mg, Total		Not Reported
	Tegretol			S	Oral	8 G, Total		Not Reported
	Lobivon			S	Oral	140 Mg, Total		Not Reported
	Quetiapine Fumarate			S	Oral	1 G, Total		Not Reported
	Amisulpride			S	Oral	600 Mg, Total		Not Reported
	En			S	Oral	20 Mg, Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Jul-2019	16532912	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-886		88 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea	Maximum Strength Mucinex Dm Tablets			S	Unknown	1200 Mg, Single		Not Reported
	Benzonatate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	15270231	NON-EXPEDITED			US-PFIZER INC-2018321320		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Sulfadiazine Silver			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	15785128	NON-EXPEDITED			US-PFIZER INC-2019002110		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	15886583	NON-EXPEDITED			US-PFIZER INC-2019041351		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Fentanyl Citrate			S		Unk		Unknown	
	Metoprolol Tartrate			S		Unk		Unknown	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cipro [Ciprofloxacin Hydrochloride Monohydrate]			S		Unk		Not Reported	
	Fenofibrate			S		Unk		Not Reported	
	Hydralazine Hcl			S		Unk		Not Reported	
	Hydrocodone Bitartrate			S		Unk		Not Reported	
	Niaspan			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oxycodone	S	Unk	Not Reported
Tetanus Toxoid	S	Unk	Not Reported
Trilipix	S	Unk	Not Reported
Bactrim Ds	S	Unk	Not Reported
Aspirin	S	Unk	Not Reported
Ceclor	S	Unk	Not Reported
Codeine Sulfate	S	Unk	Not Reported
Entex La (Guaifenesin\Phenylephrine Hydrochloride)	S	Unk	Not Reported
Tricor [Fenofibrate]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16072220	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC- 2019109292		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptococcosis; Drug Ineffective; Drug Intolerance; Drug Resistance; Enterocolitis; Multiple Organ Dysfunction Syndrome; Mycobacterium Avium Complex Infection; Nosocomial Infection	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Fluconazole			S	Oral	Unk		Pfizer
	Rifabutin			S	Oral	Unk		Pfizer
	Amikacin			S	Parenteral	Unk		Not Reported
	Clarithromycin			S	Oral	Unk		Not Reported
	Ethambutol			S	Oral	Unk		Not Reported
	Moxifloxacin Hydrochloride			S		Unk		Not Reported
	Mycophenolic Acid Sodium			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Rifampin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16531208	EXPEDITED (15-DAY)		LT, OT	IT-APOTEX-2019AP017733		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Quetiapine			S	Oral	1 G, In Total		Apotex	
	Paroxetine			S	Oral	20 Mg, In Total		Apotex	
	Azithromycin			S	Oral	1500 Mg, In Total		Not Reported	
	Novorapid			S	Subcutaneous	2 Df, In Total		Not Reported	
	Tegretol			S	Oral	8 G, In Total		Not Reported	
	Lobivon			S	Oral	140 Mg, In Total		Not Reported	
	Amisulpride			S	Oral	600 Mg, In Total		Not Reported	
	En			S	Oral	20 Mg, In Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16532825	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019279926		39 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Pregnancy On Oral Contraceptive	Novatrex			S	Oral			Pfizer	
	Cimzia			S	Subcutaneous	400 Mg, Single		Not Reported	
	Cortancyl			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16534493	EXPEDITED (15-DAY)		OT	PHHY2019US153182		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Disease Progression; Pain; Peripheral Swelling; Product Use In Unapproved Indication; Rash; Respiratory Disorder; Respiratory	Mycophenolate Mofetil			S	Unknown			Novartis	
	Prednisone			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Failure; Therapy Non-Responder	Cephalexin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16535051	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1062144		79 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Acute; Chronic Obstructive Pulmonary Disease	Amoxicillin/Clavulanic Acid			S		Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Telmisartan			S		Unk		Not Reported	
	Ibuprofen			S		Unk		Not Reported	
	Doxycycline			S		Unk		Mylan	
	Frusemide /00032601/			S		40 Milligram, Qd		Mylan	
	Eliquis			S		5 Milligram, Bid		Mylan	
	Seretide			S		250/25 Mcg. Bd		Mylan	
	Tiotropium			S		18 Microgram, Qd		Mylan	
	Atenolol			S		50 Milligram, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16535617	NON-EXPEDITED			US-PFIZER INC-2019285569		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Oxycodone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16536264	NON-EXPEDITED			US-PFIZER INC-2019280362		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Drug Intolerance	Azithromycin	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Clindamycin Hcl	S	Unk	Pfizer
	Doxycycline Hyclate	S	Unk	Pfizer
	Augmentine [Amoxicillin;Clavulanic Acid]	S	Unk	Not Reported
	Levaquin	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jul-2019	16536334	NON-EXPEDITED		OT	PHEH2019US027972			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression; Mycobacterium Abscessus Infection	Azithromycin			S	Unknown	Unk		Novartis
	Rifampin			S	Unknown	Unk		Not Reported
	Ethambutol			S	Unknown	Unk		Not Reported
	Amikacin			S	Respiratory (inhalation)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	11865978	NON-EXPEDITED			US-PFIZER INC- 2015431341		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539121	EXPEDITED (15-DAY)		LT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-212862		20 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Abuse;	Azithromycin			S	Oral	In Total		Sun

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypoglycaemia; Respiratory Failure	Paroxetine	S	Oral	In Total	Sun
	Novorapid Flexpen 100 Units/ML Solution For Injection In Pre- Filled Pe	S	Subcutaneous	In Total	Not Reported
	Tegretol 400 Mg Compresse A Rilascio Modificato	S	Oral	In Total	Not Reported
	Lobivon 5 Mg Compresse	S	Oral	In Total	Not Reported
	Quetiapine Fumarate	S	Oral	In Total	Not Reported
	Amisulpride	S	Oral	In Total	Not Reported
	En	S	Oral	In Total	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539747	NON-EXPEDITED			US-PFIZER INC- 2019287169		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Compazine			S		Unk		Not Reported
	Darvocet			S		Unk		Not Reported
	Tizanidine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539753	NON-EXPEDITED			US-PFIZER INC- 2019290596			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Septra			S		Unk		Pfizer
	Cipro [Ciprofloxacin]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16539890	NON-EXPEDITED			US-PFIZER INC- 2019281274		62 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Rash	Zithromax	S	Unk	Pfizer
	Vicodin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jul-2019	16541678	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1072442		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Azithromycin			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Oral	50 Milligram Daily;		Teva
	Quetiapine Fumarate			S	Oral	100 Milligram Daily;		Teva
	Cipro			S	Oral	500 Milligram Daily;		Not Reported
	Cipro			S	Unknown			Not Reported
	Amoxicillin			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported
	Valproate Semisodium			C	Unknown			Not Reported
	Zyprexa			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	11453291	NON-EXPEDITED			US-PFIZER INC-2015292228			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance	Zithromax			S		Unk		Pfizer
	Metformin Hydrochloride			S		Unk		Not Reported
	Augmentin			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	11630592	NON-EXPEDITED			US-PFIZER INC-2015334869			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Zyvox			S		Unk		Pfizer
	Solu-Medrol			S		Unk		Pfizer
	Daptomycin			S		Unk		Unknown
	Ampicillin Sodium			S		Unk		Unknown
	Vancomycin			S		Unk		Unknown
	Zosyn			S		Unk		Pfizer
	Advair			S		Unk		Not Reported
	Duragesic			S		Unk		Not Reported
	Maxalt			S		Unk		Not Reported
	Oxycodone			S		Unk		Not Reported
	Percocet			S		Unk		Not Reported
	Percodan			S		Unk		Not Reported
	Protopic			S		Unk		Not Reported
	Macrobid			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	15753971	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2018M1094602		65 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Cough; Drug Ineffective For Unapproved Indication; Dyspnoea; Eosinophilic Pneumonia; Pyrexia; Respiratory Failure; Therapeutic Response Decreased	Indapamide/Perindopril			S	Unknown	Unk (Dose Had Been Doubled)		Not Reported
	Lisinopril			S	Oral	Unk		Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported
	Amoxicillin/Clavulanic Acid			S				Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Alendronate			S	Unknown	Unk		Not Reported
	Sodium/Colecalciferol							
	Alendronate			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Sodium/Colecalciferol

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16445631	EXPEDITED (15-DAY)		OT	HU-MYLANLABS-2019M1055911		28 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macule; Off Label Use; Pharyngeal Enanthema; Pharyngeal Oedema; Product Use In Unapproved Indication; Skin Plaque; Syphilis	Levofloxacin			S	Unknown	Unk		Not Reported	
	Levofloxacin			S				Not Reported	
	Azithromycin			S	Unknown	Unk		Mylan	
	Azithromycin			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16454172	NON-EXPEDITED			US-PFIZER INC-2019263141		33 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lorazepam			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16542075	EXPEDITED (15-DAY)		HO, LT	CN-JNJFOC-20190633827			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Ibuprofen			S	Unknown			Not Reported	
	Paracetamol			S	Unknown			Not Reported	
	Itraconazole			S	Unknown			Not Reported	
	Analgin (Acetaminophen\Aspirin\Caffeine)			S	Unknown			Not Reported	
	Aminopyrine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Phenacetin	S	Unknown	Not Reported
Amoxicillin	S	Unknown	Not Reported
Ampicillin	S	Unknown	Not Reported
Penicillin	S	Unknown	Not Reported
Piperacillin	S	Unknown	Not Reported
Cefalexin	S	Unknown	Not Reported
Cefaclor	S	Unknown	Not Reported
Cefuroxime	S	Unknown	Not Reported
Sulperazon	S	Unknown	Not Reported
Cefotaxim	S	Unknown	Not Reported
Imipenem Cilastatin	S	Unknown	Not Reported
Meropenem	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Levofloxacin	S	Unknown	Not Reported
Sulfasalazine	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Azithromycin	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Lincomycin	S	Unknown	Not Reported
Doxycyclin	S	Unknown	Not Reported
Vancomycin	S	Unknown	Not Reported
Oxcarbazepine	S	Unknown	Not Reported
Phenobarbital	S	Unknown	Not Reported
Scopolamine	S	Unknown	Not Reported
Phenytoin	S	Unknown	Not Reported
Chlorphenamine	S	Unknown	Not Reported
Cefoperazone Sulbactam	S	Unknown	Not Reported
Cefotaxime	S	Unknown	Not Reported
Imepen	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Meropenem	S	Unknown	Not Reported
	Aneton	S	Unknown	Not Reported
	[Chlorpheniramine\Codeine\Ephedrine]			
	Methazolamide	S	Unknown	Not Reported
	Voriconazole	S	Unknown	Not Reported
	Calcium Dobesilate	S	Unknown	Not Reported
	Amitriptyline	S	Unknown	Not Reported
	Estazolam	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Piperacillin-Tazobactam	S	Unknown	Not Reported
	Imipenem-Cilastatin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16542883	EXPEDITED (15-DAY)		HO, OT	US-DEXPHARM-20190454		35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombotic Thrombocytopenic Purpura	Diclofenac Potassium			S		100 Mg Twice Daily		Not Reported	
	Vancomycin			C				Not Reported	
	Aztreonam			S				Not Reported	
	Azithromycin			S				Not Reported	
	Oseltamivir			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16543239	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR118188			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Ventolin			S		8 Df, Unk		Glaxosmithkline	
	Alendronate			S	Oral	35 Mg, Unk		Not Reported	
	Alendronate			S				Not Reported	
	Azithromycin			S	Oral	250 Mg, Unk		Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xolair	S	Subcutaneous	150 Mg, Unk	Not Reported
Calcium Carbonate	C		Unk	Glaxosmithkline
Ciclesonide	C		Unk	Not Reported
Montelukast Apotex	C		Unk	Not Reported
Spiriva	C		Unk	Not Reported
Symbicort	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16543421	EXPEDITED (15-DAY)		LT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-212944		76 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16543648	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-TEVA-2019-CA- 1071978		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Amiodarone			S	Unknown			Teva	
	Ceftriaxone For Injection Usp			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported	
	Diltiazem Cd			S	Oral			Teva	
	Furosemide			S	Oral	40 Milligram Daily;		Actavis	
	Hydromorphone			S	Intravenous (not otherwise specified)			Actavis	
	Methylprednisolone Nos			S	Intravenous (not otherwise specified)			Not Reported	
	Paclitaxel Injection			S	Intravenous (not otherwise specified)	21.2143 Milligram Daily;		Not Reported	
	Pantoprazole			S	Intravenous (not			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Adriamycin	S	otherwise specified)		Not Reported
Digoxin	S	Intravenous (not otherwise specified)	7.5714 Milligram Daily;	Not Reported
Digoxin	S	Intravenous (not otherwise specified)		Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)		Not Reported
Enoxaparin	S	Subcutaneous	40 Milligram Daily;	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)		Not Reported
Metoprolol	S	Intravenous (not otherwise specified)		Not Reported
Metoprolol	S	Intravenous (not otherwise specified)		Not Reported
Morphine Sulfate Injection Usp	S	Intravenous (not otherwise specified)		Not Reported
Pms-Azithromycin	S	Intravenous (not otherwise specified)	500 Milligram Daily;	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Milligram Daily;	Not Reported
Trastuzumab	S	Unknown		Not Reported
Dexamethasone	C			Not Reported
Emend	C			Not Reported
Filgrastim	C			Not Reported
Gabapentin	C			Not Reported
Metoclopramide	C			Not Reported
Ondansetron	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16543704	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1060636			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective;	Azithromycin	S	Unk	Not Reported
Pneumothorax	Imatinib	S	Unk	Mylan
Spontaneous; Treatment	Tacrolimus	S	Unk	Mylan
Failure	Valaciclovir	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16544243	NON-EXPEDITED			US-PFIZER INC-2019290981			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Hydroxyzine Pamoate			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Metoclopramide Hcl			S		Unk		Pfizer	
	Carafate			S		Unk		Not Reported	
	Cefalexin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Macrobid [Clarithromycin]			S		Unk		Not Reported	
	Reglan [Metoclopramide]			S		Unk		Not Reported	
	Phenergan [Promethazine]			S		Unk		Not Reported	
	Propoxyphene			S		Unk		Not Reported	
	Questran			S		Unk		Not Reported	
	Ranitidine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16546971	EXPEDITED (15-DAY)		OT	PHHY2019US153921		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterium Abscessus Infection; Neuropathy	Linezolid			S	Oral	300 Mg, Q12h		Novartis	
	Linezolid			S	Oral	600 Mg, Q12h		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Peripheral; Postoperative Wound Infection; Product Use In Unapproved Indication; Soft Tissue Infection	Azithromycin	S	Oral	250 Mg, Q24h	Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)	50 Mg, Q12h	Not Reported
	Cefoxitin	S	Intravenous (not otherwise specified)	12 G, Q12h	Not Reported
	Cefoxitin	S	Intravenous (not otherwise specified)	12 G, Q24h	Not Reported
	Amikacin	S	Intravenous (not otherwise specified)	25 Mg/Kg, Qw3	Not Reported
	Amikacin	S	Respiratory (inhalation)	250 Mg, Q24h	Not Reported
	Amikacin	S	Unknown	1 G, In 5l 0.9% Normal Saline Irrigation	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16547035	EXPEDITED (15-DAY)		OT	PL-TEVA-2019-PL-1074203		80 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Arthralgia; Diarrhoea; Dry Mouth; Eructation; Fatigue; Flatulence; Headache; Headache; Hyperhidrosis; Hypoacusis; Hypoaesthesia; Labile Blood Pressure; Micturition Urgency; Musculoskeletal Stiffness; Nausea; Neck Pain; Oedema Peripheral; Pain In Extremity; Pain In Extremity; Paraesthesia; Pruritus; Renal Pain; Urinary Tract Disorder; Vision Blurred	Sumamed			S	Oral			Not Reported
	Enarenal			C				Not Reported
	Letrox			C		Therapy Ongoing		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16547277	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1062767		24 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haemoglobin Decreased; Lung Infiltration	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported	
	Ceftriaxone			S	Unknown	2 Gram		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16548800	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT156928		32 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Cytomegalovirus Infection; Epstein-Barr Virus Infection; Flushing; Hepatocellular Injury; Hepatosplenomegaly; Inflammation; Pleurisy; Portal Vein Thrombosis; Pyrexia; Therapy Non-Responder	Amoxicillin+Clavulanic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Novartis	
	Desogestrel			S	Oral			Not Reported	
	Levothyroxine			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jul-2019	16550512	DIRECT					52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tinnitus	Z-Pak (Azithromycin)			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	15805073	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2617549-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Imuran	S	Unknown		Not Reported
	Levofloxacin	S	Unknown		Not Reported
	Methotrexate	S	Unknown		Not Reported
	Plaquenil	S	Oral		Not Reported
	Pms Azithromycin	S	Unknown		Not Reported
	Procytox	S	Unknown	2000mg/Vial	Not Reported
	Simponi	S	Subcutaneous		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Arava	S	Unknown		Not Reported
	Benadryl	S	Unknown		Not Reported
	Celebrex	S	Oral		Not Reported
	Cimzia	S	Subcutaneous		Not Reported
	Demerol	S	Unknown		Not Reported
	Enbrel	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Ezetrol	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16245265	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019GSK069199			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Chest Discomfort; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital	Salbutamol Sulphate			S		Unk		Glaxosmithkline	
	Breo Ellipta			S		Unk		Glaxosmithkline	
	Levothyroxine			S		Unk		Glaxosmithkline	
	Theophylline			S		Unk		Glaxosmithkline	
	Escitalopram			S		Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Capacity Decreased;	Zantac	S	Unk	Glaxosmithkline
Gastroesophageal Reflux	Singular	S	Unk	Glaxosmithkline
Disease; Lung Disorder;	Solu-Medrol	S	Unk	Not Reported
Lung Hyperinflation; Lung	Zithromax	S	Unk	Not Reported
Opacity; Malaise; Nasal	Tazocin	S	Unk	Not Reported
Congestion; Obstructive	Cipraxel	S	Unk	Not Reported
Airways Disorder;	Inspolito	S	Unk	Not Reported
Obstructive Airways	Atrovent	S	Unk	Not Reported
Disorder; Oropharyngeal	Amlodipine	S	Unk	Not Reported
Pain; Pain In Extremity;	Uniphyl	S	Unk	Not Reported
Rhinorrhoea; Sputum	Synthroid	S	Unk	Not Reported
Discoloured; Therapeutic	Spiriva	S	Unk	Not Reported
Product Effect Incomplete;	Prednisone	S	Unk	Not Reported
Total Lung Capacity				
Abnormal; Weight				
Increased; Wheezing				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16479624	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2019M1057674		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16514834	NON-EXPEDITED			US-PFIZER INC-2019271156			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Hydrocortisone			S		Unk		Pfizer	
	Sumatriptan			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Coumadin		S		Unk		Not Reported		
	Cymbalta		S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16535469	NON-EXPEDITED			US-PFIZER INC-2019283717		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pyrexia	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16550939	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1074481			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Alendronate			S	Oral			Actavis	
	Alendronate			S				Actavis	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Ventolin			S	Unknown			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Calcium Carbonate			C				Not Reported	
	Ciclesonide			C				Not Reported	
	Montelukast /01362602/			C				Not Reported	
Spiriva			C				Not Reported		
Symbicort			C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16550940	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1074474		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Increased; Cough; Dizziness; Drug	Amlodipine Besilate			S	Oral	10 Milligram Daily;		Teva	
	Amlodipine Besilate			S	Oral	1 Dosage Forms Daily;		Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Sputum Discoloured	Azithromycin Omalizumab Advair Ventolin Spiriva Singulair Pantoprazole Sodium Hydrochlorothiazide Brilinta Asa	S S C C C C C C C C	Oral Subcutaneous Other Other Other Oral Oral Oral Oral Oral			1 Dosage Forms Daily; 1 Dosage Forms Daily; 1 Dosage Forms Daily; 1 Dosage Forms Daily; 1 Dosage Forms Daily; 1 Dosage Forms Daily; 1 Dosage Forms Daily;	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16551058	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2019AMR121005		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Salbutamol Sulphate Zithromax Alvesco Spiriva Zenhale Prednisone			S S S S S C		100 Ug, Qd Unk Unk 2 Df, Qd 2 Df, Qd Unk		Glaxosmithkline Glaxosmithkline Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16552284	NON-EXPEDITED			US-PFIZER INC- 2019287555			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Clindamycin Azithromycin			S S		Unk Unk		Pfizer Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16552630	NON-EXPEDITED			US-PFIZER INC-2019289876		6 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jul-2019	16555006	EXPEDITED (15-DAY)		HO, OT	SK-TEVA-2019-SK-1074395		46 YR	Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous;	Azithromycin			S		Unk		Not Reported	
Influenza; Maternal	Cimzia			S		Unk		Not Reported	
Exposure During	Imuran			C		Unk		Not Reported	
Pregnancy; Myasthenia	Prednisone			C		Unk		Not Reported	
Gravis	Azithromycin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	10010901	EXPEDITED (15-DAY)		HO, OT	JP-JNJFOC-20130716605		51 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Cytopenia;	Prezista			S	Oral			Not Reported	
Diabetes Mellitus; Diabetic	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Neuropathy; Diarrhoea;	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Eosinophilic Pustular	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Folliculitis; Folate	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Deficiency;	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Hyperlipidaemia;	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Hyperuricaemia;	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Lymphadenitis;	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Mycobacterium Avium	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Complex Infection;	Valganciclovir Hydrochloride			S	Oral			Not Reported	
Nausea; Osteoporosis;	Zithromac			S	Unknown			Not Reported	
Periarthritis; Pneumonia;									

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Renal Impairment; Sinusitis	Zithromac	S	Unknown	Not Reported
	Zithromac	S	Unknown	Not Reported
	Mycobutin	S	Oral	Not Reported
	Baktar	S	Oral	Not Reported
	Baktar	S	Oral	Not Reported
	Norvir	S	Unknown	Not Reported
	Truvada	S	Oral	Not Reported
	Esanbutol	S	Oral	Not Reported
	Esanbutol	S	Oral	Not Reported
	Fosamac	S	Oral	Not Reported
	Epzicom	S	Oral	Not Reported
	BezatoI Sr	S	Oral	Not Reported
	Kefral	C	Oral	Not Reported
	Zosyn	C	Intravenous (not otherwise specified)	Not Reported
	Cravit	C	Oral	Not Reported
	Cravit	C	Oral	Not Reported
	Cravit	C	Oral	Not Reported
	Cravit	C		Not Reported
	Atovaquone	C	Oral	Not Reported
	Sawacillin	C	Oral	Not Reported
	Sawacillin	C	Oral	Not Reported
	Risumic	C	Oral	Not Reported
	Ganciclovir	C	Intravenous drip	Not Reported
	Maglax	C	Oral	Not Reported
	Cephadol	C	Oral	Not Reported
	Vfend	C	Oral	Not Reported
	Talion	C	Oral	Not Reported
	Fluconazole	C	Oral	Not Reported
	Fluconazole	C	Oral	Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Fluconazole	C	Oral	Not Reported
Enteronon-R	C	Oral	Not Reported
Omeprazole	C	Oral	Not Reported
Myonal	C	Oral	Not Reported
Loxonin	C	Oral	Not Reported
Loxonin	C	Oral	Not Reported
Loxonin	C	Oral	Not Reported
Loxonin	C	Oral	Not Reported
Loxonin	C	Oral	Not Reported
Loxonin	C	Oral	Not Reported
Tannalbin	C	Oral	Not Reported
Gasmotin	C	Oral	Not Reported
Myslee	C	Oral	Not Reported
Myslee	C	Oral	Not Reported
Marzulene-S	C	Oral	Not Reported
Rohypnol	C	Oral	Not Reported
Farom	C	Oral	Not Reported
Foscavir	C	Intravenous drip	Not Reported
Foliamin	C	Oral	Not Reported
Rebamipide	C	Oral	Not Reported
Rebamipide	C	Oral	Not Reported
Rebamipide	C	Oral	Not Reported
Lopemin [Loperamide Hydrochloride]	C	Oral	Not Reported
Lopemin [Loperamide Hydrochloride]	C	Oral	Not Reported
Nauzelin	C	Oral	Not Reported
Neutrogin	C	Unknown	Not Reported
Neutrogin	C	Unknown	Not Reported
Neutrogin	C	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neutrogin	C	Unknown	Not Reported
Neutrogin	C	Unknown	Not Reported
Neutrogin	C	Unknown	Not Reported
Neutrogin	C	Unknown	Not Reported
Neutrogin	C	Unknown	Not Reported
Cefepime Dihydrochloride	C	Unknown	Not Reported
Cefepime Dihydrochloride	C	Unknown	Not Reported
Calonal	C	Oral	Not Reported
Lipidil	C	Oral	Not Reported
Allopurinol	C	Oral	Not Reported
Metgluco	C	Oral	Not Reported
Methycobal	C	Oral	Not Reported
Lyrica	C	Oral	Not Reported
Ethyl Icosapentate	C	Oral	Not Reported
Kindavate	C	Topical	Not Reported
Inteban	C	Topical	Not Reported
Antebate	C	Topical	Not Reported
Glufast	C	Oral	Not Reported
Mucodyne	C	Oral	Not Reported
Neuzym	C	Oral	Not Reported
Allermist	C	Nasal	Not Reported
Tivicay	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	14275612	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2017GSK190031			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Contact;	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline
Diabetes Mellitus;	Azithromycin			S	Oral	250 Mg, Qd		Glaxosmithkline
Hypertension;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Staphylococcus Test Positive	Breo Ellipta	S		1 Puff(S), Qd	Glaxosmithkline
	Ventolin	S		Unk	Glaxosmithkline
	Singulair	S	Oral	10 Mg, Qd	Glaxosmithkline
	Theophylline	S	Oral	450 Mg, Qd	Glaxosmithkline
	Salbutamol	S		Unk	Glaxosmithkline
	Atrovent	S		Unk	Not Reported
	Prednisone	S	Oral	45 Mg, Unk	Not Reported
	Seebri Breezhaler	S		1 Puff(S), Qd (50 Mcg)	Not Reported
	Combivent Respimat	S		Unk Unk, Prn	Not Reported
	Xolair	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Xolair	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Ipratropium And Salbutamol	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16209495	NON-EXPEDITED			US-PFIZER INC-2019161755			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16557553	EXPEDITED (15-DAY)		OT	PHHY2019PL154721			Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Asthenia;	Azitrolek			S	Unknown	500 Mg, Unk		Novartis
Body Temperature Decreased; Decreased Appetite; Diarrhoea; Dizziness; Dry Mouth; Somnolence; Tinnitus; Visual Impairment	Azitrolek			S				Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16561474	EXPEDITED (15-DAY)		HO	PHHY2019GR156924		50 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Fatigue; Hepatomegaly; Hypergammaglobulinaemi a; Inflammatory Marker Increased; Pancytopenia; Product Use In Unapproved Indication; Pyrexia; Sepsis; Splenomegaly; Visceral Leishmaniasis	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16561572	NON-EXPEDITED			US-EPIC PHARMA LLC- 2019EPC00136		1 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Contamination Physical; Productive Cough; Rhinorrhoea	Azithromycin			S	Oral	5 MI, Once		Epic Pharm	
	Azithromycin			S	Oral	2.5 MI, 1x/Day		Epic Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16562017	NON-EXPEDITED			US-PFIZER INC- 2019290085			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ceftriaxone Sodium			S		Unk		Pfizer	
	Cleocin			S		Unk		Pfizer	
	Clindamycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Cefuroxime Axetil			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceclor	S	Unk	Not Reported
Cefaclor	S	Unk	Not Reported
Ceftin [Cefuroxime Axetil]	S	Unk	Not Reported
Cozaar	S	Unk	Not Reported
Fluoxetine	S	Unk	Not Reported
Losartan Potassium	S	Unk	Not Reported
Rocephin	S	Unk	Not Reported
Propoxyphene	S	Unk	Not Reported
Propoxyphene Hcl	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16562048	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1063740		39 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	500 Milligram, Total		Not Reported	
	Oki			C	Oral	2 Dosage Form		Mylan	
	Amoxicillina/Acido Clavulanico			C	Oral	3 Dosage Form		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jul-2019	16562111	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1064269		31 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16370813	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-029905			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apraxia; Catatonia; Delirium; Hallucination, Auditory; Hallucination,	Venlafaxine			S	Oral	75 Milligram, Once A Day		Aurobindo	
	Wellvone			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Visual; Persecutory Delusion; Psychomotor Skills Impaired	Cortancyl	S	Oral	35 Milligram, Once A Day (En Décroissance)	Not Reported
	Novatrex	S	Oral	4 Dosage Form, Every Week	Not Reported
	Novatrex	S	Oral	1 Dosage Form, At The Posology Of 1 Per Week Then 3 / Week Then 4 / Week	Not Reported
	Speciafoldine	C	Unknown	Unk	Not Reported
	Innovair	C	Unknown	2 Dosage Form, Two Times A Day, 2 Sprays Morning And Evening	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16563910	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-203255		55 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jarisch-Herxheimer Reaction	Azithromycin			S	Oral	1gm, Unk		Sun	
	Ceftriaxone			S	Intramuscular	205 Milligram		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16565521	EXPEDITED (15-DAY)		HO, OT	SE-MYLANLABS- 2019M1064279		67 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin			S		250 Milligram		Not Reported	
Confusional State;	Azithromycin			S		Unk		Not Reported	
Constipation; Dizziness;	Azithromycin			S		Unk		Not Reported	
Fatigue; Hypoaesthesia;	Xalatan			C		Unk		Mylan	
Insomnia; Mental	Symbicort Forte			C		Inhalation		Mylan	
Disorder; Muscle Spasms;									
Polyneuropathy; Syncope									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16567957	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-019217		9 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Graft Versus Host Disease; Dyspnoea Exertional; Obliterative Bronchiolitis	Prednisolone			S	Unknown			Bausch And Lomb	
	Azithromycin			S	Unknown			Not Reported	
	Ciclosporin			S	Unknown			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
	Montelukast			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Sirolimus			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2019	16568352	EXPEDITED (15-DAY)		OT	CA-009507513-1907CAN005271			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Alendronate Sodium			S	Oral	35 Milligram		Merck	
	Alendronate Sodium			S				Merck	
	Azithromycin			S	Oral	250 Milligram		Not Reported	
	Azithromycin			S				Not Reported	
	Ventolin (Albuterol Sulfate)			S	Unknown	8 Dosage Form		Not Reported	
	Xolair			S	Subcutaneous	150 Milligram		Not Reported	
	Calcium Carbonate			C				Not Reported	
	Ciclesonide			C				Not Reported	
	Montelukast			C				Not Reported	
	Spiriva			C				Not Reported	
	Symbicort			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2019	16569069	EXPEDITED (15-DAY)		OT	PHHY2019ES159635		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Laryngospasm; Paraesthesia		Azithromycin	S	Oral	500 Mg, Q24h		Novartis		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	14485039	NON-EXPEDITED			US-PFIZER INC- 2018045965			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	15631918	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2018GSK207822			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Osteonecrosis; Therapeutic Product Effect Incomplete	Salbutamol Sulphate			S	Respiratory (inhalation)	2.5 Mg, Bid		Glaxosmithkline	
	Salbutamol Sulphate			S		Unk Unk, Qd		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z (Monthly)		Glaxosmithkline	
	Advair			S		Unk Unk, Bid		Glaxosmithkline	
	Singulair			S		10 Mg, Qd		Glaxosmithkline	
	Azithromycin			S		Unk Unk, Qd		Glaxosmithkline	
	Prednisone			S		10 Mg, Qd		Not Reported	
	Spiriva Respimat			S		2.5 Ug, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	15845344	EXPEDITED (15-DAY)		OT	CN-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-196352		22 YR	Male	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Sun	
	Azithromycin			S				Sun	
	Cefoperazone			S	Unknown	Unk		Not Reported	
	Ornidazole			S	Unknown	Unk		Not Reported	
	Sulbactam			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16373969	EXPEDITED (15-DAY)		OT	PHHY2019BE094693		40 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hepatotoxicity; Nausea; Vomiting	Clofazimine			S	Oral			Novartis	
	Clofazimine			S				Novartis	
	Clarithromycin			S	Oral			Not Reported	
	Clarithromycin			S				Not Reported	
	Moxifloxacin			S	Oral			Not Reported	
	Moxifloxacin			S				Not Reported	
	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Linezolid			S				Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported	
	Tigecycline			S				Not Reported	
	Imipenem			S	Intravenous (not otherwise specified)			Not Reported	
	Imipenem			S				Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Amikacin			S				Not Reported	
	Bedaquiline			S	Unknown			Not Reported	
	Bedaquiline			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Minocycline	S	Unknown	Not Reported
Minocycline	S		Not Reported
Tacrolimus	C	Unknown Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16416151	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC-2019239929		77 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Function Abnormal; Incorrect Product Administration Duration; Toxic Skin Eruption	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer
	Irbesartan			C		100 Mg, Daily		Not Reported
	Calcitriol			C		0.25 Ug, Daily		Not Reported
	Trazenta			C		5 Mg, Daily		Not Reported
	Amlodipine Besilate			C		5 Mg, Daily		Not Reported
	Maintate			C		0.625 Mg, Daily		Not Reported
	Diart			C		30 Mg, Daily		Not Reported
	Lasix [Furosemide]			C		40 Mg, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16571725	NON-EXPEDITED			US-PFIZER INC-2019293859			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pharyngitis Streptococcal	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16571857	EXPEDITED (15-DAY)		OT	US-SA-2019SA186044		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Castleman'S Disease; Clostridium Difficile Colitis; Diarrhoea; Headache; Herpes Virus Infection;	Isoniazid			S		Unk		Not Reported
	Rifampicin			S				Sanofi
	Pyrazinamide			S				Not Reported
	Ethambutol			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Immune Reconstitution Inflammatory Syndrome; Associated Tuberculosis; Kaposi'S Sarcoma; Lymph Node Abscess; Lymphadenopathy; Malaise; Nausea; Pyrexia; Unmasking Of Previously Unidentified Disease	Efavirenz\Emtricitabine\Tenofovir\Tenofovir Disoproxil Fumarate	S	Unk	Not Reported
	Prednisone	S	60 Mg, Qd	Not Reported
	Prednisone	S	40 Mg, Qd	Not Reported
	Prednisone	S	Tapering	Not Reported
	Sulfamethoxazole/Trimethoprim	S		Not Reported
	Pyridoxine Hydrochloride	S		Not Reported
	Azithromycin	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16571895	NON-EXPEDITED			US-PFIZER INC-2019298570		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cipro [Ciprofloxacin]			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16574948	EXPEDITED (15-DAY)		HO	PHHY2019HU157562		58 YR	Male	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Conjunctivitis; Cough; Dyspnoea Exertional; Mastocytosis; Myalgia; Nasopharyngitis; Pyrexia; Rash	Cefuroxime			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Doxycyclin			S	Unknown	Unk		Not Reported
	Vit D3			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jul-2019	16575142	EXPEDITED (15-DAY)		HO	PHHY2019FR157863		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Kidney Injury; Hypocalcaemia; Hypomagnesaemia	Tobramycin	S	Intravenous (not otherwise specified)	300 Mg, Bid	Not Reported
	Azithromycine Arrow	S	Oral	250 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	12998088	NON-EXPEDITED			US-PFIZER INC- 2016552235			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Clindamycin Hcl			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Metronidazole			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Macrobid			S		Unk		Not Reported	
	Erythromycin Base			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
	Tequin			S		Unk		Not Reported	
	Mobic			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16329915	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2018GSK232417			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankle Fracture; Asthma; Condition Aggravated; Ligament Sprain; Osteonecrosis	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z, (Monthly)		Glaxosmithkline	
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z, (Monthly)		Glaxosmithkline	
	Mepolizumab			S	Intravenous (not	100 Mg, Z (Monthly)		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Advair	S	Unk, Bid	Glaxosmithkline	
Ventolin	S	Unk Unk, Qd	Glaxosmithkline	
Singulair	S	10 Mg, Qd	Glaxosmithkline	
Azithromycin	S	Unk Unk, Qd	Glaxosmithkline	
Spiriva Respimat	S	Unk Unk, Qd	Not Reported	
Prednisone	S	12.5 Mg, Qd	Not Reported	
Prednisone	S	10 Mg, Unk	Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16560874	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1063374			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematoma; Thrombocytopenia	Azithromycin			S	Unknown	Unk		Not Reported
	Abatacept			S	Unknown	125 Mg, Q2wk		Mylan
	Cymbalta			C	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16575451	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-03586			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577643	EXPEDITED (15-DAY)		OT	MX-MYLANLABS-2019M1066066		55 YR	Female	MEX

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Hypertensive Crisis; Hypoaesthesia Oral;	Dymista D			S	Nasal	2 Sprays Every 12 Hours		Mylan
	Antiflu-Des			S	Oral	Unk		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intracranial Pressure Increased; Nasal Discomfort; Off Label Use; Pharyngeal Oedema	Daflofen F	S	Oral	Unk	Mylan
	Macrozit	S	Oral	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577757	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2019M1065754			Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lower Respiratory Tract Infection; Malaise; Nasopharyngitis	Asmol (Salbutamol)			S		Up To 12 Puffs Per Day As Necessary		Mylan
	Nucala			S	Subcutaneous	100 Milligram		Mylan
	Spiriva			S		2 Puffs Each Night		Mylan
	Seretide			S		250/25mg/2 Puffs Twice A Day		Mylan
	Prednisone			S		10 Milligram, Qd		Mylan
	Ondansetron			S		10 Milligram When Required,		Mylan
	Omeprazole			S		20 Milligram, Qd		Mylan
	Lexamil			S		10 Milligram, Qd		Mylan
	Hypertonic Saline Solution			S		Via Nebuliser Qd		Mylan
	Colistimethate Sodium			S		Unk Via Nebuliser		Mylan
	Azithromycin			S		500 Milligram, Mon/Wed/Fri		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577918	NON-EXPEDITED			US-PFIZER INC-2019299988		83 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16577957	NON-EXPEDITED			US-PFIZER INC-2019301308		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16578030	NON-EXPEDITED			US-PFIZER INC-2019299129		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16578073	NON-EXPEDITED			US-PFIZER INC-2019301989		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16581424	EXPEDITED (15-DAY)		OT	CA-SHIRE-CA201922537			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Mezavant			S	Unknown			Shire	
	5-Asa			S	Unknown			Not Reported	
	Asacol			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Levonorgestrel	S	Unknown				Not Reported
	Infliximab	S	Unknown	50 Milligram			Not Reported
	Mercaptopurine	S	Unknown				Not Reported
	Para-Aminosalicylic Acid	S	Unknown				Not Reported
	Prednisone	C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jul-2019	16775877	DIRECT		LT			50 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
No Adverse Event	Keflex			S				Unknown
	Klonopin			C				Not Reported
	Adderall			C				Not Reported
	Flagyl			C				Not Reported
	Fluconazole			C				Not Reported
	Nuerotin			C				Not Reported
	Motrin			C				Not Reported
	Protonix			C				Not Reported
	Garlic			C				Not Reported
	Prednisone			S				Not Reported
	Zithromax			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	14653965	NON-EXPEDITED			US-PFIZER INC-2018114331		37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16157269	NON-EXPEDITED			US-PFIZER INC-2019140733		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Response Unexpected	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Zithromax	S		Pfizer
Prempro	C	Unk	Not Reported
Fluoxetine	C	200 Mg, Unk	Not Reported
Alprazolam	C	0.05 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16354856	EXPEDITED (15-DAY)		OT	FR-009507513-1905FRA009420		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy	Fidaxomicin			S	Oral	2 Dosage Form, Qd		Merck
	Zerbaxa			S	Intravenous (not otherwise specified)	Unk		Merck
	Vfend			S	Oral			Not Reported
	Valacyclovir Hydrochloride			S	Oral	1 Dosage Form, Qd		Not Reported
	Smecta			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Tranxene			S	Oral	2 Dosage Form, Qd		Not Reported
	Sandimmun			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Pantoprazole			S	Intravenous drip	40 Milligram, Qd		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)	Strenght: 50 Mg/MI		Not Reported
	Alprazolam			S	Oral	2 Dosage Form, Qd		Not Reported
	Zarzio			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
	Magnen B6			S	Oral	Unk Unk, Unknown Freq.		Not Reported
	Vancomycine Sandoz			S	Intravenous (not otherwise specified)	2 G, Once Daily (24 Hrs)		Not Reported
	Cellcept			S	Oral	Unk Unk, Unknown Freq		Not Reported
	Ondansetron Accord			S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq		Not Reported
	Azyter			S	Ophthalmic	Unk Unk, Unknown Freq		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftolozane	S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.	Not Reported
Celluvisc	S	Ophthalmic	Unk Unk, Unknown Freq	Not Reported
Hydroxyzine Hydrochloride	S	Oral	1 Dosage Form, Qd	Not Reported
Furosemide	S	Intravenous (not otherwise specified)	20 Mg (20 Mg/2 MI), Twice Daily (12 Hours)	Not Reported
Sulfarlem	S	Oral	Unk Unk, Unknown Freq	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16387990	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2019-030574			Unknown	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity; Nausea; Toxicity To Various Agents; Vomiting	Moxifloxacin			S	Oral	Unk		Aurobindo
	Moxifloxacin			S				Aurobindo
	Moxifloxacin			S				Aurobindo
	Moxifloxacin			S				Aurobindo
	Moxifloxacin			S				Aurobindo
	Azithromycin			S	Oral	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Tigecycline			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tigecycline			S				Not Reported
	Tigecycline			S				Not Reported
	Tigecycline			S				Not Reported
	Imipenem			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imipenem			S				Not Reported
	Imipenem			S				Not Reported
	Imipenem			S				Not Reported
	Clofazimine			S	Oral	Unk		Not Reported
	Clofazimine			S				Not Reported
	Clofazimine			S				Not Reported
	Clofazimine			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clarithromycin	S	Oral	Unk	Not Reported
Clarithromycin	S			Not Reported
Clarithromycin	S			Not Reported
Clarithromycin	S			Not Reported
Clarithromycin	S			Not Reported
Linezolid	S	Unknown	Unk	Not Reported
Linezolid	S			Not Reported
Linezolid	S			Not Reported
Linezolid	S			Not Reported
Linezolid	S			Not Reported
Amikacin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Amikacin	S			Not Reported
Amikacin	S			Not Reported
Amikacin	S			Not Reported
Bedaquiline	S	Unknown	Unk	Not Reported
Tacrolimus	S	Unknown	Unk	Not Reported
Minocycline	S	Unknown	Unk	Not Reported
Minocycline	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16424384	EXPEDITED (15-DAY)		OT	FR-ACCORD-132549		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy	Ondansetron Accord			S	Intravenous (not otherwise specified)			Accord
	Alprazolam Mylan			S	Oral	Strength:0.25 Mg, Scored Tablet		Not Reported
	Sandimmun			S	Intravenous (not otherwise specified)			Not Reported
	Zarzio			S	Intravenous (not otherwise specified)			Not Reported
	Difclir			S	Oral	Strength: 200 Mg		Not Reported
	Smecta			S	Oral	Strength: 3 G Orange-		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cellcept	S	Oral	Vanilla, Sachet	Not Reported
Vfend	S	Oral	Strength:200 Mg	Not Reported
Azyter	S	Ophthalmic		Not Reported
Magne B6	S	Oral		Not Reported
Tranxen	S	Oral	Strength: 5 Mg	Not Reported
Pantoprazole Arrow	S	Intravenous drip	Strength: 40 Mg	Not Reported
Hydroxyzine Arrow	S	Oral		Not Reported
Celluvisc	S	Ophthalmic		Not Reported
Valaciclovir Arrow	S	Oral	Strength: 500 Mg	Not Reported
Zerbaxa	S	Intravenous (not otherwise specified)		Not Reported
Vancomycin Sandoz	S	Intravenous (not otherwise specified)	Strength: 500 Mg	Not Reported
Sulfarlem	S	Oral	Pyridoxine, Vitamine B1	Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Strength 50 Mg / MI	Not Reported
Furosemide Renaudin	S	Intravenous (not otherwise specified)	Strength: 20 Mg / 2 MI	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16585201	EXPEDITED (15-DAY)		OT	ES-TEVA-2019-ES-1078120		65 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Laryngospasm; Paraesthesia	Azitromicina 500 Mg 3 Comprimidos			S	Oral	500 Mg Per Day For 1 Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jul-2019	16589583	DIRECT		DE, OT			5 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Heart Rate Decreased	Azithromycin	S	Oral	Quantity:5 MI;	Teva
	Ibuprofen	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	12122433	EXPEDITED (15-DAY)		OT	CA-TAKEDA-2016TUS003384		15 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Photodermatitis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Pantoprazole			S	Oral	Unk		Not Reported
	Lansporazole			S	Oral	Unk		Takeda
	Atorvastatin /01326102/			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Trimethoprim Sulfamethoxazole			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Voriconazole			S	Oral	Unk		Not Reported
	Voriconazole			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16013529	NON-EXPEDITED			US-PFIZER INC-2019084356		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cefuroxime			S		Unk		Unknown
	Levaquin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16340882	EXPEDITED (15-DAY)		OT	FR-ROCHE-2322762		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Encephalopathy	Vfend	S	Oral		Not Reported
	Smecta [Diosmectite]	S	Oral		Not Reported
	Sulfarlem	S	Oral		Not Reported
	Furosemide Renaudin	S	Intravenous (not otherwise specified)	20 Mg/2 MI	Not Reported
	Difclir	S	Oral		Not Reported
	Sandimmun	S	Intravenous (not otherwise specified)		Not Reported
	Vancomycine Sandoz	S	Intravenous (not otherwise specified)		Not Reported
	Valaciclovir	S	Oral		Not Reported
	Zerbaxa	S	Intravenous (not otherwise specified)		Not Reported
	Alprazolam	S	Oral		Not Reported
	Magne B6 [Magnesium Lactate;Pyridoxine Hydrochloride]	S	Oral		Not Reported
	Celluvisc [Carmellose Sodium]	S	Ophthalmic		Not Reported
	Zarzio	S	Intravenous (not otherwise specified)		Not Reported
	Hydroxyzine Arrow	S	Oral		Not Reported
	Ondansetron	S	Intravenous (not otherwise specified)		Not Reported
	Azyter	S	Ophthalmic		Not Reported
	Pantoprazole Arrow	S	Intravenous (not otherwise specified)		Not Reported
	Cellcept [Mycophenolate Mofetil]	S	Oral		Not Reported
	Oxynorm	S	Intravenous (not otherwise specified)	50 Mg/MI	Not Reported
	Tranxene	S	Oral	Last Dose On 05/Apr/2019	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16483670	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019267656		72 YR	Male	JPN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Loss Of Consciousness	Zithromac Sr 2g			S	Oral	Unk		Pfizer	
	Lovastatin			C		Unk		Not Reported	
	Lixiana			C		Unk		Not Reported	
	Bisoprolol Fumarate			C		Unk		Not Reported	
	Cetirizine Hcl			C		Unk		Not Reported	
	Marzulene S			C		Unk		Not Reported	
	Tiquizium Bromide			C		Unk		Not Reported	
	Loxoprofen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16589515	NON-EXPEDITED			PHEH2019US029416			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inappropriate Schedule Of Product Administration	Azithromycin			S	Unknown	250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16589677	EXPEDITED (15-DAY)		HO	US-SWEDISH ORPHAN BIOVITRUM-2019US0655		2 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Pneumonia	Kineret			S		2 Mg/Kg/Day (Weight = 7 Kg)		Not Reported	
	Kineret			S		2.5 Mg/Kg/Day. On 09feb2010 (Weight = 7.74kg) Daily Dose = 19.4		Not Reported	
	Kineret			S		2.96 Mg/Kg/Day (Weight= 10.6 Kg)		Not Reported	
	Kineret			S				Not Reported	
	Ceftriaxone			S				Not Reported	
	Azithromycin			S				Not Reported	
	Prednisolone			C		2 Mg/Kg/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisolone	C	1.28 Mg/Kg/Day (Weigh = 7kg)	Not Reported
Prednisolone	C	0.74 Mg/Kg/Day (Weight = 7.74kg)	Not Reported
Prednisolone	C		Not Reported
Prednisone	C		Not Reported
Prednisone	C	0.16 Mg/Kg/Day (Weight = 10.6 Kg)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16591370	EXPEDITED (15-DAY)		DE, HO	CA-BAYER-2019-132972		19 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Metabolic Acidosis; Overdose; Toxicity To Various Agents	Cipro			S	Oral	Unk		Bayer	
	Acetaminophen And Codeine			S	Oral	Unk		Not Reported	
	Aerius [Desloratadine]			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Caffeine			S	Oral	Unk		Not Reported	
	Codeine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16591595	NON-EXPEDITED			PHEH2019US029546		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergy To Animal; Drug Hypersensitivity	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis	
	Z-Pak			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16592609	EXPEDITED (15-DAY)		HO, OT	CA-BAYER-2019-133008		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oesophageal Ulcer; Oesophagitis; Rash; Stevens-Johnson Syndrome	Cipro 500 Mg	S	Oral	500 Mg, Bid	Bayer
	Azithromycin	S	Unknown	Unk	Not Reported
	Tiotropium Bromide	C		Unk	Not Reported
	Olodaterol	C		Unk	Not Reported
	Fluticasone	C		Unk	Not Reported
	Ipratropium	C		Unk	Not Reported
	Quetiapine	C		Unk	Not Reported
	Risedronate Sodium	C		Unk	Not Reported
	Salbutamol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16593904	NON-EXPEDITED			US-SWEDISH ORPHAN BIOVITRUM- 2018US1541			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Injection Site Erythema;	Kineret			S	Subcutaneous			Not Reported	
Injection Site Pruritus;	Azithromycin			S				Not Reported	
Injection Site Urticaria;	Albuterol			C				Not Reported	
Nasopharyngitis	Benadryl			C				Not Reported	
	Hydrocortisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jul-2019	16594303	EXPEDITED (15-DAY)		HO, OT	FR-MYLANLABS- 2019M1067085		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Tobramycin			S	Intravenous (not otherwise specified)	300 Milligram, Bid		Not Reported	
Hypocalcaemia;	Azithromycine Arrow			S	Oral	250 Milligram, Qd		Mylan	
Hypomagnesaemia									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16081373	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2014-10118			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Drug Level Increased; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Montelukast			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Ciprofloxacin			S	Oral	Unk		Aurobindo
	Voriconazole			S	Oral	0-22 Months Post-Ltx; Dose Increments To Achieve Therapeutic Level >1		Aurobindo
	Azithromycin			S	Oral	Unk		Aurobindo
	Pentamidine			S	Unknown	Unk		Not Reported
	Nifedipine			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported
	Tacrolimus			S				Not Reported
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S				Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Sulfatrim			S	Oral	Unk		Not Reported
	Caspofungin Acetate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Caspofungin Acetate			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16359451	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-028846			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy	Hydroxyzine Arrow			S	Oral	1 Dosage Form, Daily		Aurobindo
	Pantoprazol Arrow 40 Mg Powder For Solution For			S	Intravenous (not otherwise specified)	40 Milligram, Daily		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injection					
Pantoprazol Arrow 40 Mg Powder For Solution For Injection	S	Intravenous drip	40 Milligram, Once A Day		Aurobindo
Valaciclovir Arrow 500mg Film-Coated Tablets	S	Oral	1 Dosage Form, Daily		Aurobindo
Alprazolam Mylan	S	Oral	2 Dosage Form, Daily		Not Reported
Sandimmun	S	Intravenous (not otherwise specified)	Unk		Not Reported
Zarzio	S	Intravenous (not otherwise specified)	Unk		Not Reported
Difclir	S	Oral	2 Dosage Form, Daily		Not Reported
Smecta	S	Oral	Unk		Not Reported
Cellcept	S	Oral	Unk		Not Reported
Vfend	S	Oral	2 Dosage Form, Daily		Not Reported
Ondansetron Accord	S	Intravenous (not otherwise specified)	Unk		Not Reported
Azyter	S	Ophthalmic	Unk		Not Reported
Magne B6	S	Oral	Unk		Not Reported
Tranxene	S	Oral	2 Dosage Form, Daily		Not Reported
Celluvisc	S	Ophthalmic	Unk		Not Reported
Zerbaxa	S	Intravenous (not otherwise specified)	Unk		Not Reported
Vancomycine Sandoz	S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported
Sulfarlem	S	Oral	Unk		Not Reported
Oxynorm	S	Intravenous (not otherwise specified)	Unk		Not Reported
Furosemide Renaudin	S	Intravenous (not otherwise specified)	20 Milligram, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16595666	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US05156			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Calcium Acetate			S	Transplacental	Unk		Invagen
	Betamethasone			S	Transplacental	Unk		Not Reported
	Enoxaparin Sodium			S	Transplacental	Unk		Not Reported
	Cholecalciferol			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Amoxicillin			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16595817	EXPEDITED (15-DAY)		OT	US-CIPLA LTD.- 2019US05155			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy; Premature Delivery; Preterm Premature Rupture Of Membranes	Calcium Acetate			S	Oral	Unk, Daily		Invagen
	Cholecalciferol			S	Oral	Unk, Daily		Not Reported
	Enoxaparin Sodium			S	Unknown	30 Milligram, Bid		Not Reported
	Betamethasone			S	Intramuscular	12 Milligram, Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16595865	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2019-039922			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypocalcaemia; Hypomagnesaemia	Azithromycin Film-Coated Tablets 250mg Tobramycin			S	Oral	250 Milligram, Daily		Aurobindo
				S	Intravenous (not otherwise specified)	300 Milligram, Every Other Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16597288	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2019305905		65 YR	Female	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Laryngospasm; Paraesthesia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16600696	NON-EXPEDITED			US-PFIZER INC- 2019308772			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jul-2019	16601781	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC- 2019299770			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterocolitis Haemorrhagic; Off Label Use; Product Use In Unapproved Indication; Weight Decreased	Zithromac 250mg			S	Oral	2 Df, Daily		Pfizer	
	Voltaren [Diclofenac]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jul-2019	16600542	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2019-042008			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Laryngospasm; Paraesthesia	Azithromycin 500 Mg Film- Coated Tablets			S	Oral	500 Milligram, Daily (Every 24 Hours)		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	11323536	EXPEDITED (15-DAY)		OT	JP-VIIV HEALTHCARE LIMITED- JP2015JPN102901		52 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Diabetes	Dolutegravir			S	Oral	50 Mg, Unk		Viiiv	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mellitus; Diabetic Neuropathy; Eosinophilic Pustular Folliculitis; Hyperlipidaemia; Hyperuricaemia; Hyponatraemia; Osteoporosis; Renal Impairment; Sinusitis	Epzicom	S	Oral	1 Df, Unk	Viiv
	Abacavirsulphate+Dolutegravir+ Lamivudine	S	Oral	1 Df, 1d	Viiv
	Zithromac	S	Unknown	1200 Mg, We	Not Reported
	Zithromac	S	Unknown	600 Mg, Qd	Not Reported
	Zithromac	S	Unknown	500 Mg, Qd	Not Reported
	Lipidil	S	Oral	Unk	Not Reported
	Baktar	S	Oral		Not Reported
	Sulphamethoxazole + Trimethoprim	S	Unknown		Not Reported
	Norvir	S	Oral	100 Mg, Unk	Not Reported
	Truvada	S	Oral	1 Df, 1d	Not Reported
	Prezista Naive	S	Oral	800 Mg, Qd	Not Reported
	Fosamac	S	Oral		Not Reported
	Bezatosol	S	Oral	900 Mg, Bid	Not Reported
	Bezatosol	S	Oral	450 Mg, Bid	Not Reported
	Bezatosol	S	Oral	900 Mg, Bid	Not Reported
	Bezatosol	S	Oral	450 Mg, Bid	Not Reported
	Bezatosol	S	Oral	450 Mg, Bid	Not Reported
	Bezatosol	S	Oral	450 Mg, Bid	Not Reported
	Valixa	S	Oral	900 Mg, Bid	Not Reported
	Valixa	S	Oral	450 Mg, Bid	Not Reported
	Valixa	S	Oral	450 Mg, Qd	Not Reported
	Valixa	S	Oral	900 Mg, Bid	Not Reported
	Valixa	S	Oral	450 Mg, Bid	Not Reported
	Valixa	S	Oral	450 Mg, Bid	Not Reported
	Valixa	S	Oral	450 Mg, Bid	Not Reported
	Ethambutol	S	Oral		Not Reported
	Myslee	C		5 Mg, Qd	Not Reported
	Mucosta	C		100 Mg, Tid	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mycobutin	C	150 Mg, Unk	Not Reported
Triazolam Tablets	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	11323636	EXPEDITED (15-DAY)	OT		JP-GLAXOSMITHKLINE INC.-JP2015JPN102901		52 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Diabetes Mellitus; Diabetic Neuropathy; Eosinophilic Pustular Folliculitis; Hyperlipidaemia; Hyperuricaemia; Hyponatraemia; Osteoporosis; Renal Impairment; Sinusitis	Dolutegravir			S	Oral	50 Mg, Unk		Viiv
	Epzicom			S	Oral	1 Df, Unk		Viiv
	Abacavirsulphate+Dolutegravir+Lamivudine			S	Oral	1 Df, 1d		Viiv
	Zithromac			S	Unknown	1200 Mg, We		Not Reported
	Zithromac			S	Unknown	600 Mg, Qd		Not Reported
	Zithromac			S	Unknown	500 Mg, Qd		Not Reported
	Lipidil			S	Oral	Unk		Not Reported
	Baktar			S	Oral			Not Reported
	Sulphamethoxazole + Trimethoprim			S	Unknown			Not Reported
	Norvir			S	Oral	100 Mg, Unk		Not Reported
	Truvada			S	Oral	1 Df, 1d		Not Reported
	Prezista Naive			S	Oral	800 Mg, Qd		Not Reported
	Fosamac			S	Oral			Not Reported
	BezatoI			S	Oral	900 Mg, Bid		Not Reported
	BezatoI			S	Oral	450 Mg, Bid		Not Reported
	BezatoI			S	Oral	900 Mg, Bid		Not Reported
	BezatoI			S	Oral	450 Mg, Bid		Not Reported
	BezatoI			S	Oral	450 Mg, Bid		Not Reported
	BezatoI			S	Oral	450 Mg, Bid		Not Reported
	Valixa			S	Oral	900 Mg, Bid		Not Reported
	Valixa			S	Oral	450 Mg, Bid		Not Reported
	Valixa			S	Oral	450 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valixa	S	Oral	900 Mg, Bid	Not Reported
Valixa	S	Oral	450 Mg, Bid	Not Reported
Valixa	S	Oral	450 Mg, Bid	Not Reported
Valixa	S	Oral	450 Mg, Bid	Not Reported
Ethambutol	S	Oral		Not Reported
Myslee	C		5 Mg, Qd	Not Reported
Mucosta	C		100 Mg, Tid	Not Reported
Mycobutin	C		150 Mg, Unk	Not Reported
Triazolam Tablets	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16320508	NON-EXPEDITED			US-PFIZER INC-2019207565		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16389899	EXPEDITED (15-DAY)		OT	FR-NAPPMUNDI-GBR-2019-0066866		27 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalopathy	Oxynorm			S	Intravenous (not otherwise specified)	Unk (Strength 50mg/MI)		Purdue	
	Alprazolam			S	Oral	2 Df, Daily		Not Reported	
	Sandimmun			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Zarzio			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Smecta /00837601/			S	Oral	Unk		Not Reported	
	Cellcept /01275102/			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vfend	S	Oral	2 Df, Daily	Not Reported
Ondansetron /00955302/	S	Intravenous (not otherwise specified)	Unk	Not Reported
Azyter	S	Ophthalmic	Unk	Not Reported
Magne B6 /01431101/	S	Oral	Unk	Not Reported
Tranxene	S	Oral	2 Df, Daily	Not Reported
Pantoprazole Sodium	S	Intravenous drip	40 Mg Daily	Not Reported
Hydroxyzine /00058402/	S	Oral	1 Df, Daily	Not Reported
Celluvisc /00007002/	S	Ophthalmic	Unk	Not Reported
Valaciclovir /01269702/	S	Oral	1 Df Daily (Strength 500 Mg)	Not Reported
Vancomycine	S	Intravenous (not otherwise specified)	2 G, Q24h	Not Reported
Sulfarlem-Choline	S	Oral	Unk	Not Reported
Furosemide	S	Intravenous (not otherwise specified)	20 Mg, Q12h	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607463	NON-EXPEDITED			US-INSMED, INC.-US-INS-19-01998			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Dry Throat; Fatigue; Gastrointestinal Disorder; Thirst; Vocal Cord Inflammation	Arikayce			S	Respiratory (inhalation)			Insmmed
	Lamira Nebulizer System			S				Insmmed
	Azithromycin			S				Not Reported
	Rifampin			S				Not Reported
	Ethambutol			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16607682	EXPEDITED (15-DAY)		OT	AU-ACCORD-139273			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lung Disorder	Montelukast			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Mycophenolic Acid	S							Accord
	Azithromycin	S							Not Reported
	Methylprednisolone	S							Not Reported
	Jakavi	S							Not Reported
	Sirolimus	S							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16608014	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2019297609		77 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Increased; Nausea; Off Label Use; Pallor; Product Use Issue; Skin Discolouration	Zithromac 250mg			S	Oral	250 Mg, Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16608989	EXPEDITED (15-DAY)		HO	HR-MYLANLABS-2019M1067108		60 YR	Female	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Oedema; Haematoma; Periorbital Oedema; Pruritus; Pyrexia; Rash; Skin Lesion; Skin Plaque; Urticaria	Quetiapine			S	Oral	1x1		Not Reported	
	Pregabalin			S	Oral	50 Mg; 2x1		Not Reported	
	Detralex			S	Oral	1000 Milligram, Qd		Mylan	
	Sumamed			S	Oral	500 Mg; 1x1 3 Dana		Mylan	
	Andol /00002701/			S	Oral	300 Mg; 2x1		Mylan	
	Spasmomen			S	Oral	Unk		Mylan	
	Normabel			S	Oral	5 Mg; Pp		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16610442	EXPEDITED (15-DAY)		OT	PL-TEVA-2019-PL-1080037		26 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Swelling; Urticaria	Sumamed 500 Mg			S		500mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jul-2019	16613253	EXPEDITED (15-DAY)		OT	PHHY2019US166642		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Product Use In Unapproved Indication	Vancomycin			S	Unknown			Not Reported	
	Vancomycin			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Clindamycin			S	Unknown			Not Reported	
	Clindamycin			S				Not Reported	
	Piperacillin, Tazobactam			S	Unknown			Not Reported	
	Piperacillin, Tazobactam			S				Not Reported	
	Amoxicillin			S	Unknown			Not Reported	
	Amoxicillin			S				Not Reported	
	Metronidazole			S	Unknown			Novartis	
	Metronidazole			S				Novartis	
	Meropenem			S	Unknown			Not Reported	
	Meropenem			S				Not Reported	
	Gentamycin			S	Unknown			Not Reported	
	Gentamycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	15944745	NON-EXPEDITED			US-PFIZER INC-2019060916		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Dilantin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Neurontin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax	S	Unk	Pfizer
Carbamazepine	S	Unk	Not Reported
Divalproex	S	Unk	Not Reported
Erythromycin Estolate	S	Unk	Not Reported
Oxycodone	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16462660	EXPEDITED (15-DAY)		DE, HO, OT	CA-AUROBINDO-AUR- APL-2019-034301			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptococcosis; Drug Ineffective; Drug Intolerance; Drug Resistance; Enterocolitis; Multiple Organ Dysfunction Syndrome; Mycobacterium Avium Complex Infection; Nosocomial Infection	Moxifloxacin			S	Unknown	Unk		Aurobindo
	Azithromycin For Injection Usp			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Clarithromycin			S	Oral	Unk		Not Reported
	Ethambutol			S	Oral	Unk		Not Reported
	Fluconazole			S	Oral	Unk		Not Reported
	Mycophenolate Sodium			S	Intracardiac	Unk		Not Reported
	Amikacin			S	Parenteral	Unk		Not Reported
	Prednisone			S	Intracardiac	Unk		Not Reported
	Rifabutin			S	Oral	Unk		Not Reported
	Rifampin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tacrolimus			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16613499	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2019-040777			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chest Pain; Chills; Empyema; Night Sweats; Productive Cough; Respiration Abnormal; Treatment Failure	Azithromycin Atorvastatin Lisinopril Metformin Saxagliptin	S C C C C	Unknown Unknown Unknown Unknown Unknown	Unk, 5-Day Course Unk Unk Unk Unk	Aurobindo Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16613805	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2019304542		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy	Vfend			S	Oral	400 Mg, 1x/Day		Pfizer
	Smecta [Diosmectite]			S	Oral	Unk		Not Reported
	Sandimmun			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole Arrow			S	Intravenous drip	40 Mg, 1x/Day		Not Reported
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S	Oral	Unk		Not Reported
	Oxynorm			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Valaciclovir Arrow			S	Oral	1 Df, 1x/Day		Not Reported
	Tranxene			S	Oral	2 Df, 1x/Day		Not Reported
	Sulfarlem			S	Oral	Unk		Not Reported
	Biotine (Biotin)			S		Unk		Not Reported
	Choline			S		Unk		Not Reported
	Calcium Pantothenate Fuso			S		Unk		Not Reported
	Cyanocobalamine			S		Unk		Not Reported
	Folic Acid			S		Unk		Not Reported
	Nicotinamide			S		Unk		Not Reported
	Pyridoxine			S		Unk		Not Reported
	Vitamine B1			S		Unk		Not Reported
	Furosemide Renaudin			S	Intravenous (not	20 Mg, 2x/Day (Every 12		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	Hours)	
Difclir	S	Oral	400 Mg, 1x/Day	Not Reported
Ciclosporine	S		Unk	Not Reported
Vancomycine Sandoz	S	Intravenous (not otherwise specified)	2 G, 1x/Day	Not Reported
Zerbaxa	S	Intravenous (not otherwise specified)	Unk	Not Reported
Alprazolam Mylan	S	Oral	2 Df, 1x/Day	Not Reported
Magne B6 [Magnesium Lactate;Magnesium Pidolate;Pyridoxine Hydrochlorid Celluvisc Md	S	Oral	Unk	Not Reported
Zarzio	S	Ophthalmic	Unk	Not Reported
	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydroxyzine Arrow	S	Oral	1 Df, 1x/Day	Not Reported
Ondansetron Accord	S	Intravenous (not otherwise specified)	Unk	Not Reported
Azyter	S	Ophthalmic	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16613904	EXPEDITED (15-DAY)		OT	FR-ZYDUS-038798		62 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Brintellix			S	Oral			Not Reported
	Azithromycin			S	Oral			Zydus Pharm
	Oxomemazine			S	Oral			Not Reported
	Rabeprazole/Rabeprazole Sodium			C				Not Reported
	Olanzapine			C	Oral			Not Reported
	Prazepam			C	Oral			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614092	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1068608		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Vancomycin			S	Unknown			Not Reported	
	Vancomycin			S				Not Reported	
	Vancomycin			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Clindamycin			S	Unknown			Not Reported	
	Clindamycin			S				Not Reported	
	Clindamycin			S				Not Reported	
	Piperacillin/Tazobactam			S	Unknown			Not Reported	
	Piperacillin/Tazobactam			S				Not Reported	
	Piperacillin/Tazobactam			S				Not Reported	
	Metronidazole			S	Unknown			Not Reported	
	Metronidazole			S				Not Reported	
	Metronidazole			S				Not Reported	
	Gentamicin			S	Unknown			Mylan	
	Gentamicin			S				Mylan	
	Gentamicin			S				Mylan	
	Amoxicillin			S	Unknown			Mylan	
	Amoxicillin			S				Mylan	
	Amoxicillin			S				Mylan	
	Meropenem			S	Unknown			Mylan	
	Meropenem			S				Mylan	
	Meropenem			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614534	NON-EXPEDITED		HO	US-PFIZER INC-2019310141		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Amoxicillin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Zithromax			S				Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614563	NON-EXPEDITED			US-PFIZER INC-2019311395		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614966	NON-EXPEDITED			US-PFIZER INC-2019313350		9 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614991	NON-EXPEDITED			US-PFIZER INC-2019314219		44 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16614998	NON-EXPEDITED			US-PFIZER INC-2019312725		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
	Nystatin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16615871	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-041449			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Cough; Dyspnoea; Gastroesophageal Reflux Disease; Therapeutic Product Effect Incomplete	Montelukast			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Pulmicort			S	Unknown	Unk		Not Reported
	Salbutamol Sulfate			S	Unknown	2 Dosage Form		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	2 Dosage Form, Once A Day		Not Reported
	Symbicort			S	Unknown	2 Dosage Form, Two Times A Day		Not Reported
	Erythromycin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16617260	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1067968		64 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Extrasystoles; Tachycardia	Azithromycin			S	Oral	Unk		Not Reported
	Nozinan /00038601/			S	Oral	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16617309	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019306475		3 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypothermia	Zithromac 10%			S	Oral			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jul-2019	16617456	EXPEDITED (15-DAY)		HO, LT	ES-MYLANLABS-2019M1068134		50 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Hepatitis Cholestatic	Linezolid			S	Intravenous (not otherwise specified)	600 Milligram, Bid(12h)		Not Reported	
	Azitromicina			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Mylan	
	Tamiflu			S	Oral	75 Milligram, Qd		Mylan	
	Voriconazol			S	Oral	500 Milligram, Qd		Mylan	
	Amoxicilina + Acido Clavulanico			S	Intravenous (not otherwise specified)	1 Dosage Form, Q8h		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	15596573	NON-EXPEDITED		OT	US-APOTEX-2018AP024029		2 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Liver Function Test Abnormal	Azithromycin			S	Unknown			Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	15601351	NON-EXPEDITED		OT	US-APOTEX-2018AP024154			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jul-2019	15611865	NON-EXPEDITED		OT	US-APOTEX-2018AP024030			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Liver Function Test Abnormal	Azithromycin			S	Unknown	Unk Unk, Unknown		Apotex	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	15727837	NON-EXPEDITED			US-PFIZER INC-2018517495		72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lidocaine Hcl			S		Unk		Unknown	
	Phenergan [Promethazine]			S		Unk		Not Reported	
	Iodine			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16622555	EXPEDITED (15-DAY)		OT	ES-ZYDUS-038955		65 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea; Laryngospasm; Paraesthesia	Azithromycin			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16623697	NON-EXPEDITED		OT	US-APOTEX-2018AP024153			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug-Induced Liver Injury	Azithromycin			S	Unknown			Apotex	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16625425	NON-EXPEDITED			US-PFIZER INC-2019315687		21 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Jul-2019	16626395	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-		58 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2018SP010906

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection	Tacrolimus			S	Unknown	Unk		Strides
	Mycophenolate Mofetil			S	Unknown	Unk		Strides
	Prednisolone			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16625240	NON-EXPEDITED			US-PFIZER INC-2019316218		53 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16629891	EXPEDITED (15-DAY)		HO	PHHY2019GB170265		33 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Chest Discomfort; Condition Aggravated; Cough; Decreased Appetite; Dry Throat; Hypersomnia; Influenza; Nasopharyngitis	Omeprazole			S	Oral	40 Mg, Unk		Novartis
	Paracetamol			S	Oral	500 Mg, (Max 4g Qd, 1000 Mg Four Times A Day Prn 7 Days)		Not Reported
	Paracetamol			S				Not Reported
	Azithromycin			S	Oral	250 Mg, Qd (Each Morning 28 Days)		Not Reported
	Salbutamol			S	Unknown	100 Ug, (2 Puff(S) Prn 28 Days)		Not Reported
	Montelukast Sodium			S	Oral	10 Mg, Qd (Each Night 28 Days)		Not Reported
	Docusate Sodium			S	Oral	200 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Macrogol	S	Oral	1 Df, Bid (1 Sachet Twice Daily At L0am And 10pm 10 Days)	Not Reported
Colobreathe	S	Respiratory (inhalation)	1 Df, Qd (1662500 lu, Twice Daily)	Not Reported
Colobreathe	S			Not Reported
Multi Vitamin	S	Oral	1 Df, Qd (Tablets/Capsules - 1 Tablet Each Morning 28 Days)	Not Reported
Creon	S	Oral	10000 Mg, (5 Capsule 3 Times A Day With Food 07:00, 12:00, 17:00)	Not Reported
Ciclesonide	S	Unknown	160 Ug, Qd (Each Morning)	Not Reported
Colecalciferol	S	Oral	800 Df, (Capsules/Tablets, 800 Unit Each Morning 28 Days)	Not Reported
Sodium Chloride	S	Unknown	4 Ml, Qd (Every Morning At 6 A.M., Mucolytic)	Not Reported
Alpha-Tocopherol, DI-	S	Oral	134 Mg, Qd (Every Morning At 6 Am)	Not Reported
Fluticasone Furoate	S	Unknown	27.5 Mg, Qd (Each Morning)	Not Reported
Dornase Alfa	S	Unknown	2.5 Mg, (Each Morning 2 Days, Mucolytic)	Not Reported
Vitamin A & D [Retinol\ Vitamin D Nos]	S	Oral	2 Df, Qd (Every Morning At 6 Am)	Not Reported
Zopiclone	S	Oral	3.75 Mg, Qd (Each Night 28 Days)	Not Reported
Sodium Chloride	S	Oral	600 Mg, (1800 Mg 3 Times A Day)	Not Reported
Symbicort	S	Unknown	Budesonide 200 Mcg/ Formetrol 6 Mcg, 2 Puff(S) Twice Daily Morning	Not Reported
Carbocysteine	S	Oral	375 Mg, (750 Mg Three	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Times A Day, Mucolytic)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16630434	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2019-032667			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin 250 Mg Tablets Usp			S	Unknown	2 Dosage Form, Once A Day		Aurobindo	
	Azithromycin 250 Mg Tablets Usp			S	Unknown	1 Dosage Form, Once A Day		Aurobindo	
	Hydrocodone			C	Unknown	Unk		Not Reported	
	Tizanidine			C	Unknown	Unk		Not Reported	
	Cetirizine Hcl			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Ezetimibe			C	Unknown	Unk		Not Reported	
	Loxitane			C	Unknown	Unk		Not Reported	
	Dextroamphetamine			C	Unknown	Unk		Not Reported	
	Vitamin B12			C	Unknown	Unk		Not Reported	
	Vitamin C			C	Unknown	Unk		Not Reported	
	Vitamin D3			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16630988	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-043216			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort;	Azithromycin			S	Unknown	Unk		Aurobindo	
Cytomegalovirus Infection;	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
Epstein-Barr Virus	Desogestrel			S	Oral	Unk		Not Reported	
Infection; Flushing;	Levothyroxine			C	Unknown	Unk		Not Reported	
Hepatocellular Injury;									
Hepatosplenomegaly;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inflammation; Pleurisy;
Portal Vein Thrombosis;
Pyrexia; Therapy Non-
Responder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16631051	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-043417			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adrenal Disorder; Asthma; Blood Potassium Abnormal; Cardiomegaly; Dyspnoea; Herpes Zoster; Infection; Mast Cell Activation Syndrome; Nasal Discharge Discolouration; Neoplasm Malignant; Pneumonitis; Productive Cough; Rhinorrhoea; Sputum Discoloured; Wheezing	Azithromycin			S	Oral	1 Dosage Form		Aurobindo	
	Diltiazem			S	Oral	1 Dosage Form, Once A Day		Not Reported	
	Omalizumab			S	Subcutaneous	375 Milligram,1 Every 2 Weeks		Not Reported	
	Omalizumab			S	Subcutaneous	375 Milligram,1 Every 2 Weeks		Not Reported	
	Omalizumab			S	Subcutaneous	375 Milligram,1 Every 2 Weeks		Not Reported	
	Omalizumab			S	Subcutaneous	375 Milligram,1 Every 2 Weeks		Not Reported	
	Omalizumab			S	Subcutaneous	375 Milligram,1 Every 2 Weeks		Not Reported	
	Acetylsalicylic Acid;Codeine			C	Oral	1 Dosage Form, Once A Day		Not Reported	
	Esomeprazole			C	Oral	1 Dosage Form, Two Times A Day		Not Reported	
	Rhinocort			C	Nasal	4 Dosage Form, Two Times A Day		Not Reported	
	Rhinocort Singulair			C C	Oral	1 Dosage Form, Once A Day		Not Reported Not Reported	
	Spiriva			C				Not Reported	
	Symbicort			C		2 Dosage Form, 3 Times A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Synthroid	C	Oral	1 Dosage Form, Once A Day	Not Reported
Ventolin	C		2 Dosage Form	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16631152	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1081094		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Diltiazem			S	Unknown	1 Dosage Forms Daily;		Teva
Alopecia; Asthenia;	Prednisone			S	Unknown			Actavis
Asthma; Balance Disorder;	Prednisone			S	Unknown			Actavis
Bladder Disorder; Blood	Prednisone			S	Unknown			Actavis
Glucose Abnormal; Blood	Prednisone			S	Unknown			Actavis
Pressure Systolic	Prednisone			S	Unknown			Actavis
Increased; Body	Omalizumab			S	Subcutaneous			Not Reported
Temperature Decreased;	Ventolin			S	Unknown			Not Reported
Brain Hypoxia; Breath	Ventolin			S	Respiratory (inhalation)			Not Reported
Odour; Breath Sounds								
Abnormal; Bronchitis;								
Carbon Dioxide Increased;								
Chest Discomfort; Chest	Ventolin			S	Unknown			Not Reported
Pain; Cough; Crepitations;	Ventolin			S	Unknown			Not Reported
Diarrhoea; Drug								
Ineffective; Dyspepsia;	Ventolin			S	Unknown			Not Reported
Dyspnoea; Dyspnoea	Zithromax			S	Unknown			Not Reported
Exertional; Fall; Fatigue;	Zithromax			S	Unknown			Not Reported
Feeling Abnormal; Forced	Zithromax			S	Unknown			Not Reported
Expiratory Volume	Zithromax			S	Unknown			Not Reported
Decreased; Frustration	Zenhale			C	Unknown			Not Reported
Tolerance Decreased;	Tums			C	Unknown			Not Reported
Gait Disturbance;	Spiriva			C	Unknown	2 Dosage Forms Daily;		Not Reported
Gastrooesophageal Reflux	Ipratropium Bromide +			C	Unknown			Not Reported
Disease; General Physical	Salbutamol Sulphate							
Health Deterioration;	Dexilant			C	Unknown	1 Dosage Forms Daily;		Not Reported
Haemarthrosis; Headache;	Atrovent			C	Unknown	8 Dosage Forms Daily;		Not Reported
Heart Rate Increased;								
Humidity Intolerance;	Alvesco			C	Unknown	8 Dosage Forms Daily;		Not Reported
Hypersensitivity;								
Hypoventilation; Infection;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injury; Insomnia; Joint Swelling; Lung Disorder; Malaise; Memory Impairment; Muscle Disorder; Muscle Spasms; Musculoskeletal Discomfort; Nasopharyngitis; Odynophagia; Oral Candidiasis; Oropharyngeal Pain; Pain In Extremity; Paraesthesia; Peak Expiratory Flow Rate Abnormal; Peak Expiratory Flow Rate Decreased; Peripheral Swelling; Pneumonia; Pollakiuria; Poor Quality Sleep; Productive Cough; Pulmonary Function Test Decreased; Pyrexia; Respiratory Rate Increased; Respiratory Tract Congestion; Rhinorrhoea; Seasonal Allergy; Sputum Discoloured; Stress; Tendonitis; Tremor; Viral Infection; Vomiting; Weight Decreased; Wheezing	Advair	C	Respiratory (inhalation)	2 Dosage Forms Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16632004	EXPEDITED (15-DAY)		DE, OT	CN-PFIZER INC-2019313809			Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16632852	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1081785		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Diarrhoea; Feeling Abnormal; Hyperhidrosis; Loss Of Consciousness; Loss Of Personal Independence In Daily Activities; Malaise	Azithromycin Teva			S	Unknown			Not Reported	
	Omeprazole			S	Unknown			Actavis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16632980	NON-EXPEDITED			US-PFIZER INC-2019318350		39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Benzympenicillin Potassium			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jul-2019	16810067	DIRECT		HO, LT			79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Dyspnoea; Influenza; Pyrexia; Rash	Azithromycin 250mg			S	Oral	Other Frequency:21 Days;		Not Reported	
	Azithromycin 250mg			S		Other Frequency:5 Days;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	12159802	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2016US008118		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug	Atorvastatin			S	Oral	Unk Unk, Unknown Freq.		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Interaction; Photodermatitis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Tacrolimus	S	Oral	Unk Unk, Unknown Freq.	Astellas
	Pantoprazole	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Lansoprazole	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Azithromycin	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Voriconazole	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Voriconazole	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Mycophenolate Mofetil	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Prednisone	S	Oral	Unk Unk, Unknown Freq.	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Oral	Unk Unk, Unknown Freq.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16600574	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2019-042364			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Aspirine			C	Unknown	Unk		Not Reported	
	Telmisartan			C	Unknown	Unk		Not Reported	
	Macrogol 4000			C	Unknown	Unk		Not Reported	
	Permixon			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16635812	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-215116		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Laryngospasm; Paraesthesia	Azithromycin			S	Oral	500 Milligram, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16636224	NON-EXPEDITED			US-PFIZER INC- 2019316580		67 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colitis; Off Label Use; Product Use In Unapproved Indication	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16636323	EXPEDITED (15-DAY)		OT	NL-MYLANLABS- 2019M1069218		62 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Basal Cell Carcinoma; Keratoacanthoma; Photosensitivity Reaction	Azithromycin			S	Oral	3x Week 500mg		Not Reported	
	Calcium			C		Unk		Mylan	
	Ascal /00002702/			C		Unk		Mylan	
	D3			C		Unk		Mylan	
	Persantin			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16636451	NON-EXPEDITED			PHEH2019US031145			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16636468	NON-EXPEDITED			US-PFIZER INC- 2019319675		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Fentanyl Citrate			S		Unk		Unknown	
	Codeine			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetaminophen;Hydrocodone	S	Unk	Not Reported
Soma [Carisoprodol]	S	Unk	Not Reported
Tylenol With Codeine	S	Unk	Not Reported
Biaxin	S	Unk	Not Reported
Fluoxetine Hcl	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16636476	NON-EXPEDITED			US-PFIZER INC-2019318425		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Miliaria	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16636755	EXPEDITED (15-DAY)		OT	PHHY2019CA172824		11 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Madarosis	Azithromycin Sandoz			S	Oral	400 Mg, Qd		Novartis	
	Azithromycin Sandoz			S	Oral	200 Mg, Qd		Novartis	
	Fluoxetine			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Guanfacina			C	Unknown	Unk		Not Reported	
	Montelukast			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jul-2019	16639520	NON-EXPEDITED			PHEH2019US031188			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2019	16236869	EXPEDITED (15-DAY)		DE	ES-ACCORD-123666		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rhabdomyolysis	Simvastatin			S	Oral			Accord	
	Azithromycin Cinfa			S	Oral	1 Sachet Per Day, Strength : 500 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jul-2019	16640133	EXPEDITED (15-DAY)		HO, LT	PHHY2019GB174736		78 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenic Sepsis	Azithromycin			S	Oral	250 Mg, Qd		Novartis	
	Amitriptyline Hydrochloride			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Ethambutol			C	Unknown	Unk		Not Reported	
	Seretide			C	Unknown	Unk		Not Reported	
	Accrete D3			C	Unknown	Unk		Not Reported	
	Rifampicin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2019	16640259	EXPEDITED (15-DAY)		HO, OT	PHHY2019PT172388		63 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Granulomatosis With Polyangiitis; Temporal Arteritis	Azithromycin			S	Unknown	Unk		Novartis	
	Norfloxacin			S	Unknown	Unk		Not Reported	
	Prednisolon			C	Unknown	5 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	12858333	NON-EXPEDITED			US-PFIZER INC-2016485100		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16641616	EXPEDITED (15-DAY)		HO, OT	GR-AUROBINDO-AUR-APL-2019-043776			Unknown	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Fatigue; Hepatomegaly; Hypergammaglobulinaemi a; Inflammatory Marker Increased; Pancytopenia; Product Use In Unapproved Indication; Pyrexia; Sepsis; Splenomegaly; Visceral Leishmaniasis	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16641811	EXPEDITED (15-DAY)		DS, OT	CA-BAYER-2019-132990		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Diarrhoea;	Cipro 500 Mg			S	Oral	500 Mg, Qd		Bayer	
Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea;	Cipro 500 Mg			S				Bayer	
Obesity; Renal Disorder; Renal Impairment	Ciprofloxacin			S	Unknown	Unk		Not Reported	
	Ciprofloxacin			S				Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Quetiapine			S	Oral	100 Mg, Qd		Not Reported	
	Quetiapine			S	Oral	Unk Unk, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Risperidone	C	Unk	Not Reported
Amoxicillin	C	Unk	Not Reported
Valproate Semisodium	C	Unk	Not Reported
Zyprexa	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16641812	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-132985		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Biopsy	Cipro			S	Oral	Unk		Bayer
Colon Abnormal; Blood Pressure Decreased; C-Reactive Protein	Avelox			S	Unknown	Unk		Bayer
Increased; Diarrhoea; Dysbiosis; Enteritis;	Pms Azithromycin			S	Unknown	Unk		Not Reported
Frequent Bowel Movements;	Pms Azithromycin			S	Unknown	Unk		Not Reported
Gastroenteritis	Cefixime			S	Unknown	Unk		Not Reported
Staphylococcal; Gastrointestinal Mucosa Hyperaemia;								
Haematochezia; Heart Rate Increased; Nausea; Purulence; Staphylococcal Infection; Weight Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16642428	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019319153		3 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Zithromax			S	Oral	1.25 Df, 1x/Day		Pfizer
Diarrhoea; Haematochezia	Zithromax			S	Oral	1.25 Df, 1x/Day		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16642616	NON-EXPEDITED			US-PFIZER INC-2019318076		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Lortab [Hydrocodone Bitartrate;Paracetamol]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16642880	EXPEDITED (15-DAY)		OT	CA-UCBSA-2019030839			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Cimzia			S	Subcutaneous	Unk		Not Reported	
	Arava			S		Unk		Not Reported	
	Celebrex			S	Oral	Unk		Not Reported	
	Benadryl [Diphenhydramine Hydrochloride]			S		Unk		Not Reported	
	Demerol			S		Unk		Not Reported	
	Enbrel			S		Unk		Not Reported	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Imuran [Azathioprine]			S		Unk		Not Reported	
	Levofloxacin			S		Unk		Not Reported	
	Methotrexate			S		Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S		Unk		Not Reported	
	Azithromycin			S		250 Milligram, Once Daily (Qd)		Not Reported	
	Procytox			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Xeljanz			S	Oral	5 Milligram, 2x/Day (Bid)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ezetrol			C			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
29-Jul-2019	16642937	NON-EXPEDITED		OT	US-PFIZER INC-2019320626		48 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Discomfort; Diarrhoea; Nasal Mucosal Discolouration; Nausea	Azithromycin			S		Unk		Pfizer		
	Prednisone			S		Unk		Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16643139	NON-EXPEDITED			US-PFIZER INC-2019321677		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Indomethacin			S		Unk		Unknown	
	Atorvastatin Calcium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Allopurinol			S		Unk		Not Reported	
	Acetaminophen;Hydrocodone			S		Unk		Not Reported	
	Baclofen			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Duloxetine			S		Unk		Not Reported	
	Gluten			S		Unk		Not Reported	
	Glimepiride			S		Unk		Not Reported	
	Lantus			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Losartan			S		Unk		Not Reported	
	Lovaza			S		Unk		Not Reported	
	Metformin			S		Unk		Not Reported	
	Paxil			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Penicilline	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Vicodin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16643144	NON-EXPEDITED			US-PFIZER INC-2019322265			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Neurontin			S		Unk		Pfizer	
	Protonix (Pantoprazole)			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Lipitor			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Aciphex			S		Unk		Not Reported	
	Butisol			S		Unk		Not Reported	
	Ceftin (Cefuroxime Axetil)			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Crestor			S		Unk		Not Reported	
	K-Dur			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Toprol			S		Unk		Not Reported	
	Trandate			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16643383	NON-EXPEDITED			US-PFIZER INC-2019324019			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16644271	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2019M1070740		34 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Face Oedema; Periorbital Oedema; Pruritus	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jul-2019	16644530	EXPEDITED (15-DAY)		DE, HO, OT	CA-BAYER-2019-135629		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cryptococcosis; Drug Ineffective; Drug Intolerance; Enterocolitis; Multiple Organ Dysfunction Syndrome; Mycobacterium Avium Complex Infection; Nosocomial Infection	Avelox			S	Unknown	Unk		Bayer	
	Amikacin			S	Parenteral	Unk		Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Clarithromycin			S	Oral	Unk		Not Reported	
	Ethambutol			S	Oral	Unk		Not Reported	
	Fluconazole			S	Oral	Unk		Not Reported	
	Mycophenolate Sodium			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Rifabutin			S	Oral	Unk		Not Reported	
	Rifampin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	14768347	NON-EXPEDITED			US-PFIZER INC-2018157140		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16054417	EXPEDITED (15-DAY)		HO, LT	JP-ROCHE-2277929		50 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Hepatic Function Abnormal; Renal Impairment; Vomiting	Xofluza			S	Oral			Not Reported	
	Zithromac			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16069770	EXPEDITED (15-DAY)		DE	ES-009507513-1903ESP002108		61 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rhabdomyolysis	Simvastatin			S	Oral	Unk		Merck	
	Azithromycin			S	Oral	1 Sachet Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16403929	EXPEDITED (15-DAY)		OT	JP-ROCHE-2333959		56 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Diarrhoea; Loss Of Consciousness; Nausea	Xofluza			S	Oral			Not Reported	
	Azithromycin Hydrochloride			S	Oral			Not Reported	
	Methoxyphenamine			C				Not Reported	
	Diprophylline			C				Not Reported	
	Biofermin R			C				Not Reported	
	Tranexamic Acid			C				Not Reported	
	Flaveric			C				Not Reported	
	Huscode			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16451502	EXPEDITED (15-DAY)		DE, OT	CA-APOTEX-2019AP016407		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Death;	Ciprofloxacin	S	Unknown	Unk	Apotex
Decreased Appetite; Drug	Azithromycin	S	Unknown	Unk	Apotex
Ineffective; Fatigue;	Trimethoprim	S	Unknown	Unk	Not Reported
Malignant Neoplasm	Afinitor	S	Oral	5 Mg, Qd	Not Reported
Progression; Pancreatic	Octreotide Acetate	S	Subcutaneous	Unk	Not Reported
Neuroendocrine Tumour;	Sandostatin	S	Unknown	60 Mg, Unk	Not Reported
Platelet Count Decreased;					
Rash; Somnolence;					
Weight Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16568502	EXPEDITED (15-DAY)		HO, OT	PHHY2019IT158168		16 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Azitromicina			S	Unknown	Unk		Novartis	
Endocarditis Bacterial;	Cefixime			S	Unknown	Unk		Not Reported	
Joint Swelling; Pharyngitis;									
Pyrexia									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16646806	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2019-043499			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bordetella Infection;	Methylprednisolone			S	Unknown			Aurobindo	
Bronchitis; Cough	Prednisone			S	Oral	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Cephalexin			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Cefepime			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16646875	EXPEDITED (15-DAY)		OT	KR-PFIZER INC- 2019318084			Unknown	KOR

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Failure	Zithromax			S	Intravenous drip	2.0mg/MI Infused Over One Hour		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16646935	NON-EXPEDITED			US-NEOPHARMA INC-000125			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Augmentin			S				Not Reported
	Sertraline			S				Not Reported
	Azithromycin			S				Not Reported
	Cephalexin			S				Not Reported
	Ultram (Tramadol Hydrochloride)			S				Not Reported
	Buspirone			S				Not Reported
	Bactrim			S				Not Reported
	Celexa			S				Not Reported
	Duloxetine/Duloxetine Hydrochloride			S				Not Reported
	Paxil (Paroxetine Hydrochloride)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16648134	NON-EXPEDITED			US-009507513-1907USA009321		11 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction	Isentress Chewable Tablets			S	Oral	Unk		Merck
	Emtricitabine (+) Tenofovir			S		Unk		Not Reported
	Abacavir			S				Not Reported
	Darunavir (+) Ritonavir			S				Not Reported
	Cyclophosphamide			S		50 Mg/Kg X 2		Not Reported
	Fludarabine Phosphate			S		25 Mg/M2 x 3		Not Reported
	Cyclosporine			S	Intravenous (not otherwise specified)			Not Reported
	Cyclosporine			S	Oral	Unk		Not Reported
	Mycophenolic Acid			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Pentamidine Isethionate		S					Not Reported
		Micafungin		S					Not Reported
		Azithromycin		S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16648834	EXPEDITED (15-DAY)		HO	PHHY2019SK174724		8 YR	Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Movement Disorder; Muscle Spasms; Nausea	Azithromycin Sandoz			S	Unknown	500 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jul-2019	16649120	NON-EXPEDITED			US-PFIZER INC-2019322882			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	15628821	EXPEDITED (15-DAY)		OT	CA-ASTELLAS-2018US048913		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Tacrolimus			S	Oral	Unk, Unknown Freq.		Astellas	
	Apo Azithromycin			S	Oral	Unk, Unknown Freq.		Not Reported	
	Cancidas			S	Intravenous (not otherwise specified)	Unk, Unknown Freq.		Not Reported	
	Ciprofloxacin			S	Oral	Unk, Unknown Freq.		Not Reported	
	Montelukast Sodium			S	Oral	Unk, Unknown Freq.		Not Reported	
	Mycophenolate Mofetil			S	Oral	Unk, Unknown Freq.		Not Reported	
	Nifedipine			S	Oral	Unk, Unknown Freq.		Not Reported	
	Pantoprazole			S	Oral	Unk, Unknown Freq.		Not Reported	
	Pantoprazole			S	Intravenous (not	Unk, Unknown Freq.		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Prednisone	S	Oral	Unk, Unknown Freq.		Not Reported
Sulfatrim /00086101/	S	Oral	Unk, Unknown Freq.		Not Reported
Voriconazole	S	Oral	Unk, Unknown Freq.		Not Reported
Azithromycin	S	Oral	Unk, Unknown Freq.		Not Reported
Apo Montelukast	S	Oral	Unk, Unknown Freq.		Not Reported
Apo Mycophenolate	S	Oral	Unk, Unknown Freq.		Not Reported
Apo Sulfatrim	S	Oral	Unk, Unknown Freq.		Not Reported
Caspofungin Acetate	S	Intravenous (not otherwise specified)	Unk, Unknown Freq.		Not Reported
Ciprofloxacin Hydrochloride	S	Oral	Unk, Unknown Freq.		Not Reported
Pantoprazole Sodium Anhydrous	S	Oral	Unk Unk, Unknown Freq.		Not Reported
Pantoprazole Sodium Anhydrous	S	Intravenous (not otherwise specified)	Unk Unk, Unknown Freq.		Not Reported
Pms Azithromycin	S	Oral	Unk Unk, Unknown Freq.		Not Reported
Voriconazole	S	Intravenous (not otherwise specified)	Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16348751	EXPEDITED (15-DAY)		OT	BE-ACCORD-128396		40 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity; Nausea; Vomiting	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported
	Linezolid			S				Not Reported
	Imipenem			S	Intravenous (not otherwise specified)			Not Reported
	Moxifloxacin/Moxifloxacin Hydrochloride			S	Oral			Not Reported
	Clarithromycin			S	Oral			Not Reported
	Clofazimine			S	Oral			Not Reported
	Amikacin			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	otherwise specified)	
Bedaquiline	S	Not Reported
Tacrolimus	C	Not Reported
Minocycline	S	Not Reported
Azithromycin	S	Not Reported
	Oral	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16535743	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1072309		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Enterovirus Infection; Graft Infection; Lung Transplant Rejection; Rhinovirus Infection; Transplant Rejection	Azithromycin			S	Unknown	250 Mg		Not Reported
	Mycophenolic Acid			S	Unknown	2 Gram Daily;		Teva
	Prednisone			S	Unknown			Actavis
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Methylprednisolone			S	Unknown			Not Reported
	Valganciclovir			S	Unknown			Actavis
	Abacavir			S	Unknown			Not Reported
	Sulfamethoxazole			S	Unknown			Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Tivicay			S	Unknown			Not Reported
	Trimethoprim			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16650896	EXPEDITED (15-DAY)		OT	BE-ACCORD-149870		21 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Hepatotoxicity; Nausea; Vomiting	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported
	Linezolid			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bedaquiline	S	Unknown	Unk	Not Reported
Clofazimine	S	Oral	Unk	Not Reported
Amikacin	S	Unknown	Unk	Not Reported
Imipenem	S	Intravenous (not otherwise specified)	Unk	Not Reported
Azithromycin	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16651452	EXPEDITED (15-DAY)	HO		GB-STRIDES ARCOLAB LIMITED- 2019SP006358		33 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Chest Discomfort; Condition Aggravated; Cough; Decreased Appetite; Hypersomnia; Influenza; Nasopharyngitis; Off Label Use	Macrogol, Sodium Chloride, Potassium Chloride, Sodium Bicarbonate			S	Oral	1 Sachet Twice Daily At Loam And 10pm 10 Days (Powder)		Arrow
	Colecalciferol			S	Oral	800 Df Capsules/Tablets, 800 Unit Each Morning 28 Days		Not Reported
	Docusate Sodium			S	Oral	200 Milligram Daily		Not Reported
	Paracetamol			S	Oral	500 Mg (Max 4g Daily 1000 Mg Four Times A Day Prn 7 Days)		Not Reported
	Paracetamol			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg (Each Morning 28 Days)		Not Reported
	Multivitamins /00116001/			S	Oral	Tablets/Capsules - 1 Tablet Each Morning 28 Days		Not Reported
	Creon			S	Oral	10000 Mg (5 Capsule Three Times A Day With Food 07:00, 12:00, 17:00)		Not Reported
	Ciclesonide			S	Unknown	160 Mg Each Morning		Not Reported
	Omeprazole			S	Oral	40 Mg, Unknown		Not Reported
	Sodium Chloride			S	Unknown	4 Ml, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sodium Chloride	S	Oral	1800 Mg, Tid (Tablet)	Not Reported
Alfa-Tocopheryl Acetate	S	Oral	134 Mg, Every Morning At 6 A.M.	Not Reported
Fluticasone Furoate	S	Unknown	27.5 Mg Each Morning	Not Reported
Colobreathe	S	Unknown	Unk	Not Reported
Colobreathe	S		166250 Iu, Bid (Inhalation Powder, Hard Capsule)	Not Reported
Dornase Alfa	S	Unknown	2.5 Mg, 2.5 Mg Each Morning 2~ Days, Mucolytic (Nebuliser Solution)	Not Reported
Vitamin A & D /00343801/	S	Oral	2 Capsules Every Morning At 6 A.M.	Not Reported
Salbutamol	S	Unknown	100 Mg, 2 Puff(S) Prn 28 Days	Not Reported
Montelukast	S	Oral	10 Mg, Each Night 28 Days	Not Reported
Zopiclone	S	Oral	3.75 Mg, Each Night 28 Days	Not Reported
Symbicort	S	Unknown	Budesonide 200mcg I Formetrol6mcg, 2 Puff(S) Twice Daily Morning	Not Reported
Carbocisteine	S	Oral	375 Mg,(750 Mg Three Times A Day, Mucolytic)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16652397	EXPEDITED (15-DAY)		OT	PHHY2019US174237			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Betamethasone			S	Transplacental	Maternal Dose: 12 Mg		Novartis
	Calcium			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Amoxicillin			S	Transplacental			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enoxaparin Sodium	S	Transplacental	Maternal Dose; 30 Mg Bid	Not Reported
Cholecalciferol	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16652413	EXPEDITED (15-DAY)	HO		PHHY2019GB174381		78 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Cough; Delirium; Febrile Neutropenia; Malaise; Night Sweats; Pyrexia; Skin Abrasion; Urticaria	Azithromycin			S	Oral	250 Mg, Qd		Novartis
	Meropenem			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Rifampicin			C	Unknown	Unk (Stopped Last Week)		Not Reported
	Oilatum			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Ethambutol			C	Unknown	Unk (Stopped Last Week)		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Adcal-D3			C	Unknown	Unk		Not Reported
	Paracetamol			C	Unknown	Unk		Not Reported
	Seretide			C	Unknown	Unk		Not Reported
	Cetraben Emollient			C	Unknown	Unk		Not Reported
	Betnovate			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653137	NON-EXPEDITED			US-PFIZER INC- 2019324202		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Lisinopril			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653393	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1071227		82 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Anaemia; Drug Interaction	Prednisone			S	Oral	25 Milligram, Qd		Not Reported	
	Zitromax			S	Oral	1 Dosage Form, Qd		Mylan	
	Coumadin			S	Oral	1 Dosage Form, Qd		Mylan	
	Augmentin /00756801/			S	Oral	2 Dosage Form, Qd		Mylan	
	Zyloric			C	Oral	1 Dosage Form		Mylan	
	Bisoprolol Hemifumarate			C	Oral	1.25 Milligram		Mylan	
	Triatec /00116401/			C	Oral	1 Dosage Form		Mylan	
	Lasix /00032601/			C	Oral	2 Dosage Form		Mylan	
	Spiriva Respimat			C	Respiratory (inhalation)	2 Dosage Form		Mylan	
	Amiodarone Hydrochloride			C	Oral	200 Milligram		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653750	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019323160		334 DAY	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria	Zithromax			S	Oral	0.8 Df, Daily		Pfizer	
	Zithromax			S	Oral	1 Df, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jul-2019	16653924	NON-EXPEDITED			US-PFIZER INC-2019326501			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Palpitations	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	15157802	NON-EXPEDITED			US-PFIZER INC-2018288159		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Lexiscan			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16637316	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019316315		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Sputum Discoloured	Amlodipine Besilate			S	Oral	1 Df, 1x/Day		Pfizer	
	Amlodipine Besilate			S	Oral	10 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	3 Df, Unk		Pfizer	
	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
	Omalizumab			S	Subcutaneous	225 Mg, Unk		Not Reported	
	Xolair			S	Subcutaneous	225 Mg, Unk		Not Reported	
	Advair			C	Other	1 Df, Unk		Not Reported	
	Advair			C	Other	1 Df, 2x/Day		Not Reported	
	Asa			C	Oral	1 Df, 1x/Day		Not Reported	
	Brilinta			C	Oral	1 Df, 1x/Day		Not Reported	
	Hydrochlorothiazide			C	Oral	1 Df, 1x/Day		Not Reported	
	Pantoprazole Sodium			C	Oral	1 Df, 1x/Day		Not Reported	
	Mylan Pantoprazole			C	Oral	1 Df, 1x/Day		Not Reported	
	Singulair			C	Oral	1 Df, 1x/Day		Not Reported	
	Spiriva			C	Other	1 Df, 1x/Day		Not Reported	
	Ventolin [Salbutamol]			C	Other	2 Df, Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16654871	EXPEDITED (15-DAY)		HO, LT, OT	PT-ALKEM LABORATORIES LIMITED-PT-ALKEM- 2019-02488		41 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Cefuroxime Axetil			S	Unknown	Unknown		Alkem	
	Amoxicillin, Clavulanic Acid			S	Unknown	Unknown		Not Reported	
	Azithromycin			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655006	EXPEDITED (15-DAY)			CA-ALKEM LABORATORIES LIMITED-CA-ALKEM- 2018-08109		85 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Above Therapeutic; Drug Interaction	Cefuroxime Axetil			S	Unknown	Unk		Alkem	
	Warfarin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655353	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2019-044269			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Lip Oedema	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16655492	EXPEDITED (15-DAY)		OT	US-ZYDUS-039352		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic	Metronidazole			S	Unknown			Cadila	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Symptoms; Face Oedema; Pyrexia	Azithromycin	S	Unknown	Zydus Pharm
	Clindamycin	S	Unknown	Zydus Pharm
	Gentamicin/Gentamicin Sulfate	S	Unknown	Not Reported
	Piperacillin Sodium/Tazobactam Sodium	S	Unknown	Not Reported
	Amoxicillin	S	Unknown	Not Reported
	Meropenem/Meropenem Trihydrate	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Aug-2019	16657034	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019325525		21 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liver Disorder; Off Label Use; Portal Hypertension; Product Use Issue	Zithromax			S	Oral	750 Mg, Weekly		Pfizer	
	Bactrim			S	Oral	200 Mg, Daily		Not Reported	
	Imurel [Azathioprine]			S	Oral	75 Mg, Daily		Not Reported	
	Solupred [Prednisolone Metasulfobenzoate Sodium]			S	Oral	5 Mg, Weekly		Not Reported	
	Aerius [Desloratadine]			C		Unk		Not Reported	
	Budesonide			C		Unk		Not Reported	
	Cetirizine Dihydrochloride			C		Unk		Not Reported	
	Clairyg			C		Unk		Not Reported	
	Colobreathe			C		Unk		Not Reported	
	Diamox [Acetazolamide]			C		Unk		Not Reported	
	Diffu K			C		Unk		Not Reported	
	Granocyte			C		Unk		Not Reported	
	Hec			C		Unk		Not Reported	
	Noxafil			C		Unk		Not Reported	
	Singulair			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tobi [Tobramycin]	C	Unk	Not Reported
Ventolin [Salbutamol Sulfate]	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657115	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019326674		51 YR	Female	CHN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Erythema; Pruritus; Urticaria	Zithromax			S	Oral	0.25 G, 1x/Day		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16657121	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1071916		7 YR	Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chronic Graft Versus Host Disease; Obliterative Bronchiolitis; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Not Reported
	Flovent			C	Unknown	Unk		Mylan
	Montelukast			C	Unknown	Unk		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Aug-2019	16658429	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2019M1072096		61 YR	Female	ESP

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Diarrhoea; Rhabdomyolysis	Simvastatin			S	Oral	Unk		Not Reported
	Azitromicina Cinfa 500 Mg Polvo Para Suspension Oral Efg , 3 Sobres			S	Oral	Unk Unk, Q3d		Mylan

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Aug-2019	15547182	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2018-CA-967859		81 YR	Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Actinic Keratosis; Acute	Teva-Risedronate			S	Unknown			Teva

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Kidney Injury; Adjustment Disorder; Anaemia;	Teva-Risedronate	S	Unknown		Teva
Angina Pectoris; Atrophy;	Codeine	S	Unknown		Not Reported
Back Pain; Bundle Branch Block Left; Drug	Aclasta	S	Intravenous drip		Not Reported
Hypersensitivity; Drug Intolerance; Hepatic Steatosis;	Aclasta	S	Intravenous (not otherwise specified)		Not Reported
Hypercalcaemia;	Aclasta	S	Intravenous (not otherwise specified)	5 Mg Every Year	Not Reported
Hypertension; Monoclonal Gammopathy;	Aclasta	S	Intravenous drip		Not Reported
Musculoskeletal Pain;	Aclasta	S	Intravenous drip		Not Reported
Osteoarthritis; Palmar Erythema; Plasma Cell Myeloma; Sacroiliitis;	Aclasta	S	Intravenous (not otherwise specified)	5mg Every Year	Not Reported
Spinal Disorder; Toxicity To Various Agents	Aclasta	S	Intravenous (not otherwise specified)	5 Mg, Every Year	Not Reported
	Amoxil	S	Unknown		Not Reported
	Zithromax	S	Unknown		Not Reported
	Dilaudid	C	Unknown		Not Reported
	Esomeprazole Sodium	C	Unknown		Not Reported
	Nitroglycerin	C	Unknown		Not Reported
	Propranolol Hydrochloride	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	15590272	NON-EXPEDITED			US-PFIZER INC-2018431396		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		600 Mg, Unk		Pfizer
	Dexamethasone Intensol			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16060228	EXPEDITED (15-DAY)		DE	ES-ZYDUS-034537		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Rhabdomyolysis	Simvastatin Azithromycin	S S	Oral Oral						Zydus Pharm Not Reported
				1 About The Day					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16316650	EXPEDITED (15-DAY)		OT	PHHY2019BE106556		21 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Hepatotoxicity; Nausea; Off Label Use; Product Use In Unapproved Indication; Vomiting	Tigecycline			S	Intravenous (not otherwise specified)	Unk		Novartis
	Tigecycline			S				Novartis
	Tigecycline			S				Novartis
	Azithromycin			S	Oral	Unk		Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported
	Linezolid			S	Unknown	Unk		Not Reported
	Linezolid			S				Not Reported
	Bedaquiline			S	Unknown	Unk		Not Reported
	Bedaquiline			S				Not Reported
	Bedaquiline			S				Not Reported
	Bedaquiline			S				Not Reported
	Imipenem			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imipenem			S				Not Reported
	Imipenem			S				Not Reported
	Clofazimine			S	Oral	Unk		Not Reported
	Clofazimine			S				Not Reported
Clofazimine			S				Not Reported	
Clofazimine			S				Not Reported	
Amikacin			S	Unknown	Unk		Not Reported	
Amikacin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16569048	EXPEDITED (15-DAY)		HO, OT	PHHY2019AU157209		31 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Diarrhoea; Drug Resistance; Fatigue; Paratyphoid Fever; Product Use In Unapproved Indication; Pyrexia	Azithromycin	S	Unknown	250 Mg, Qd	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16599286	EXPEDITED (15-DAY)		OT	PHHY2019RU164672		4 YR	Male	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Pulmonary Air Leakage	Montelukast Sodium			S	Transdermal			Novartis	
	Montelukast Sodium			S				Novartis	
	Azithromycin			S	Transdermal			Not Reported	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16660500	NON-EXPEDITED			US-TEVA-2019-US-1085161			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Muscle Spasms; Nausea	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16660501	NON-EXPEDITED			US-TEVA-2019-US-1084947			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sneezing; Vomiting	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16660573	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1086123		30 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper; Lip Oedema	Azithromycin	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2019	16661557	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019329959		30 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Lip Oedema	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2019	16665002	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-045290			Unknown	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Granulomatosis With Polyangiitis; Temporal Arteritis	Azithromycin			S	Unknown	Unk		Aurobindo
	Norfloxacin			S	Unknown	Unk		Not Reported
	Prednisolon			C	Unknown	5 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2019	16665202	EXPEDITED (15-DAY)		HO	GB-AUROBINDO-AUR-APL-2019-045066			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Chest Discomfort; Condition Aggravated; Cough; Decreased Appetite; Dry Throat; Hypersomnia; Influenza; Nasopharyngitis	Azithromycin Film-Coated Tablets			S	Oral	250 Milligram (Each Morning 28 Days)		Aurobindo
	Carbocisteine			S	Oral	375 Milligram (750 Mg Three Times A Day)		Not Reported
	Macrogol Powder For Oral Solution			S	Oral	Unk (1sachet Twice Daily At Loam)		Not Reported
	Montelukast Film-Coated Tablet			S	Oral	10 Milligram (Each Night 28 Days)		Aurobindo
	Paracetamol Tablet			S	Oral	500 Milligram (Max 4g Daily 1000 Mg Four Times		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paracetamol	S	Unknown	A Day)	Aurobindo
Zopiclone Film Coated Tablet	S	Oral	Unk	Not Reported
			3.75 Milligram (Each Night 28 Days)	
Docusate Sodium	S	Oral	200 Milligram Daily	Not Reported
Multivitamins	S	Oral	Unk (Tablets/Capsules - 1 Tablet Each Morning 28 Days)	Not Reported
Creon	S	Oral	10000 Milligram (5 Capsule Three Times A Day With Food)	Not Reported
Ciclesonide	S	Unknown	160 Microgram (160 Microgram Each Morning)	Not Reported
Omeprazole	S	Oral	40 Milligram	Not Reported
Colecalciferol	S	Oral	800 Dosage Form (Capsules/Tablets, 800 Unit)	Not Reported
Sodium Chloride	S	Unknown	Unk (4 MI Every Morning At 6 A.M.)	Not Reported
Tocopherol Acetate	S	Oral	134 Milligram (Every Morning At 6 A.M.)	Not Reported
Fluticasone Furoate	S	Unknown	27.5 Microgram Each Morning	Not Reported
Colobreathe	S	Unknown	Unk	Not Reported
Dornase Alfa	S	Unknown	2.5 Mg Each Morning 2-Days, Mucolytic	Not Reported
Vitamin A & D [Ergocalciferol\Retinol]	S	Oral	Unk (2 Capsules Every Morning At 6 A.M.)	Not Reported
Salbutamol	S	Unknown	100 Microgram (2 Puff(S) Prn 28 Days)	Not Reported
Colobreathe	S	Respiratory (inhalation)	1,662,500 Iu; Twice Daily.	Not Reported
Sodium Chloride	S	Oral	600 Milligram (1800 Mg Three Times A Day)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Symbicort	S	Unknown	Unk (Budesonide 200mcg I Formetrol6mcg, 2 Puff(S) Twice Daily Morning)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Aug-2019	16665203	EXPEDITED (15-DAY)		HO	GB-JNJFOC- 20190737531		33 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Chest Discomfort; Condition Aggravated; Cough; Decreased Appetite; Dry Throat; Hypersomnia; Influenza; Nasopharyngitis	Paracetamol			S	Oral	Max 4g Daily 1000 Mg Four Times A Day Prn 7 Days		Not Reported
	Paracetamol			S				Not Reported
	Docusate Sodium			S	Oral	Daily		Not Reported
	Macrogol			S	Oral	1sachet Twice Daily At 10 Am And 10pm 10 Days		Not Reported
	Azithromycin			S	Oral	Each Morning 28 Days		Not Reported
	Multivitamins /00116001/			S	Oral	Tablets/Capsules - 1 Tablet Each Morning 28 Days		Not Reported
	Creon			S	Oral	5 Capsule Three Times A Day With Food 07:00, 12:00, 17:00		Not Reported
	Ciclesonide			S	Unknown	160 Microgram Each Morning		Not Reported
	Omeprazole			S	Oral			Not Reported
	Colecalciferol			S	Oral	Capsules/Tablets, 800 Unit Each Morning 28 Days		Not Reported
	Sodium Chloride			S	Unknown	4 Ml Every Morning At 6 A.M., Mucolytic		Not Reported
	Alfa-Tocopheryl Acetate			S	Oral	Every Morning At 6 A.M		Not Reported
	Fluticasone Furoate			S	Unknown	27.5 Microgram Each Morning		Not Reported
	Colobreathe			S	Respiratory	1,662,500 Iu; Twice Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			(inhalation)		
Colobreathe	S				Not Reported
Dornase Alfa	S	Unknown	2.5 Mg Each Morning 2 Days, Mucolytic		Not Reported
Vitamin A & D /00343801/	S	Oral	2 Capsules Every Morning At 6 A.M.		Not Reported
Salbutamol	S	Unknown	2 Puff(S) Prn 28 Days		Not Reported
Montelukast	S	Oral	Each Night 28 Days		Not Reported
Zopiclone	S	Oral	Each Night 28 Days		Not Reported
Sodium Chloride	S	Oral	1800 Mg Three Times A Day		Not Reported
Symbicort	S	Unknown	Budesonide 200mcg, Formetrol6mcg, 2 Puff(S) Twice Daily Morning		Not Reported
Carbocisteine	S	Oral	750 Mg Three Times A Day, Mucolytic		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	14816257	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2018167700		46 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Cardiac Failure; Ejection Fraction Decreased; Feeling Abnormal	Zithromax			S		Unk		Pfizer
	Zithromax			S		20 Mg, Unk		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer
	Amlodipine			C		Unk		Not Reported
	Klor-Con			C		Unk		Not Reported
	Carvedilol			C		Unk		Not Reported
	Furosemide			C		Unk		Not Reported
	Warfarin			C		Unk		Not Reported
	Losartan			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Montelukast	C	10 Mg, 1x/Day	Not Reported
Spiriva	C	Unk (2 Puff 1x)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16628080	EXPEDITED (15-DAY)		OT	BE-JNJFOC-20190721661		40 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatotoxicity; Nausea; Off Label Use; Product Use In Unapproved Indication; Vomiting	Bedaquiline			S	Oral	Unk		Not Reported
	Bedaquiline			S				Not Reported
	Azithromycin			S	Oral			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Linezolid			S	Unknown			Not Reported
	Linezolid			S				Not Reported
	Clofazimine			S	Unknown			Not Reported
	Clofazimine			S				Not Reported
	Amikacin Sulfate			S	Unknown			Not Reported
	Amikacin Sulfate			S	Intravenous (not otherwise specified)			Not Reported
	Minocycline			S	Unknown			Not Reported
	Minocycline			S				Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Clarithromycin			S				Not Reported
	Imipenem			S	Intravenous (not otherwise specified)	Intravenous (Not Otherwise Specified)		Not Reported
	Imipenem			S				Not Reported
	Moxifloxacin			S	Unknown			Not Reported
	Moxifloxacin			S				Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported
	Tigecycline			S				Not Reported
	Tacrolimus Unspecified			C	Unknown			Not Reported
	Tacrolimus Unspecified			C	Unknown	At A Reduced Dose		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16664480	EXPEDITED (15-DAY)		OT	PHHY2019NL178040		50 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Pathogen Resistance; Product Use In Unapproved Indication	Clofazimine			S	Unknown	100 Mg, Qd		Novartis	
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported	
	Clarithromycin			S	Unknown	500 Mg, Bid		Not Reported	
	Rifabutin			S	Unknown	300 Mg, Qd		Not Reported	
	Ethambutol			S	Unknown	1200 Mg, Qd		Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)	15 Mg/Kg, Qw3		Not Reported	
	Amikacin			S	Respiratory (inhalation)	Unk		Not Reported	
	Bedaquiline			S	Unknown	400 Mg, Qd		Not Reported	
	Bedaquiline			S	Unknown	200 Mg, Qw3		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16667769	EXPEDITED (15-DAY)		HO, LT	GB-PFIZER INC-2019331750		78 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenic Sepsis	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
	Amitriptyline Hydrochloride			C		Unk		Not Reported	
	Salbutamol			C		Unk		Not Reported	
	Ethambutol			C		Unk		Not Reported	
	Seretide			C		Unk		Not Reported	
	Accrete D3			C		Unk		Not Reported	
	Rifampicin			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16668145	NON-EXPEDITED			GB-PFIZER INC-2019327675			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Azithromycin			S	Oral	250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16668221	NON-EXPEDITED			US-PFIZER INC-2019330418		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Noncompliance	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16668308	NON-EXPEDITED			US-PFIZER INC-2019330706		35 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Urticaria	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16668443	NON-EXPEDITED			US-PFIZER INC-2019330123		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Dextromethorphan Hbr		Y	S		Unk		Unknown	
	Ceftin [Cefatrizine Propyleneglycolate]			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Motrin [Ibuprofen]			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16668987	NON-EXPEDITED			PHEH2019US032247			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16669749	EXPEDITED (15-DAY)		OT	PHEH2019US031916			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphthous Ulcer; Glossodynia; Lip Swelling	Azithromycin			S	Unknown	250 Mg, Unk		Novartis	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Calcium			C	Unknown	Unk		Not Reported	
	Vitamin C			C	Unknown	Unk		Not Reported	
	Airborne			C	Unknown	Unk		Not Reported	
	Vitamin E			C	Unknown	Unk		Not Reported	
	Vitamin D			C	Unknown	Unk		Not Reported	
	Spectrum			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2019	16866517	DIRECT	Y	HO, LT			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Sepsis	Azithromycin			S				Not Reported	
	Pantaprazole			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	14221170	NON-EXPEDITED			US-PFIZER INC-2017505274			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Urticaria	Azithromycin	S	Unk	Pfizer
	Phenytoin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	15525842	EXPEDITED (15-DAY)		DE, OT	CA-ALLERGAN-1849864US			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Acute	Actonel 5 Mg			S	Unknown	Unk		Allergan
Kidney Injury; Adjustment	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Every Year		Not Reported
Disorder; Anaemia;	Aclasta			S	Intravenous drip	Unk		Not Reported
Angina Pectoris; Atrophy;	Aclasta			S	Intravenous drip	Unk		Not Reported
Back Pain; Bundle Branch	Aclasta			S	Intravenous drip	Unk		Not Reported
Block Left; Drug	Aclasta			S	Intravenous drip	Unk		Not Reported
Hypersensitivity; Drug	Aclasta			S	Intravenous drip	Unk		Not Reported
Intolerance; Hepatic	Aclasta			S	Intravenous drip	Unk		Not Reported
Steatosis;	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Unk		Not Reported
Hypercalcaemia;	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Every Year		Not Reported
Hypertension; Monoclonal	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Every Year		Not Reported
Gammopathy;	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Every Year		Not Reported
Musculoskeletal Pain;	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Every Year		Not Reported
Osteoarthritis; Palmar	Aclasta			S	Intravenous (not otherwise specified)	5 Mg, Every Year		Not Reported
Erythema; Plasma Cell	Amoxil			S	Unknown	Unk		Not Reported
Myeloma; Sacroiliitis;	Codeine			S	Unknown	Unk		Not Reported
Spinal Disorder; Toxicity	Zithromax			S	Unknown	Unk		Not Reported
To Various Agents	Dilaudid			C	Unknown	1 Mg, Unk		Not Reported
	Esomeprazole Sodium			C	Unknown	40 Mg, Qd		Not Reported
	Nitroglycerin			C	Oral	1 Df, Unk		Not Reported
	Propranolol Hydrochloride			C	Unknown	80 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16077274	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019109040		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Enterovirus Infection; Transplant Rejection	Azithromycin	S	250 Mg, Unk	Pfizer
	Abacavir	S	Unk	Not Reported
	Mycophenolic Acid	S	1 G, 2x/Day	Not Reported
	Prednisone	S	15 Mg, 1x/Day	Not Reported
	Sulfamethoxazole	S	800 Mg, Unk	Not Reported
	Tacrolimus	S	Unk	Not Reported
	Tivicay	S	Unk	Not Reported
	Trimethoprim	S	160 Mg, Unk	Not Reported
	Valganciclovir	S	900 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16322488	EXPEDITED (15-DAY)		OT	PHHY2019BE106285		33 YR	Male	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Product Use In Unapproved Indication; Relapsing Fever	Linezolid			S	Unknown	Unk		Novartis
	Linezolid			S	Oral	Unk		Novartis
	Meropenem			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Meropenem			S				Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Moxifloxacin			S	Unknown	Unk		Not Reported
	Moxifloxacin			S	Oral	Unk		Not Reported
	Cefoxitin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Cefoxitin			S				Not Reported
	Amikacin Sulfate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amikacin Sulfate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16596318	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2019-041398			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Endocarditis Bacterial; Joint Swelling; Pharyngitis; Pyrexia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Cefixime			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16672800	EXPEDITED (15-DAY)		OT	US-TARO PHARMACEUTICALS USA.,INC- 2019SUN00354		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms	Clindamycin			S	Unknown	Unk		Taro	
	Metronidazole			S	Unknown	Unk		Taro	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Gentamicin			S	Unknown	Unk		Not Reported	
	Piperacillin-Tazobactam			S	Unknown	Unk		Not Reported	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Vancomycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16672990	EXPEDITED (15-DAY)		HO, OT	JP-PFIZER INC- 2019327632		72 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Febrile Neutropenia; Rash	Zithromac			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Silece	S	Oral	2 Mg, Daily	Not Reported
	Takecab	S	Oral	20 Mg, Daily	Not Reported
	Omeprazole	C		Unk	Not Reported
	Meropenem	C		Unk	Not Reported
	Precedex	C		Unk	Not Reported
	Midazolam Hydrochloride	C		Unk	Not Reported
	Cravit	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16673634	EXPEDITED (15-DAY)		HO	PHHY2019FR178264		26 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Neutropenia	Lamprene			S	Oral	100 Mg, Qd		Novartis	
	Azithromycin Monohydrate			S	Oral	500 Mg, Qd		Not Reported	
	Vimpat			S	Oral	200 Mg, Qd		Not Reported	
	Imukin			S	Subcutaneous	300 Ug, Qw (100µg 3x/Semaine)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Aug-2019	16675197	NON-EXPEDITED			US-TEVA-2019-US- 1087235		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Live Birth; Maternal Exposure During Pregnancy	Enoxaparin Sodium			S	Unknown	60 Milligram Daily; 30 Mg Twice Daily		Teva	
	Azithromycin			S	Unknown			Teva	
	Amoxicillin			S	Unknown			Not Reported	
	Betamethasone			S	Intramuscular			Not Reported	
	Colecalciferol			S	Oral			Not Reported	
	Calcium Acetate			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16526438	EXPEDITED (15-DAY)		LT, OT	IT-APOTEX-2019AP017552		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Paroxetine			S	Oral	20 Mg, Qd		Apotex	
	Azithromycin			S	Oral	1500 Mg, Qd		Apotex	
	Quetiapine			S	Oral	1 G, Qd		Apotex	
	Tegretol			S	Oral	8 G, Qd		Not Reported	
	Lobivon			S	Oral	140 Mg, Qd		Not Reported	
	Novorapid			S	Subcutaneous	2 Df, Qd		Not Reported	
	Amisulpride			S	Oral	600 Mg, Qd		Not Reported	
	En			S	Oral	20 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677038	EXPEDITED (15-DAY)		HO, LT, OT	GB-AUROBINDO-AUR-APL-2019-045662			Unknown	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenic Sepsis	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Amitriptyline Hydrochloride			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Ethambutol			C	Unknown	Unk		Not Reported	
	Seretide			C	Unknown	Unk		Not Reported	
	Accrete D3			C	Unknown	Unk		Not Reported	
	Rifampicin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677349	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2019332001		78 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Confusional State; Cough; Delirium; Febrile	Azithromycin	S	Oral	250 Mg, Daily	Pfizer
Neutropenia; Malaise; Night Sweats; Pyrexia; Skin Abrasion; Urticaria	Meropenem	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Rifampicin	C		Unk	Not Reported
	Oilatum [Light Liquid Paraffin;White Soft Paraffin]	C		Unk	Not Reported
	Fexofenadine	C		Unk	Not Reported
	Salbutamol	C		Unk	Not Reported
	Ethambutol	C		Unk	Not Reported
	Amitriptyline	C		Unk	Not Reported
	Adcal D3	C		Unk	Not Reported
	Paracetamol	C		Unk	Not Reported
	Seretide	C		Unk	Not Reported
	Cetaben [Light Liquid Paraffin;White Soft Paraffin]	C		Unk	Not Reported
	Betnovate	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677438	EXPEDITED (15-DAY)		HO, OT	GB-AUROBINDO-AUR- APL-2019-045696			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Cough; Delirium; Febrile	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
Neutropenia; Malaise; Night Sweats; Pyrexia; Skin Abrasion; Urticaria	Meropenem			C	Unknown	Unk		Not Reported
	Enoxaparin			C	Unknown	Unk		Not Reported
	Rifampicin			C	Unknown	Unk, Stopped Last Week		Not Reported
	Oilatum			C	Unknown	Unk		Not Reported
	Fexofenadine			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Ethambutol			C	Unknown	Unk, Stopped Last Week		Not Reported
	Amitriptyline			C	Unknown	Unk		Not Reported
	Adcal D3			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Paracetamol	C	Unknown	Unk				Not Reported	
	Seretide	C	Unknown	Unk				Not Reported	
	Cetraben	C	Unknown	Unk				Not Reported	
	Betnovate	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677536	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019331823		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Facial Paralysis; Varicella Zoster Virus Infection	Novatrex			S	Oral	20 Mg, Unk		Pfizer	
	Cimzia			S	Subcutaneous	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16677875	NON-EXPEDITED			US-PFIZER INC-2019335160			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Aug-2019	16679201	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR133655			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Avamys			S		Unk		Glaxosmithkline	
	Flovent			S		Unk		Glaxosmithkline	
	Amoxicillin Trihydrate			S		Unk		Glaxosmithkline	
	Habitrol			S		Unk		Glaxosmithkline	
	Bactroban (Mupirocin)			S		Unk		Glaxosmithkline	
	Mupirocin			S		Unk		Glaxosmithkline	
	Nicotine Polacrilex			S		Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin Dihydrate	S	Unk	Glaxosmithkline	
Betaderm	S	Unk	Glaxosmithkline	
Betamethasone Dipropionate	S	Unk	Glaxosmithkline	
Bisacodyl	S	Unk	Glaxosmithkline	
Cetirizine	S	Unk	Glaxosmithkline	
Clotrimazole	S	Unk	Glaxosmithkline	
Diphenhydramine	S	Unk	Glaxosmithkline	
Entocort	S	Unk	Glaxosmithkline	
Metronidazole	S	Unk	Glaxosmithkline	
Nicoderm	S	Unk	Glaxosmithkline	
Pantoprazole	S	Unk	Glaxosmithkline	
Triamcinolone Acetonide	S	Unk	Glaxosmithkline	
Vitamin D3	S	Unk	Glaxosmithkline	
Acetaminophene	S	Unk	Not Reported	
Alprazolam	S	Unk	Not Reported	
Apo Hydro	S	Unk	Not Reported	
Atorvastatin	S	Unk	Not Reported	
Biaxin XI	S	Unk	Not Reported	
Clarithromycin	S	Unk	Not Reported	
Desonide	S	Unk	Not Reported	
Dilaudid	S	Unk	Not Reported	
Ertapenem Sodium	S	Unk	Not Reported	
Glycerine	S	Unk	Not Reported	
Gramicidin + Neomycin + Polymyxin B Sulfate	S	Unk	Not Reported	
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog	S	Unk	Not Reported	
Macrogol + Potassium Chloride + Sodium Bicarbonate + Sodium Chloride + Ms Ir	S	Unk	Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nadolol	S	Unk	Not Reported
Pentasa	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Pregabalin	S	Unk	Not Reported
Pulmicort	S	Unk	Not Reported
Refresh Tears	S	Unk	Not Reported
Salinex (Salt Water)	S	Unk	Not Reported
Sinus Rinse	S	Unk	Not Reported
Sulfamethoxazole + Trimethoprim	S	Unk	Not Reported
Calcium Carbonate + Vitamin D3	S	Unk	Not Reported
Valsartan	C	Unk	Glaxosmithkline
Calcium Carbonate + Vitamin D3	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	15133449	NON-EXPEDITED			US-PFIZER INC-2018282184		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16388208	NON-EXPEDITED			US-PFIZER INC-2019238352		52 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16648473	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1084137		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Reaction With Eosinophilia And Systemic Symptoms	Azithromycin	S	Unknown	Teva
	Azithromycin	S		Teva
	Clindamycin	S	Unknown	Actavis
	Clindamycin	S		Actavis
	Gentamicin	S	Unknown	Not Reported
	Gentamicin	S		Not Reported
	Amoxicillin	S	Unknown	Teva
	Amoxicillin	S		Teva
	Metronidazole	S	Unknown	Barr
	Metronidazole	S		Barr
	Vancomycin	S	Unknown	Not Reported
	Vancomycin	S		Not Reported
	Meropenem	S	Unknown	Not Reported
	Meropenem	S		Not Reported
	Piperacillin/Tazobactam	S	Unknown	Not Reported
	Piperacillin/Tazobactam	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16680892	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-216736		30 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Lip Oedema	Azithromycin			S	Unknown	Unk		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16682227	EXPEDITED (15-DAY)		HO	GB-TEVA-2019-GB- 1089297		78 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Cough; Delirium; Febrile	Azithromycin			S	Oral	250 Mg		Not Reported	
Neutropenia; Malaise;	Meropenem			C				Not Reported	
Night Sweats; Pyrexia;	Enoxaparin			C				Not Reported	
Skin Abrasion; Urticaria	Rifampicin			C		Stopped Last Week		Not Reported	
	Oilatum			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Fexofenadine	C							Not Reported
	Salbutamol	C							Not Reported
	Ethambutol	C			Stopped Last Week				Not Reported
	Amitriptyline	C							Not Reported
	Adcal-D3	C							Not Reported
	Paracetamol	C							Not Reported
	Seretide	C							Not Reported
	Cetraben Emollient Cream	C							Not Reported
	Betnovate	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16682816	NON-EXPEDITED			US-PFIZER INC-2019339710		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684801	NON-EXPEDITED			US-PFIZER INC-2019340521		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Aug-2019	16684939	EXPEDITED (15-DAY)		HO	US-ELI_LILLY_AND_COMP ANY-US201908000572			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction; Pneumonia; Throat Tightness; Wheezing	Tadalafil			S	Unknown	40 Mg, Unknown		Eli Lilly And Co	
	Zithromycin			S	Unknown	Unk, Unknown		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	14979169	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2018223891		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cholestasis; Hepatocellular Injury; Off Label Use; Product Use In Unapproved Indication	Novatrex	S	Oral	5 Mg, Weekly	Pfizer
	Methotrexate Sodium	S	Intramuscular	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16686629	EXPEDITED (15-DAY)		HO, LT	GB-TEVA-2019-GB-1089582		78 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neutropenic Sepsis	Azithromycin			S	Oral	250 Mg		Not Reported	
	Amitriptyline Hydrochloride			C				Not Reported	
	Salbutamol			C				Not Reported	
	Ethambutol			C				Not Reported	
	Seretide			C				Not Reported	
	Accrete D3			C				Not Reported	
	Rifampicin			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16687803	NON-EXPEDITED			US-PFIZER INC-2019341050		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lipitor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Pravastatin			S		Unk		Not Reported	
	Crestor			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Aug-2019	16689961	NON-EXPEDITED			PHEH2019US032487			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea	Azithromycin 250 Mg			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	14312571	NON-EXPEDITED			US-PFIZER INC-2017542606		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
	Avelox			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	15879791	EXPEDITED (15-DAY)		DE, LT	PT-PFIZER INC-2019032965		56 YR	Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Ethambutol			S		Unk		Not Reported	
	Rifampicin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16098898	NON-EXPEDITED			US-PFIZER INC-2019118310		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Oxycodone			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Imitrex			S		Unk		Not Reported	
	Sumatriptan Succinate			S		Unk		Not Reported	
	Sumatriptan			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16690987	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-035434			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hypersensitivity	Azithromycin			S	Unknown	Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16691560	EXPEDITED (15-DAY)		HO	FR-ZYDUS-039608		26 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Agranulocytosis; Neutropenia	Azithromycin			S	Oral			Zydus Pharm	
	Lamprene			S	Oral			Not Reported	
	Vimpat			S	Oral			Not Reported	
	Interferon Gamma			S	Subcutaneous	100microgram 3x / Week		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16692814	NON-EXPEDITED			US-MYLANLABS-2019M1072464			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Pruritus; Skin Exfoliation	Azithromycin			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693331	EXPEDITED (15-DAY)		DE	DE-PFIZER INC-2019343486			Unknown	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Montelukast			S		Unk		Not Reported	
	Fluticason			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
12-Aug-2019	16693526	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019340520		73 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Aortic Dilatation; Off Label Use; Product Use In Unapproved Indication	Novatrex	S	Oral	7.5 Mg, Weekly	Pfizer
	Simponi	S	Subcutaneous	50 Mg, Every 5 Weeks	Not Reported
	Coversyl [Perindopril Erbumine]	C		Unk	Not Reported
	Speciafoldine	C		Unk	Not Reported
	Crestor	C		Unk	Not Reported
	Sotalol Arrow	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16694088	EXPEDITED (15-DAY)		OT	US-GLAXOSMITHKLINE-US2019142245			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Oral Candidiasis; Oral Discomfort; Osteoporosis; Pneumonia; Rib Fracture; Spinal Fracture	Advair Hfa			S	Unknown	Unk (115/21 Mcg)		Glaxosmithkline
	Advair Hfa			S	Unknown	Unk (230/21 Mcg)		Glaxosmithkline
	Trelegy Ellipta			S	Unknown	Unk, Qd		Glaxosmithkline
	Azithromycin			S	Unknown	500 Mg, (3 Times A Week)		Glaxosmithkline
	Prednisone			C	Oral	Unk		Not Reported
	Oxygen			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Aug-2019	16694147	EXPEDITED (15-DAY)		DE	PHHY2019US186567			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Infection	Azithromycin			S	Unknown			Novartis
	Ceftriaxone			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	14453140	NON-EXPEDITED			US-PFIZER INC-2018038866		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16274042	EXPEDITED (15-DAY)		OT	BE-JNJFOC-20190500671		21 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Hepatotoxicity; Nausea; Off Label Use; Product Use In Unapproved Indication; Vomiting	Bedaquiline			S	Oral			Not Reported	
	Bedaquiline			S	Oral			Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported	
	Tigecycline			S				Not Reported	
	Imipenem			S	Intravenous (not otherwise specified)			Not Reported	
	Imipenem			S				Not Reported	
	Clofazimine			S	Oral			Not Reported	
	Clofazimine			S				Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
	Linezolid			S	Unknown			Not Reported	
	Linezolid			S				Not Reported	
	Amikacin Sulfate /00391001/			S	Unknown			Not Reported	
	Amikacin Sulfate /00391001/			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16627826	NON-EXPEDITED		OT	US-JNJFOC-20190707041			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Epistaxis; Internal Haemorrhage; Sinusitis; Wrong Technique In Product Usage Process	Xarelto			S	Oral			Not Reported	
	Xarelto			S	Oral			Not Reported	
	Xarelto			S	Oral			Not Reported	
	Z-Pak			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16636317	EXPEDITED (15-DAY)		OT	BE-APOTEX-2019AP018796		40 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatotoxicity; Nausea; Toxicity To Various Agents; Vomiting	Azithromycin			S	Oral	Unk		Apotex	
	Azithromycin			S				Apotex	
	Moxifloxacin			S	Oral	Unk		Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Tigecycline			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Tigecycline			S				Not Reported	
	Tigecycline			S				Not Reported	
	Tigecycline			S				Not Reported	
	Imipenem			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Imipenem			S				Not Reported	
	Imipenem			S				Not Reported	
	Imipenem			S				Not Reported	
	Clofazimine			S	Oral	Unk		Not Reported	
	Clofazimine			S	Oral	Unk, Restarted		Not Reported	
	Clofazimine			S				Not Reported	
	Clofazimine			S				Not Reported	
	Clofazimine			S				Not Reported	
	Clarithromycin			S	Oral	Unk		Not Reported	
	Clarithromycin			S				Not Reported	
	Clarithromycin			S				Not Reported	
	Clarithromycin			S				Not Reported	
	Linezolid			S	Unknown	Unk		Not Reported	
	Linezolid			S	Unknown	Unk, Restarted		Not Reported	
	Linezolid			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Linezolid	S			Not Reported
Linezolid	S			Not Reported
Linezolid	S			Not Reported
Amikacin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Amikacin	S			Not Reported
Amikacin	S			Not Reported
Amikacin	S			Not Reported
Bedaquiline	S	Unknown	Unk	Not Reported
Bedaquiline	S			Not Reported
Tacrolimus	S	Unknown	Unk	Not Reported
Minocycline	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695084	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-053277			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Vancomycin			S	Unknown	Unk		Aurobindo
	Vancomycin			S				Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Clindamycin			S	Unknown	Unk		Aurobindo
	Clindamycin			S				Aurobindo
	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Piperacillin+Tazobactam			S				Aurobindo
	Amoxicillin			S	Unknown	Unk		Aurobindo
	Amoxicillin			S				Aurobindo
	Meropenem			S	Unknown	Unk		Aurobindo
	Meropenem			S				Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Metronidazole			S				Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Gentamicin			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695600	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1090545		7 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Graft Versus Host Disease; Obliterative Bronchiolitis; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Teva	
	Flovent			C	Unknown			Not Reported	
	Montelukast			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16695937	EXPEDITED (15-DAY)		OT	BE-APOTEX-2019AP019747		33 YR	Male	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Pyrexia; Toxicity To Various Agents	Moxifloxacin			S	Oral	Unk		Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S				Apotex	
	Moxifloxacin			S	Oral	Unk		Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S				Apotex	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Apotex	
	Meropenem			S				Not Reported	
	Meropenem			S				Not Reported	
	Meropenem			S				Not Reported	
	Meropenem			S				Not Reported	
	Meropenem			S				Not Reported	
	Meropenem			S				Not Reported	
	Amikacin			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					otherwise specified)				
Amikacin	S								Not Reported
Amikacin	S								Not Reported
Amikacin	S								Not Reported
Amikacin	S								Not Reported
Amikacin	S								Not Reported
Amikacin	S								Not Reported
Linezolid	S	Oral			Unk				Not Reported
Linezolid	S								Not Reported
Linezolid	S								Not Reported
Linezolid	S								Not Reported
Linezolid	S								Not Reported
Linezolid	S								Not Reported
Cefoxitin	S	Intravenous (not otherwise specified)			Unk				Not Reported
Cefoxitin	S								Not Reported
Cefoxitin	S								Not Reported
Cefoxitin	S								Not Reported
Cefoxitin	S								Not Reported
Cefoxitin	S								Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16697197	NON-EXPEDITED			US-PFIZER INC- 2019345020		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Leflunomide			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Meloxicam			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
	Propoxyphene			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16697981	EXPEDITED (15-DAY)		DE	DE-PFIZER INC-2019343384			Unknown	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Montelukast			S		Unk		Not Reported	
	Fluticason			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16698842	EXPEDITED (15-DAY)		CA, DE, OT	US-VIIV HEALTHCARE LIMITED-BW2019GSK146250			Unknown	BWA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Foetal Exposure During Pregnancy;	Dolutegravir			S	Transplacental	Unk		Viiv	
Gastroschisis; Premature Baby	Metronidazole			S	Transplacental	Unk		Glaxosmithkline	
	Azithromycin			S	Transplacental	Unk Unk, Single		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16699831	EXPEDITED (15-DAY)		HO	PHHY2019CZ186549		41 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gastrointestinal Inflammation; Intestinal Haemorrhage	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Aug-2019	16893726	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Duplicate Therapy Error;	Azithromycin			S				Not Reported	
Product Dispensing Error	Keppra			S				Not Reported	
	Warfarin Sodium			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16700881	EXPEDITED (15-DAY)		HO, OT	US-CONCORDIA PHARMACEUTICALS INC.-GSH201908- 001872		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis Bacterial; Atypical Mycobacterial Infection; Disease Recurrence; Disseminated Mycobacterium Avium Complex Infection; Nephropathy Toxic; Osteomyelitis; Subcutaneous Abscess; Treatment Failure	Hydroxychloroquine			S	Unknown			Concordia	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Amikacin Sulfate			S	Intravenous (not otherwise specified)	Parenteral Amikacin		Not Reported	
	Amikacin Sulfate			S		Implantation Of Amikacin Beads		Not Reported	
	Linezolid			S	Intravenous (not otherwise specified)			Not Reported	
	Linezolid			S	Oral			Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported	
	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported	
	Clofazimine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16701841	NON-EXPEDITED			US-NEOPHARMA INC- 000155			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Augmentin			S				Not Reported	
	Pregabalin			S	Oral	Take 1 Capsule 75 Mg Total By Mouth 2 Times Daily		Not Reported	
	Gabapentin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Biaxin	S							Not Reported
Zithromax	S	Oral	Take 500 Mg By Mouth 3 (Three) Times A Week (Monday, Wednesday And Friday)					Not Reported
Atarax	S	Oral	Take 25 Mg By Mouth 3 (Three) Times Daily As Needed					Not Reported
Flu Shot	S							Not Reported
Pregabalin	S	Oral	Take 1 Capsule 75 Mg Total By Mouth 2 Times Daily					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16702410	NON-EXPEDITED			US-PFIZER INC-2019346716		82 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Flagyl			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Darvocet A500			S		Unk		Not Reported	
	Flonase [Fluticasone Propionate]			S		Unk		Not Reported	
	Phenergan [Promethazine]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16702426	NON-EXPEDITED			US-PFIZER INC-2019345006		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Aug-2019	16705820	DIRECT		OT				Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash; Swelling Face	Flagyl Zithromax			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	15856267	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002452			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	15856284	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002455			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	15856285	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002448			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	15856299	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002445			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Maternal Exposure During Pregnancy Azithromycin S Unknown Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	15856300	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002434			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16684215	NON-EXPEDITED			US-PFIZER INC-2019339329		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Apixaban			S	Unknown	Unk		Not Reported
	Rivaroxaban			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Warfarin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16706238	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019345871		12 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pruritus; Rash Maculo-Papular	Sulperazon			S	Intravenous drip	0.8 G, 3x/Day		Pfizer
	Zithromax			S	Intravenous drip	0.45 G, 1x/Day		Pfizer
	Zithromax			S	Intravenous drip	0.45 G, 1x/Day		Pfizer
	Sodium Chloride			C	Intravenous drip	100 MI, 3x/Day		Not Reported
	Amoxicillin Sodium And			C	Intravenous drip	1.35 G, 3x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clavulanate Potassium	C	Intravenous drip	5 MI, 1x/Day	Not Reported
Sterilized Water For Injections	C	Intravenous drip	5 MI, 1x/Day	Not Reported
Sterilized Water For Injections	C	Intravenous drip	500 MI, 1x/Day	Not Reported
Glucose	C	Intravenous drip	500 MI, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16706907	NON-EXPEDITED		OT	PHEH2019US033843			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mycobacterium Avium Complex Infection; Treatment Failure	Azithromycin			S	Unknown	Unk		Novartis
	Rifabutin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Aug-2019	16706948	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1092652		26 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Neutropenia	Azithromycine Anhydre			S	Oral	500mg		Not Reported
	Lamprene			S	Oral	100mg		Not Reported
	Vimpat 50 Mg, Comprimé			S	Oral	200 Microgram		Not Reported
	Pelliculé Imukin			S	Subcutaneous	100g 3x/Week		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	14555292	NON-EXPEDITED			US-PFIZER INC-2018071423			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Eruption; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	15762109	NON-EXPEDITED			US-PFIZER INC-2018526644		51 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Drug Intolerance	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16524911	EXPEDITED (15-DAY)		DS, HO, OT	HU-PFIZER INC-2019280064		58 YR	Male	HUN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Arthralgia; Asthenia;	Azithromycin			S	Oral	500 Mg, 1x/Day (1-0-0)		Pfizer	
Conjunctivitis; Cough;	Zinnat [Cefuroxime Sodium]			S	Oral	500 Mg, Unk		Not Reported	
Dyspnoea Exertional;	Cetirizin			S	Oral	10 Mg, Unk		Not Reported	
Mastocytosis; Myalgia;	Doxycyclin [Doxycycline]			S	Oral	100 Mg, Unk		Not Reported	
Nasopharyngitis; Pyrexia;									
Rash									
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16539974	NON-EXPEDITED			US-PFIZER INC-2019289406		36 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
16-Aug-2019	16683294	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2019332330		16 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective;	Azithromycin			S	Unknown	Unk		Pfizer	
Endocarditis Bacterial;	Cefixime			S	Unknown	Unk		Not Reported	
Joint Swelling; Pharyngitis									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16709975	NON-EXPEDITED			US-PFIZER INC-2019351079			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710318	NON-EXPEDITED			US-PFIZER INC-2019351002		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710472	NON-EXPEDITED			US-PFIZER INC-2019351269		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710896	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019347789		7 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Faeces Discoloured; Off Label Use; Product Use Issue	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16710935	EXPEDITED (15-DAY)		HO	PL-BAUSCH-BL-2019-022614		334 DAY	Male	POL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Hepatosplenomegaly; Hiv Viraemia; Hypertension; Livedo Reticularis; Motor Developmental Delay; Oxygen Saturation Decreased; Pneumonia; Sepsis; Skin Candida; Tachycardia; Tachypnoea; Thyroid Hormones Decreased; Weight Gain Poor	Dexamethasone			S	Unknown			Bausch And Lomb
	Azithromycin Dihydrate			S	Unknown			Not Reported
	Lamivudine			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported
	Vancomycin			S	Unknown			Not Reported
	Biseptol			S	Unknown			Not Reported
	Abacavir			S	Unknown			Not Reported
	Lopinavir Plus Ritonavir			S	Unknown			Not Reported
	Furosemide			C				Not Reported
	Co-Trimoxazole			C				Not Reported
	Calcium Folate			C				Not Reported
	Zydowudyna			C				Not Reported
	Dopamine			C				Not Reported
	Levonor			C				Not Reported
	Prednisone			C				Not Reported
	Iron			C				Not Reported
	Ethacrynic Acid			C				Not Reported
	Amoxicillin Plus Clavulanic Acid			C				Not Reported
	Colecalciferol			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Aug-2019	16712687	NON-EXPEDITED			PHEH2019US034130			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Drug Ineffective; Rash	Rifampin			S	Unknown	Unk Unk, Qd		Novartis
	Zithromax			S	Unknown	Unk Unk, Qd		Not Reported
	Ethambutol			S	Unknown	Unk Unk, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16712871	EXPEDITED (15-DAY)		OT	ES-APOTEX- 2019AP020190		65 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Laryngospasm; Paraesthesia	Azithromycin	S	Oral	500 Mg, Qd	Apotex

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Aug-2019	16713041	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR- APL-2019-053865			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea;	Azithromycin			S	Unknown	Unk		Aurobindo
Hepatosplenomegaly; Hiv	Lamivudine			S	Unknown	Unk		Not Reported
Viraemia; Hypertension;	Meropenem			S	Unknown	Unk		Not Reported
Livedo Reticularis; Motor	Dexamethasone			S	Unknown	Unk		Not Reported
Developmental Delay;	Vancomycin			S	Unknown	Unk		Not Reported
Oxygen Saturation	Biseptol			S	Unknown	Unk		Not Reported
Decreased; Pneumonia;	Abacavir			S	Unknown	Unk		Not Reported
Sepsis; Skin Candida;	Furosemide			C	Unknown	Unk		Not Reported
Tachycardia; Tachypnoea;	Colecalciferol			C	Unknown	Unk		Not Reported
Thyroid Hormones	Calcium Folate			C	Unknown	Unk		Not Reported
Decreased; Weight Gain	Dopamine			C	Unknown	Unk		Not Reported
Poor	Prednisone			C	Unknown	Unk		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Co-Trimoxazole			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Aug-2019	15883891	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US- 1004358		30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastritis; Gastrointestinal	Dexamethasone			S	Unknown			Actavis
Haemorrhage; Maternal	Azithromycin			S	Unknown			Not Reported
Exposure During	Etoposide			C	Unknown	Weekly		Not Reported
Pregnancy; Normal	Etoposide			C	Other	Discharged With		Not Reported
Newborn								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

				Etoposide Outpatient Infusion (Week 6 Of Hlh Protocol)					
	Etoposide	C	Unknown	Restarted Hlh-94 Protocol; Twice Weekly		Not Reported			
	Rituximab	C	Unknown	On Day 15 Of Readmission		Not Reported			
	Ampicillin	C	Unknown			Not Reported			
	Gentamicin	C	Unknown			Not Reported			
	Clindamycin	C	Unknown			Not Reported			
	Ganciclovir	C	Unknown			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	12294829	NON-EXPEDITED			US-PFIZER INC-2016189479		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	15213074	NON-EXPEDITED			US-PFIZER INC-2018304711		27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16443882	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033449			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction;	Atorvastatin Tablets			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Photodermatosis;	Voriconazole	S	Oral	Unk	Aurobindo
Photosensitivity Reaction;	Voriconazole	S	Oral	Unk	Aurobindo
Solar Lentigo; Squamous	Azithromycin	S	Oral	Unk	Aurobindo
Cell Carcinoma Of Skin	Pantoprazole	S	Oral	Unk	Aurobindo
	Lansoprazole	S	Oral	Unk	Not Reported
	Mycophenolate Mofetil	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Sulfamethoxazole;Trimethoprim	S	Oral	Unk	Not Reported
	Tacrolimus	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16643364	NON-EXPEDITED			US-PFIZER INC-2019321923		70 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Obstructive Pulmonary Disease;	Azithromycin			S		Unk		Pfizer	
Diarrhoea; Drug Hypersensitivity;	Cimetidine			S		Unk		Not Reported	
Haemorrhoids	Ranitidine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Aug-2019	16714564	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-217818		26 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Neutropenia	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Lamprene			S	Oral	100 Milligram, Daily		Not Reported	
	Vimpat 50 Mg, Comprime Pellicule			S	Oral	200 Milligram, Daily		Not Reported	
	Imukin			S	Subcutaneous	100ug 3x/Semaine		Not Reported	
	Imukin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16715869	NON-EXPEDITED			US-PFIZER INC-2019354128		57 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16715930	EXPEDITED (15-DAY)		HO, OT	GR-MYLANLABS-2019M1076444		66 YR	Female	GRC
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Encephalopathy; Jarisch-Herxheimer Reaction; Product Use In Unapproved Indication	Azithromycin			S		Unk (For 3 Days)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16716196	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019350166			Female	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain; Liver Injury	Azithromycin			S		750 Mg, Weekly		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16717922	NON-EXPEDITED			PHEH2019US034069			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Ear Infection; Hypoacusis; Tinnitus	Azithromycin			S	Unknown	Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Aug-2019	16904454	DIRECT						Unknown	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Extra Dose Administered; Product Dispensing Error	Azithromycin 200mg/5ml 9.5 MI Qd			S				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15347429	EXPEDITED (15-DAY)		HO, OT	ZA-TEVA-2018-ZA-950438		24 YR	Female	ZAF
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Live Birth; Maternal Exposure During Pregnancy; Nausea; Tachypnoea; Vomiting	Azithromycin			S	Unknown			Not Reported	
	Metronidazole			S	Unknown			Not Reported	
	Ringer'S Lactate			C	Other	Route: {Infusion}		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851362	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001870			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851371	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001873			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851373	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001881			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Maternal Exposure During Pregnancy Azithromycin S Unknown Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851386	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001891			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851542	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001899			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851557	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001902			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15851564	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001905			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851798	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001841			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851799	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001844			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851820	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001852			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851821	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001847			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851836	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001863			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851838	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001860			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15851856	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001867			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15852139	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001914			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15852173	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001921			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15852174	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001939			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15852397	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001943			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
20-Aug-2019	15856420	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001908			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	15861141	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001911			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16049417	NON-EXPEDITED			US-PFIZER INC-2019094167		67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16719026	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-053505			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Graft Versus Host Disease; Obliterative Bronchiolitis; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo	
	Fluticasone Propionate			C	Unknown	Unk		Not Reported	
	Montelukast			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16720597	NON-EXPEDITED		HO, OT	US-APOTEX-2019AP020553		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Thrombocytopenia	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Aug-2019	16721631	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1077397		25 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Thrombocytopenia; Rash Maculo-Papular	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851255	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002010			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851263	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001985			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851275	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001993			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851277	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001972			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous;
Maternal Exposure During
Pregnancy

Azithromycin

S

Unknown

Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15851278	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001974			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15851291	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001966			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15851293	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002006			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Aug-2019	15851297	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001991			Female	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851310	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001997			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851311	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001986			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851313	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001989			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851374	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001872			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851375	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001876			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851383	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001887			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851384	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001896			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851413	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001959			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851416	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001958			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851418	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001961			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851566	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001904			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851575	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001901			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851792	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001840			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851796	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001843			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851809	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001851			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851818	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001846			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851839	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001862			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851840	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001858			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851854	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001866			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15851862	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001869			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852140	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001920			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852142	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001913			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852171	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001942			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852172	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001936			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852392	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001945			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852430	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001946			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852437	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001948			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852439	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001951			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15852440	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001949			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15856422	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001907			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15856934	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001952			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15856969	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001956			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15856970	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001955			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	15861151	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001910			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16064117	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2019M1022486		41 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctival Hyperaemia; Leukocytosis; Odynophagia; Off Label Use; Oral Disorder; Oral Mucosal Exfoliation; Oropharyngeal Plaque; Pyrexia; Rash; Rash Pustular; Stevens-Johnson Syndrome	Amoxicillin/Clavulanic Acid			S	Oral	Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S				Not Reported	
	Azithromycin			S	Oral	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Cefuroxime			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16438406	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033280			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Candida Infection; Pneumonia	Amoxicillin	S	Unknown	500 Milligram, 1 Every 5 Times A Day,Every 5 Days	Aurobindo
	Azithromycin	S	Unknown	250 Milligram, 1 Every 3 Times A Day,Every 3 Days	Aurobindo
	Stelara	S	Subcutaneous	45 Milligram, 1 Every 8 Week (S)	Not Reported
	Stelara Stelara	S S	Subcutaneous	45 Milligram 1 Every 8 Week(S)	Not Reported Not Reported
	Stelara	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16722516	EXPEDITED (15-DAY)		DE, OT	PHHY2019CA194622		81 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Acute Kidney Injury; Adjustment Disorder; Anaemia; Angina Pectoris; Atrophy; Back Pain; Bundle Branch Block Left; Drug Hypersensitivity; Drug Intolerance; Hepatic Steatosis; Hypercalcaemia; Hypertension; Monoclonal Gammopathy; Musculoskeletal Pain; Osteoarthritis; Palmar Erythema; Plasma Cell Myeloma; Sacroiliitis; Spinal Disorder; Toxicity To Various Agents	Aclasta			S	Intravenous drip	Unk		Not Reported
	Codeine Phosphate			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Amoxil			S	Unknown	Unk		Not Reported
	Teva Risedronate			S	Unknown	Unk		Not Reported
	Dilaudid			C	Unknown	Unk		Not Reported
	Esomeprazole Sodium			C	Unknown	Unk		Not Reported
	Propranolol Hydrochloride			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16723348	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-053380			Unknown	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Lower; Chlamydial Infection; Drug Resistance; Metrorrhagia; Vaginal Discharge	Azithromycin			S	Unknown	1 Gram		Aurobindo	
	Azithromycin			S	Unknown	1 Gram		Aurobindo	
	Azithromycin			S	Unknown	1 Gram (On Day 1 And Day 7)		Aurobindo	
	Doxycycline			S	Unknown	100 Milligram, Two Times A Day (7 Days)		Not Reported	
	Doxycycline			S	Unknown	100 Milligram, Two Times A Day (For 2 Weeks)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16723432	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-053944			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Headache	Cefixime			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Remicade			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16724478	EXPEDITED (15-DAY)		OT	PT-MYLANLABS- 2019M1060740		73 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective; Treatment Failure	Azithromycin			S		Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16724732	NON-EXPEDITED			US-PFIZER INC- 2019356450		68 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Swelling

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16724762	NON-EXPEDITED			US-PFIZER INC-2019355856		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16725082	NON-EXPEDITED			US-PFIZER INC-2019357998		8 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Pruritus	Azithromycin			S	Oral	Unk (200mg Per 5 MI)		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Aug-2019	16726310	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK104205			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bacterial Disease Carrier; Blood Count Abnormal; Bronchial Secretion Retention; Bronchial Wall Thickening; Cough; Drug Ineffective; Dyspnoea; Dyspnoea; Fall; Ill-Defined Disorder; Intervertebral Disc Protrusion; Obstructive Airways Disorder; Rales; Spinal Cord Compression; Sputum Discoloured; Therapeutic Product Effect	Fluticasone Propionate+Salmeterol Xinafoate			S	Respiratory (inhalation)	2 Puff(S), Bid(250/25 Mcg)		Glaxosmithkline	
	Ventolin			S		Unk Unk, Prn		Glaxosmithkline	
	Ventolin			S	Respiratory (inhalation)	Unk(Uses Every 3 To 4 Hours)		Glaxosmithkline	
	Singular			S		10 Mg, 1d		Glaxosmithkline	
	Calcium			S		Unk		Glaxosmithkline	
	Vitamin D			S		Unk		Glaxosmithkline	
	Zopiclone			S		5 Mg, Qd(At Bedtime)		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Incomplete; Upper Limb Fracture; Wheezing; Wrist Fracture	Hydroxyzine	S		Unk Unk, Prn	Glaxosmithkline
	Azithromycin	S		250 Mg, Qd	Glaxosmithkline
	Alvesco	S		300 Ug, Bid(100 Mcg Qam And 200 Mcg Qpm)	Not Reported
	Alvesco	S		200 Mg, Bid	Not Reported
	Spiriva	S	Respiratory (inhalation)	2 Puff(S), 1d(2.5 Mcg)	Not Reported
	Daxas	S	Respiratory (inhalation)	500 Ug, 1d	Not Reported
	Daxas	S	Respiratory (inhalation)	100 Ug, Qd	Not Reported
	Pantoloc	S		40 Mg, 1d	Not Reported
	Celebrex	S		Unk	Not Reported
	Histex	S		Unk Unk, Prn	Not Reported
	Imodium	S		Unk Unk, Prn	Not Reported
	Hycodan	S		Unk	Not Reported
	Prednisone	S		Unk	Not Reported
	Xolair	S		Unk	Not Reported
	Fasenra	S	Intravenous (not otherwise specified)	Unk, Z(Every 2 Months)	Not Reported
	Omalizumab	S		225 Mg, Z(Every 2 Weeks)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	14487776	EXPEDITED (15-DAY)		HO	CN-TEVA-2018-CN-853338		30 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Maternal Exposure During Pregnancy; Normal Newborn	Azithromycin			S	Unknown	500 Mg Loading Dose		Not Reported
	Azithromycin			S	Unknown	250 Mg Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851254	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001978			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851262	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001992			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851290	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002001			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851294	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001967			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851298	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001987			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851361	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001871			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851372	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001875			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851377	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001883			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851385	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001895			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851415	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001960			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851565	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001903			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851583	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001900			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15851797	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001845			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15851808	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001842			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15851810	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001850			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	15851841	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001855			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851842	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001861			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851855	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001864			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15851861	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001868			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852141	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001932			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852143	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001912			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852144	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001915			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852170	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001941			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852429	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001947			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852441	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001944			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15852449	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001950			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15856262	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002435			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15856277	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002430			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15856417	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001906			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15856933	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001957			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15856967	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001953			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	15861119	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1001909			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16448916	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034706			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthropathy;	Azithromycin			S	Unknown	250 Milligram		Aurobindo	
Blister; Burning Sensation;	Azithromycin			S	Unknown	Unk		Aurobindo	
Chest Pain; Cough;	Azithromycin			S				Aurobindo	
Cystitis; Dizziness; Drug	Azithromycin			S				Aurobindo	
Ineffective; Fall; Feeling	Azithromycin			S				Aurobindo	
Abnormal; Gait	Azithromycin			S				Aurobindo	
Disturbance; Headache;	Pantoprazole			S	Unknown	Unk Unk, Daily		Aurobindo	
Heart Rate Increased;	Pantoprazole			S	Unknown	40 Milligram, Daily		Aurobindo	
Hypertension; Incorrect	Xolair			S	Subcutaneous	300 Milligram, 1 Every 2		Not Reported	
Dose Administered;						Week			
Influenza Like Illness;	Xolair			S	Subcutaneous	225 Milligram, 1 Every 2		Not Reported	
Injection Site Rash;						Week			
Insomnia; Lip Swelling;	Xolair			S	Subcutaneous	200 Milligram, 1 Every 2		Not Reported	
Mobility Decreased;						Week			
Muscular Weakness;	Xolair			S	Unknown	150 Milligram, 1 Every 2		Not Reported	
Nasopharyngitis; Pain;						Week			
Pain In Extremity; Painful	Xolair			S	Subcutaneous	300 Milligram		Not Reported	
Respiration; Peripheral									
Swelling; Product Storage	Xolair			S	Unknown	Unk		Not Reported	
Error; Pruritus; Rash;	Cetirizine			C	Unknown	Unk		Not Reported	
Respiratory Tract	Demulen			C	Unknown	Unk		Not Reported	
Congestion; Sensation Of	Fucidin			C	Unknown	Unk		Not Reported	
Foreign Body; Stress;	Hydroxyzine			C	Unknown	Unk		Not Reported	
Swelling; Tooth Fracture;	Metronidazole			C	Unknown	Unk		Not Reported	
Urticaria	Nystatin			C	Unknown	Unk		Not Reported	
	Pepcid			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk, Daily		Not Reported	
	Reactine [Cetirizine			C	Unknown	Unk Unk, Daily		Not Reported	
	Hydrochloride;Pseudoephedrine								
	Hydrochloride]								
	Sertraline			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Singulair	C	Unknown	Unk	Not Reported
Ventolin	C	Unknown	Unk	Not Reported
Aluminium Hydroxide Gel, Dried;Magnesium Carbonate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16727582	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR- APL-2019-054112			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Cough; Drug Ineffective; Dyspnoea; Gastroesophageal Reflux Disease; Lung Disorder; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Rhinorrhoea; Sputum Discoloured; Weight Increased; Wheezing	Amlodipine Tablets			S	Unknown	Unk		Aurobindo
	Escitalopram			S	Unknown	Unk		Aurobindo
	Atrovent			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Unknown	Unk		Not Reported
	Cipraxel			S	Unknown	Unk		Not Reported
	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
	Olodaterol + Tiotropium			S	Unknown	Unk		Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Solu-Medrol			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	Unk		Not Reported
	Synthroid			S	Unknown	Unk		Not Reported
	Theophylline			S	Unknown	Unk		Not Reported
	Uniphyl			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16728080	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-053913			Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Blood Test Abnormal; Cough; Distal Intestinal Obstruction Syndrome; Dyspnoea; Eosinophil Count Increased; Glucose Tolerance Impaired; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Obstructive Airways Disorder; Pancreatic Failure; Productive Cough; Renal Failure; Therapeutic Product Effect Incomplete	Ciprofloxacin			S	Oral	750 Milligram, Two Times A Day		Aurobindo	
	Ciprofloxacin			S	Oral	500 Milligram		Aurobindo	
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo	
	Ceftazidime			S	Unknown	2 Gram, Two Times A Day		Not Reported	
	Fluticasone Propionate;Salmeterol Xinafoate			S	Unknown	1 Dosage Form, Two Times A Day		Not Reported	
	Nucala			S	Intravenous (not otherwise specified)	100 Milligram		Not Reported	
	Nystatin			S	Unknown	Unk Unk, Four Times/Day		Not Reported	
	Prednisone			S	Unknown	45 Milligram, Once A Day		Not Reported	
	Pulmicort			S	Unknown	2 Dosage Form, Two Times A Day		Not Reported	
	Septra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported	
	Singulair			S	Unknown	10 Milligram, Once A Day		Not Reported	
	Spiriva			S	Unknown	18 Milligram, Once A Day		Not Reported	
	Ventolin			S	Unknown	2 Dosage Form		Not Reported	
	Zopiclone			S	Unknown	7.5 Milligram		Not Reported	
	Cayston			C	Unknown	75 Milligram, 3 Times A Day		Not Reported	
	Pulmozyme			C	Unknown	2.5 Milligram, Once A Day		Not Reported	
	Vitamin D			C	Unknown	Unk, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16728094	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR-APL-2019-055276			Unknown	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Gastrointestinal Inflammation; Intestinal Haemorrhage	Azithromycin			S	Unknown	Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16728104	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054411			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250.0 Milligram, Daily		Aurobindo	
	Montelukast			S	Oral	10 Milligram, Daily		Aurobindo	
	Breo Ellipta			S	Unknown	1 Dosage Form, Daily		Not Reported	
	Ipratropium Bromide			S	Unknown	Unk		Not Reported	
	Ipratropium Bromide;Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Omalizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			S	Oral	45.0 Milligram		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Seebri Breezhaler			S	Unknown	1 Dosage Form, Daily		Not Reported	
	Theophylline			S	Oral	450.0 Milligram, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2019	16728291	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054149			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia;	Azithromycin			S	Oral	1 Dosage Form, Once A Day		Aurobindo	
	Fluoxetine			S	Unknown	Unk		Aurobindo	
	Omalizumab			S	Unknown	300 Milligram		Not Reported	
	Avamys			C	Unknown	Unk		Not Reported	
	Prozac			C	Unknown	Unk		Not Reported	
	Quetiapine			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rash Pustular;
Staphylococcal Infection;
Syncope

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729771	NON-EXPEDITED			US-PFIZER INC-2019357681		49 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Zosyn			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16729849	NON-EXPEDITED			US-PFIZER INC-2019360069			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16730718	EXPEDITED (15-DAY)		HO, OT	IT-PFIZER INC-2019356370		12 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Conjunctivitis; Erythema Multiforme	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Ibuprofen			C		Unk		Not Reported	
	Amoxicillin			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Aug-2019	16731405	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1078271		52 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Rectal Haemorrhage; Vomiting	Azithromycin			S	Oral	250 Milligram		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	9574741	NON-EXPEDITED			US-PFIZER INC-2013276783		63 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	15856261	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002450			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	15856274	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002444			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	15856276	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002442			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Aug-2019	15856282	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002454			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	15856283	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002451			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	15856286	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002433			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	15856287	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002447			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	15856294	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002446			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous; Maternal Exposure During Pregnancy Azithromycin S Unknown Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	15856297	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002453			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	15856298	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002436			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16444316	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-034440			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Azithromycin			S	Unknown	Unk		Aurobindo
Cognitive Disorder;	Ocrevus			S	Intravenous (not otherwise specified)	300 Milligram, 1 Every 2 Weeks		Not Reported
Depression; Dizziness;	Cipralext			C	Unknown	Unk		Not Reported
Drug Intolerance; Fatigue;	Clonazepam			C	Unknown	0.5 Milligram, Two Times A Day		Not Reported
Feeling Abnormal; Feeling Hot; Ill-Defined Disorder;	Lyrice			C	Unknown	Unk		Not Reported
Impaired Gastric Emptying; Insomnia;	Oxycontin			C	Unknown	Unk		Not Reported
Intentional Overdose;								
Malaise; Multiple Sclerosis Relapse; Musculoskeletal Stiffness; Night Sweats; Pain; Pain In Extremity;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Suicide Attempt

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16449265	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-033861			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal;	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
Blood Pressure Increased;	Azithromycin			S	Oral	250 Milligram		Aurobindo
Body Temperature								
Increased; Cataract;	Advair			S	Unknown	1 Dosage Form, Two		Not Reported
Cough; Drug Dependence;						Times A Day		
Heart Rate Increased;	Prednisone			S	Oral	8 Milligram, Daily		Not Reported
Lung Diffusion Test								
Decreased; Nasal	Salbutamol			S	Unknown	Unk		Not Reported
Disorder; Nasopharyngitis;	Spiriva			S	Unknown	Unk		Not Reported
Obstructive Airways								
Disorder; Pyrexia;	Spiriva			S	Unknown	18 Microgram, Daily		Not Reported
Restrictive Pulmonary								
Disease; Therapeutic	Mometasone			S	Unknown	1 Dosage Form, Two		Not Reported
Response Decreased;						Times A Day		
Type 2 Diabetes Mellitus	Zenhale			S	Unknown	2 Dosage Form, Two		Not Reported
						Times A Day		
	Zenhale			S	Unknown	1 Dosage Form, Two		Not Reported
						Times A Day		
	Cetirizine			C	Unknown	Unk		Not Reported
	Cetirizine			C	Unknown	20 Milligram, Daily		Not Reported
	Pariet			C	Unknown	Unk		Not Reported
	Rosuvastatin			C	Unknown	Unk		Not Reported
	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16732599	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-054237			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Autism Spectrum Disorder; Blood Pressure	Azithromycin			S	Oral	1 Dosage Form, Daily		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Cough;	Fluoxetine	S	Unknown	Unk	Aurobindo
Dermatitis; Eczema;	Omalizumab	S	Unknown	300 Milligram	Not Reported
Forced Expiratory Volume	Fluticasone	C	Unknown	Unk	Not Reported
Decreased; Heart Rate	Guanfacine Hydrochloride	C	Unknown	Unk	Not Reported
Abnormal; Lower	Prozac	C	Unknown	Unk	Not Reported
Respiratory Tract	Quetiapine	C	Unknown	300 Milligram	Not Reported
Infection; Malaise; Nasal					
Congestion; Obstructive					
Airways Disorder;					
Oropharyngeal Pain;					
Pharyngeal Paraesthesia;					
Rash Pustular;					
Staphylococcal Infection;					
Syncope					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16732683	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-054514			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Oral	500.0 Milligram, Daily		Aurobindo
	Aspirin			C	Oral	81.0 Milligram, Daily		Not Reported
	Folic Acid			C	Oral	1.0 Milligram, Daily		Not Reported
	Hydrochlorothiazide With Triamterene			C	Oral	25.0 Milligram, Daily		Not Reported
	Infliximab			C	Intravenous (not otherwise specified)	315.0 Milligram		Not Reported
	Methotrexate			C	Oral	20.0 Milligram, Every Week		Not Reported
	Pantoprazole Sodium Anhydrous			C	Oral	40.0 Milligram		Not Reported
	Vitamin B12			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733107	EXPEDITED (15-DAY)		OT	AE-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-218542		33 YR	Female	ARE

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Resistance	Azithromycin			S	Unknown	Unk		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733145	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054504			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Milligram, Daily		Aurobindo	
	Atrovent			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	1 Dosage Form, Daily		Not Reported	
	Omalizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			S	Oral	45 Milligram		Not Reported	
	Ratio-Ipra Sal Udv			S	Unknown	Unk		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Seebri Breezhaler			S	Unknown	1 Dosage Form, Daily		Not Reported	
	Singulair			S	Oral	10 Milligram, Daily		Not Reported	
Theophylline			S	Oral	450 Milligram, Daily		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733151	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-054520			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250.0 Milligram, Daily		Aurobindo	
	Atrovent			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	1.0 Dosage Form, Daily		Not Reported	
	Ipratropium Bromide;Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Omalizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	45.0 Milligram	Not Reported
Salbutamol Sulfate	S	Unknown	Unk	Not Reported
Seebri Breezhaler	S	Unknown	1.0 Dosage Form, Daily	Not Reported
Singulair	S	Oral	10.0 Milligram, Daily	Not Reported
Theophylline	S	Oral	450.0 Milligram, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733391	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-054519			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Aurobindo
	Lamivudine			S	Transplacental	150 Milligram		Aurobindo
	Zidovudine			S	Unknown	300 Milligram		Aurobindo
	Aciclovir			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Milligram		Not Reported
	Prezista			S	Transplacental	600 Milligram		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Milligram		Not Reported
	Ritonavir			S	Transplacental	100 Milligram		Not Reported
	Tenofovir			S	Transdermal	300 Milligram		Not Reported
	Abacavir			C	Transplacental	300 Milligram		Not Reported
	Calcium D			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Magnesium Gluconate			C	Unknown	Unk		Not Reported
	Nicotinamide			C	Unknown	Unk		Not Reported
	Pyridoxine Hydrochloride			C	Unknown	Unk		Not Reported
	Retinol Palmitate			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Riboflavin	C	Unknown	Unk	Not Reported
Thiamine Mononitrate	C	Unknown	Unk	Not Reported
Vitamin B12 Nos	C	Unknown	Unk	Not Reported
Ascorbic Acid	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16733442	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-055105			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adenocarcinoma; Asthma;	Azithromycin			S	Unknown	Unk		Aurobindo
Blood Count Abnormal;	Pantoprazole			S	Unknown	Unk		Aurobindo
Breath Sounds Abnormal;	Calcium			S	Unknown	Unk		Not Reported
Emphysema; Eosinophilia;	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
Gastroesophageal Reflux	Metoprolol			S	Unknown	Unk		Not Reported
Disease; Hypercapnia;	Potassium Chloride			S	Unknown	Unk		Not Reported
Hypertension;	Prednisone			S	Unknown	Unk		Not Reported
Hyperthyroidism;	Rabeprazole			S	Unknown	Unk		Not Reported
Influenza; Multiple	Roflumilast			S	Unknown	Unk		Not Reported
Allergies; Osteoporosis;	Salbutamol			S	Unknown	Unk		Not Reported
Pain In Extremity;	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
Pneumonitis;	Symbicort			S	Unknown	Unk		Not Reported
Pneumothorax	Thyroxine			S	Unknown	Unk		Not Reported
Spontaneous; Polymyalgia	Tiotropium			S	Unknown	Unk		Not Reported
Rheumatica; Productive	Vitamin D			S	Unknown	Unk		Not Reported
Cough; Respiratory Tract								
Infection; Upper								
Respiratory Tract Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16735466	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019348385			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Zithromac Sr 2g			S	Oral	Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Gastric Mucosal Lesion;
Gastric Ulcer; Polyp;
Stomach Mass

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16735543	EXPEDITED (15-DAY)		DS, HO, LT, OT	GB-MYLANLABS-2019M1078439		35 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Psychotic Disorder; Suicide Attempt	Azithromycin			S	Oral	2, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16735820	NON-EXPEDITED			US-PFIZER INC-2019360198		26 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16735822	NON-EXPEDITED			US-PFIZER INC-2019361021			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Triamcinolone Acetonide			S		Unk		Pfizer	
	Cephalexin Monohydrate			S		Unk		Not Reported	
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported	
	Phenazopyridine Hydrochloride			S		Unk		Not Reported	
	Sitagliptin			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16737258	EXPEDITED (15-DAY)		OT	CA-MYLANLABS-2019M1075044			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Biaxin XI			S	Unknown	Unk		Mylan
	Amoxicillin			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Mylan
	Apo Hydro			S	Unknown	Unk		Mylan
	Avamys			S	Unknown	Unk		Mylan
	Azithromycin Dihydrate			S	Unknown	Unk		Mylan
	Bactroban /00753901/			S	Unknown	Unk		Mylan
	Betaderm /00008501/			S	Unknown	Unk		Mylan
	Betamethasone Dipropionate			S	Unknown	Unk		Mylan
	Bisacodyl			S	Unknown	Unk		Mylan
	Calcium Carbonate			S	Unknown	Unk		Mylan
	W/Colecalciferol//01980901/							
	Calcium Carbonate/Vitamin D3			S	Unknown	Unk		Mylan
	Cetirizine			S	Unknown	Unk		Mylan
	Clarithromycin			S	Unknown	Unk		Mylan
	Clotrimazole			S	Unknown	Unk		Mylan
	Ascorbic Acid;Cupric Oxide;DL-Alpha/12693401/			S	Unknown	Unk		Mylan
	Desonide			S	Unknown	Unk		Mylan
	Dilaudid			S	Unknown	Unk		Mylan
	Diphenhydramine			S	Unknown	Unk		Mylan
	Entocort			S	Unknown	Unk		Mylan
	Ertapenem Sodium			S	Unknown	Unk		Mylan
	Flovent			S	Unknown	Unk		Mylan
	Glycerine			S	Unknown	Unk		Mylan
	Gramicidin W/Neomycin Sulfate/Polymycin B			S	Unknown	Unk		Mylan
	Habitrol /01033301/			S	Unknown	Unk		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Unk	Mylan
Kenalog /00031902/	S	Unknown	Unk	Mylan
Lomotil /00034001/	S	Oral	Unk Unk, Qid	Mylan
Macrogol 3350 W/Potassium Chloride//01618701/	S	Unknown	Unk	Mylan
Metronidazole	S	Unknown	Unk	Mylan
Ms Ir	S	Unknown	Unk	Mylan
Mupirocin	S	Topical	Unk	Mylan
Nadolol	S	Unknown	Unk	Mylan
Nicoderm	S	Unknown	Unk	Mylan
Nicotine Polacrilex	S	Unknown	Unk	Mylan
Pantoprazole	S	Unknown	Unk	Mylan
Pentasa	S	Unknown	Unk	Mylan
Prednisone	S	Unknown	Unk	Mylan
Pregabalin	S	Unknown	Unk	Mylan
Pulmicort	S	Unknown	Unk	Mylan
Refresh Tears	S	Ophthalmic	Unk	Mylan
Salinex /00075401/	S	Unknown	Unk	Mylan
Sinus Rinse	S	Unknown	Unk	Mylan
Statex /00036302/	S	Unknown	Unk	Mylan
Sulfamethoxazole W/Trimethoprim	S	Unknown	Unk	Mylan
Triamcinolone Acetonide	S	Unknown		Mylan
Vitamin D3	S	Unknown	Unk	Mylan
Calcium Carbonate/Vitamin D3	C		Unk	Mylan
Valsartan	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16737348	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1078599		73 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Alkaline	Azithromycin	S	Oral	250 Milligram, Qd	Not Reported
Phosphatase Increased;	Rifadine /00146901/	S	Oral	1 Dosage Form, Qd	Mylan
Electrocardiogram Qt	Lamprene /00224701/	S	Oral	1 Dosage Form, Qd	Mylan
Prolonged; General	Paracetamol	C		Unk	Mylan
Physical Health	Lactulose	C		Unk	Mylan
Deterioration; Malaise;					
Rhabdomyolysis;					
Transaminases Increased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2019	16737652	NON-EXPEDITED			US-TEVA-2019-US-1097020			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Expired Product Administered	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	14499961	EXPEDITED (15-DAY)		HO, OT	ES-MYLANLABS-2018M1007747		66 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Pain; Fatigue; Flank Pain; Gait Disturbance; Hypoaesthesia; Large Intestinal Ulcer; Myalgia; Paraesthesia; Pyrexia	Prednisone			S	Oral	20 Mg, Unk		Not Reported
	Prednisone			S	Oral	60 Mg, Unk		Not Reported
	Prednisone			S	Oral	60 Mg, Once Daily (Qd), 30 Mg, 2x/Day (At Breakfast Time)		Not Reported
	Prednisone			S	Oral	30 Milligram, Qd		Not Reported
	Prednisone			S	Oral	20 Mg, Qd		Not Reported
	Prednisone			S	Oral	20 Milligram, Qd		Not Reported
	Prednisone			S	Oral	60 Milligram, Qd (30 Mg, 2x/Day (At Breakfast Time))		Not Reported
	Cellcept /01275102/			S	Oral	2 At Breakfast And 2 At Dinner		Mylan
	Cellcept /01275102/			S	Oral	1000 Mg, 2x/Day (Bid),		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			500 Mg, 4x/Day (2 At Breakfast And 2 At Dinner)	
Cellcept /01275102/	S	Oral	500 Mg, 4x/Day (Qid)	Mylan
Cellcept /01275102/	S	Oral	500 Milligram, Q6h	Mylan
Cellcept /01275102/	S	Oral	500 Milligram, Q6h	Mylan
Valcyte	S	Oral	900 Mg,Qd	Mylan
Valcyte	S	Oral	450 Mg, Qd	Mylan
Septrin	S	Oral	Sulfamethoxazole 400 Mg]/Trimethoprim 80 Mg At Lunch Time	Mylan
Septrin	S	Oral	1 Dosage Form, Qd (Once A Day (At Lunch Time))	Mylan
Septrin	S	Oral	Once A Day (At Lunch Time)	Mylan
Zitromax	S	Oral	250 Mg, Q2d (250 Mg, At Lunch Time Every 48 Hours)	Mylan
Zitromax	S	Oral	Unk	Mylan
Prograf	S	Oral	5 Mg, 2x/Day (Bid) (1 In Morning And 1 Before Dinner)	Mylan
Prograf	S	Oral	8.5 Mg, Qd	Mylan
Prograf	S	Oral	4.5 Mg Before Breakfast And 4 Mg Before Dinner	Mylan
Prograf	S	Oral	4.5 Milligram, Bid (4.5 Mg Before Breakfast And 4 Mg Before Dinner)	Mylan
Prograf	S	Oral	Unk Unk, Bid	Mylan
Mycophenolate Mofetil	S	Oral	500 Milligram, Qid	Mylan
Mycophenolate Mofetil	S	Oral	500 Milligram, Q6h	Mylan
Paracetamol	C	Oral	500 Mg (2 At Breakfast, 2 At Lunch, 2 At Dinner), As Needed	Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dexketoprofen	C	Unknown	25 Mg, Tid	Mylan
Dexketoprofen	C	Oral	At 25 Mg (1 At Breakfast, 1 At Lunch, 1 At Dinner), As Needed	Mylan
Omeprazole	C	Oral	20 Mg, Qd At Breakfast/ 20 Mg, 1x/Day (At Breakfast)	Mylan
Lorazepam	C	Oral	1 Mg, 1x/Day (At Bedtime)	Mylan
Abelcet	C	Unknown	1 Unk, Unk	Mylan
Abelcet	C	Respiratory (inhalation)	In The Afternoon)	Mylan
Abelcet	C	Respiratory (inhalation)	50 Mg, Weekly (On Mondays In The Afternoon)	Mylan
Calcium & Vitamin D /09279801/	C	Oral	Unk Unk, 2x/Day (Bid), 500/400	Mylan
Calcium & Vitamin D /09279801/	C	Oral	Unk, 2x/Day	Mylan
Azithromycin	S	Oral	250 Milligram, Q2d	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	15826525	EXPEDITED (15-DAY)		HO	PHHY2018CZ196349		25 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Drug Ineffective; Leukocytosis; Nausea; Oropharyngeal Discomfort; Polycythaemia; Prescribed Overdose; Rash Vesicular	Desloratadine			S	Oral	5 Mg, Qd		Novartis
	Prednisone			S	Oral	10 Mg, Unk		Not Reported
	Prednisone			S	Unknown	60 Mg, Qd		Not Reported
	Prednisone			S	Oral	40 Mg, Qd		Not Reported
	Prednisone			S	Oral	10 Mg, Qd		Not Reported
	Azithromycin			S	Unknown	500 Mg, Qd		Not Reported
	Azithromycin			S				Not Reported
	Amoxicillin			S	Oral	1 G, Bid		Not Reported
	Amoxicillin			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bilastine	S	Oral	20 Mg, Qd	Not Reported
Bilastine	S	Oral	60 Mg, Qd	Not Reported
Bilastine	S	Oral	40 Mg, Qd	Not Reported
Bilastine	S	Unknown	40 Mg, Qd	Not Reported
Bilastine	S	Unknown	20 Mg, Qd	Not Reported
Bilastine	S	Oral	60 Mg, Qd	Not Reported
Bilastine	S	Oral	40 Mg, Qd	Not Reported
Bisulepin Hydrochloride	C	Unknown	Unk	Not Reported
Bisulepin Hydrochloride	C	Unknown	Unk Unk, Unknown Freq.	Not Reported
Betamethasone Dipropionate	C	Intramuscular	Unk	Not Reported
Betamethasone Dipropionate	C			Not Reported
Betamethasone	C	Topical	Unk	Not Reported
Diprophos	C	Intramuscular	1 MI, Unk	Not Reported
Xolair	C	Unknown	Unk	Not Reported
Xolair	C	Unknown	Unk Unk, Cyclic	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16536090	NON-EXPEDITED			US-PFIZER INC-2019286068		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16694349	EXPEDITED (15-DAY)		CA, OT	US-VIIV HEALTHCARE LIMITED-BW2019GSK146247			Unknown	BWA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cleft Lip; Foetal Exposure During Pregnancy; Holoprosencephaly; Live	Dolutegravir			S	Transplacental	Unk		Viiv	
	Iron Sulfate			S	Transplacental	Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Birth	Ceftriaxone	S	Transplacental	Unk, Single	Glaxosmithkline
	Azithromycin	S	Transplacental	Unk, Single	Glaxosmithkline
	Metronidazole	S	Transplacental	Unk, Single	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16725640	EXPEDITED (15-DAY)		LT, OT	AU-PFIZER INC-2019353003		64 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Glucose Increased; Coma Scale Abnormal; Cyanosis; Electrocardiogram Qt Prolonged; Hypotension; Liver Function Test Abnormal; Nausea; Oxygen Saturation Decreased; Tachypnoea	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Daily		Pfizer	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16741903	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1079350		39 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Rhabdomyolysis	Azithromycin			S		Unk		Not Reported	
	Risperidone			S		Unk		Not Reported	
	Chlorpromazine			S		Unk		Mylan	
	Fluvoxamine			S		Unk		Mylan	
	Amlodipine W/Perindopril			C		Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2019	16742073	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1096082			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Abdominal Pain; Liver Injury		Azithromycin		S		750 Mg		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
26-Aug-2019	16742130	NON-EXPEDITED			US-PFIZER INC-2019364403			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Intolerance	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16678466	NON-EXPEDITED			US-PFIZER INC-2019335537			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16743736	EXPEDITED (15-DAY)		HO	CZ-TEVA-2019-CZ-1096327		41 YR	Female	CZE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Gastrointestinal Inflammation; Intestinal Haemorrhage	Azitromycin			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Aug-2019	16744874	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1079942		76 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Oral			Not Reported	
	Rifampicin			S	Oral			Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)			Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Clofazimine		S	Oral				Mylan	
	Ethambutol		S	Oral				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16744875	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1079946		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Clofazimine			S	Oral			Mylan	
	Amikacin			S	Intravenous (not otherwise specified)			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745030	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1080034		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Oral			Not Reported	
	Linezolid			S	Oral			Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)			Mylan	
	Imipenem			S	Intravenous (not otherwise specified)			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745235	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1079947		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Oral			Not Reported	
	Rifampicin			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Amikacin		S	Intravenous (not otherwise specified)				Mylan	
	Clofazimine		S	Oral				Mylan	
	Ethambutol		S	Oral				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745236	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1080036		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Azithromycin				S	Oral			Not Reported
	Amikacin				S	Intravenous (not otherwise specified)			Mylan
	Imipenem				S	Intravenous (not otherwise specified)			Mylan
	Clofazimine				S	Oral			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745238	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1079994		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medical Device Site Joint Infection; Mycobacterium Avium Complex Infection; Treatment Failure	Prednisone				S	Unknown			Not Reported
	Azithromycin				S	Oral			Not Reported
	Rifampicin				S	Oral			Not Reported
	Ethambutol				S	Oral			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745298	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1098668		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Immune Thrombocytopenia; Rash Maculo-Papular	Azithromycin				S	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745301	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1080047		55 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Azithromycin			S	Oral			Not Reported
	Amikacin			S	Intravenous (not otherwise specified)			Mylan
	Amikacin			S	Unknown	Amikacin Containing Antibacterial Spacer		Mylan
	Tigecycline			S	Intravenous (not otherwise specified)			Mylan
	Imipenem			S	Intravenous (not otherwise specified)			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16745303	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1080043		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Medical Device Site Joint Infection; Mycobacterium Avium Complex Infection; Treatment Failure	Prednisone			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Moxifloxacin			S	Oral	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Ethambutol			S	Oral	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Aug-2019	16747314	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1079950		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Azithromycin			S	Oral			Not Reported
	Amikacin			S	Intravenous (not otherwise specified)			Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trimethoprim Sulfamethoxazole
Ethambutol

S Oral
S Oral

Mylan
Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	13373714	NON-EXPEDITED			US-PFIZER INC-2017128357		51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Septra			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Erythromycin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Sulfamethoxazole			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16365723	EXPEDITED (15-DAY)		DE, LT, OT	PL-AUROBINDO-AUR-APL-2019-029577			Unknown	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Neoplasm;	Montelukast Film-Coated Tablet			S	Oral	Unk		Aurobindo
Bronchopulmonary	Montelukast Film-Coated Tablet			S				Aurobindo
Aspergillosis; Device	Azithromycin			S	Unknown	Unk		Aurobindo
Related Infection; Disease	Methylprednisolone			S	Unknown	2 Milligram/Kilogram		Not Reported
Progression; Drug	Mitoxantrone Hydrochloride			C	Unknown	Unk		Not Reported
Ineffective; Graft Versus	Cyclophosphamide			C	Unknown	Unk		Not Reported
Host Disease In	Cytarabine			C	Unknown	Unk		Not Reported
Gastrointestinal Tract;	Amphotericin B			C	Unknown	Unk		Not Reported
Graft Versus Host Disease	Azacitidine			C	Unknown	Unk		Not Reported
In Lung; Product Use In	Posaconazole			C	Unknown	Unk		Not Reported
Unapproved Indication;	Fludarabine Phosphate			C	Unknown	Unk		Not Reported
Stenotrophomonas	Treosulfan			C	Unknown	Unk		Not Reported
Infection	Voriconazole			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tacrolimus	C	Unknown	Unk	Not Reported
Fluticasone	C	Unknown	Unk	Not Reported
Busulfan	C	Unknown	Unk	Not Reported
Daunorubicin	C	Unknown	Unk	Not Reported
Cladribine	C	Unknown	Unk	Not Reported
Fluconazole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16749527	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019363607		3 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blister; Off Label Use;	Zithromax			S	Intravenous drip	0.13 G, 1x/Day		Pfizer
Product Use Issue;	Zithromax			S	Intravenous drip	0.18 G, 1x/Day		Pfizer
Pruritus; Rash; Urticaria								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16750200	NON-EXPEDITED			US-PFIZER INC-2019368859		61 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Augmentin			S		Unk		Not Reported
	[Amoxicillin;Clavulanic Acid]							
	Lorabid			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16750454	NON-EXPEDITED			US-PFIZER INC-2019368632		40 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16750461	NON-EXPEDITED			US-PFIZER INC-2019368651		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Influenza Virus Vaccine			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Aug-2019	16750540	NON-EXPEDITED			US-PFIZER INC-2019368790		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Entresto			S		Unk		Not Reported	
	Humalog			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	12667363	NON-EXPEDITED			US-PFIZER INC-2016389029		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Lethargy	Zithromax			S		Unk		Pfizer	
	Phenergan [Promethazine]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	12919699	NON-EXPEDITED			US-PFIZER INC-2016512973		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inderal	S	Unk	Pfizer
Levaquin	S	Unk	Not Reported
Lovastatin	S	Unk	Not Reported
Quinidine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	15878142	NON-EXPEDITED			US-PFIZER INC-2014276100		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Sertraline Hcl			S		Unk		Pfizer
	Cymbalta			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported
	Losartan Potassium			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16444857	EXPEDITED (15-DAY)		HO	CZ-MYLANLABS-2019M1055602		25 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Drug Ineffective; Leukocytosis; Nausea; Oropharyngeal Discomfort; Polycythaemia; Prescribed Overdose; Rash Vesicular	Desloratadine			S		5 Milligram, Qd		Not Reported
	Desloratadine			S	Oral	5 Milligram, Qd		Not Reported
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Azithromycin			S		Unk		Not Reported
	Azithromycin			S	Unknown	500 Milligram, Qd		Not Reported
	Prednisone			S	Oral	10 Milligram, Qd		Mylan
	Prednisone			S	Oral	60 Milligram, Qd		Mylan
	Prednisone			S	Oral	40 Mg, Qd		Mylan
	Prednisone			S	Oral	10 Milligram, Qd		Mylan
	Prednisone			S	Oral	10 Milligram, Qd		Mylan
	Prednisone			S	Oral	10 Milligram, Qd		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	60 Milligram, Qd	Mylan
Prednisone	S	Oral	40 Milligram, Qd	Mylan
Prednisone	S	Oral	10 Milligram, Qd	Mylan
Amoxicillin	S	Oral	Unk Unk, Unknown Freq.	Mylan
Amoxicillin	S	Oral	Unk	Mylan
Amoxicillin	S	Oral	1 Gram, Bid 1 Gram, Q12h	Mylan
Amoxicillin	S	Oral	1 Gram, Bid 1 Gram, Q12h	Mylan
Bilastine	S	Oral	20 Milligram, Qd	Mylan
Bilastine	S	Oral	20 Milligram, Qd	Mylan
Bilastine	S	Oral	60 Milligram, Qd	Mylan
Bilastine	S	Oral	40 Milligram, Qd	Mylan
Bilastine	S	Oral	60 Milligram	Mylan
Bilastine	S	Oral	40 Milligram, Qd	Mylan
Bilastine	S	Oral	60 Milligram, Qd	Mylan
Bilastine	S	Oral	40 Milligram, Qd	Mylan
Bilastine	S	Oral	40 Milligram, Qd	Mylan
Bilastine	S	Oral	20 Milligram, Qd	Mylan
Bilastine	S	Oral	40 Milligram, Qd	Mylan
Bisulepin Hydrochloride	C	Unknown	Unk Unk, Unknown Freq.	Mylan
Bisulepin Hydrochloride	C	Unknown	Unk	Mylan
Betamethasone	C	Topical	Unk Unk, Unknown Freq.	Mylan
Xolair	C	Unknown	Unk Unk, Cycle Unk Unk, Unknown Freq.	Mylan
Xolair	C	Unknown	Unk Unk, Cyclic	Mylan
Xolair	C	Unknown	Unk	Mylan
Betamethasone Dipropionate	C	Intramuscular	Unk	Mylan
Betamethasone Dipropionate	C	Intramuscular	Unk	Mylan
Betamethasone Dipropionate	C	Intramuscular	1 MI, Unknown Freq.	Mylan
Betamethasone Sodium Phosphate	C	Intramuscular	Unk	Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Betamethasone Sodium Phosphate	C	Intramuscular	Unk	Mylan
	Diprophos	C	Intramuscular	1 Milliliter	Mylan
	Diprophos	C	Intramuscular	1 Milliliter, Qd (1 ML, Unknown Freq.)	Mylan
	Omalizumab	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16578131	EXPEDITED (15-DAY)		DS, HO, OT	HU-BAUSCH-BL-2019-019610		58 YR	Male	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Conjunctivitis; Cough; Dyspnoea Exertional; Mastocytosis; Myalgia; Nasopharyngitis; Pyrexia; Rash	Doxycycline			S	Oral			Not Reported
	Azithromycin			S	Oral	1-0-0		Not Reported
	Cetirizin			S	Oral			Not Reported
	Zinnat			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16717209	NON-EXPEDITED			US-PFIZER INC-2019354956			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Cipro [Ciprofloxacin Hydrochloride]			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Floxin Otic			S		Unk		Not Reported
	Fluoxetine			S		Unk		Not Reported
	Triamterene			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16753605	NON-EXPEDITED			US-TEVA-2019-US-1100588			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Injury	Azithromycin		S	Unknown					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16754076	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019365759		6 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cold Sweat; Dizziness; Drug Hypersensitivity; Off Label Use; Pallor; Product Use Issue; Vomiting	Azithromycin			S	Intravenous drip	180 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16754386	NON-EXPEDITED			US-PFIZER INC-2019367781		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16754842	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1079991		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthritis Bacterial; Mycobacterial Infection; Osteomyelitis Bacterial; Pyrexia; Subcutaneous Abscess; Treatment Failure	Hydroxychloroquine			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Linezolid			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Linezolid			S	Oral			Not Reported	
	Tigecycline			S	Intravenous (not			Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clofazimine	S	otherwise specified)			Mylan
Amikacin	S	Intravenous (not otherwise specified)			Mylan
Amikacin	S	Unknown	Amikacin Containing Spacer		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16754857	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1080023		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis Bacterial; Mycobacterium Avium Complex Infection; Treatment Failure	Azathioprine			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Rituximab			S	Unknown	Unk		Mylan
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Mylan
	Ethambutol			S	Oral	Unk		Mylan
	Rifabutin			S	Oral			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2019	16756735	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2019GSK154315		63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Amoxicillin Trihydrate			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Lamotrigine			S		Unk		Glaxosmithkline
	Clozapine			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	15852451	EXPEDITED (15-DAY)		HO	CZ-AUROBINDO-AUR-APL-2019-001298			Unknown	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Lower; Drug Ineffective; Leukocytosis; Nausea; Polycythaemia; Prescribed Overdose; Rash Vesicular	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Unknown	Unk, 6 Days		Aurobindo
	Amoxicillin			S	Oral	Unk		Not Reported
	Amoxicillin			S	Oral	1 Gram, Two Times A Day		Not Reported
	Amoxicillin			S				Not Reported
	Prednisone			S	Oral	10 Milligram, Once A Day		Not Reported
	Prednisone			S	Oral	60 Milligram, Once A Day		Not Reported
	Prednisone			S	Oral	40 Milligram, Once A Day		Not Reported
	Prednisone			S	Oral	10 Milligram, Once A Day		Not Reported
	Bilastine			S	Unknown	20 Milligram, Once A Day		Not Reported
	Bilastine			S	Oral	40 Milligram, Once A Day		Not Reported
	Bilastine			S	Oral	60 Milligram, Once A Day		Not Reported
	Bilastine			S	Unknown	40 Milligram, Once A Day		Not Reported
	Bisulepin Hydrochloride			C	Unknown	Unk		Not Reported
	Betamethasone			C	Topical	Unk		Not Reported
	Diprophos			C	Intramuscular	1 Milliliter, Unk		Not Reported
	Xolair			C	Unknown	Unk, Cyclical		Not Reported
	Xolair			C	Unknown	Unk, Cyclical		Not Reported
	Betamethasone Sodium Phosphate			C	Intramuscular	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16243962	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2019170636		77 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Tikosyn			S	Oral	0.25 Mg, 2x/Day		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Saliva Altered	Tikosyn		S					Pfizer
	Guaifenesin	Y	S	Oral	10 Mg, Suspension Three Times Daily As Needed			Unknown
	Guaifenesin	Y	S					Unknown
	Azithromycin		S	Oral	500 Mg, Daily (250mg Two Tablets Once Daily, Two The First Time)			Not Reported
	Azithromycin		S	Oral	250 Mg (1 Tablet), Daily			Not Reported
	Prednisone		S	Oral	20 Mg, Daily			Not Reported
	Warfarin		C		Unk			Not Reported
	Metoprolol		C		Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16759690	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019366585		53 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Squamous Cell Carcinoma Of The Oral Cavity	Enbrel			S	Subcutaneous	50 Mg, Unk (Every 15 Days) (Every Week Before 01/2015)		Pfizer
	Novatrex			S	Oral	1 Df, Weekly		Pfizer
	Humira			S	Subcutaneous	1 Df, Weekly		Not Reported
	Plaquenil			S	Oral	1 Df, Weekly		Not Reported
	Arava			S	Oral	20 Mg, 1x/Day		Not Reported
	Metobject			S	Subcutaneous	1 Df, Weekly		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16759867	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2019369440			Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S				Pfizer
	Atarax [Hydroxyzine]			S		0.5 Df, 1x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Aug-2019	16760060	NON-EXPEDITED			US-PFIZER INC-2019372635			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2019	16762460	EXPEDITED (15-DAY)		OT	GB-MICRO LABS LIMITED-ML2019-02077		89 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Levofloxacin			S				Micro Labs	
	Azithromycin			S				Not Reported	
	N-Acetylcysteine			S				Not Reported	
	Paracetamol/Codeine			S				Not Reported	
	Furosemide			S				Not Reported	
	Omeprazole			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2019	16762678	EXPEDITED (15-DAY)		OT	GB-DEXPHARM-20190699		89 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Omeprazole			S				Not Reported	
	Azithromycin			S				Not Reported	
	N Acetylcysteine			S				Not Reported	
	Furosemide			S				Not Reported	
	Levofloxacin			S				Not Reported	
	Paracetamol/Codeine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	11888202	EXPEDITED (15-DAY)		OT	JP-ASTELLAS-2010JP003369		43 YR	Female	JPN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Allergic Cough; Aphthous Ulcer; Arthritis; Back Pain; Back Pain; Dental Caries; Diarrhoea; Diarrhoea; Drug Interaction; Drug Interaction; Dry Skin; Dyspepsia; Eczema; Enterocolitis Viral; Hyperlipidaemia; Iron Deficiency Anaemia; Muscle Spasms; Nasopharyngitis; Nasopharyngitis; Oropharyngeal Pain; Pain In Extremity; Prescribed Overdose; Prescribed Underdose; Pruritus; Rash; Tibia Fracture	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Tacrolimus			S	Oral			Astellas
	Lipitor			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral			Not Reported
	Prednisolone			S	Oral	20-5mg, Alternately/2 Days		Not Reported
	Prednisolone			S	Oral	17.5-5mg, Alternately/2 Days		Not Reported
	Prednisolone			S	Oral	15-5mg, Alternately/2 Days		Not Reported
	Prednisolone			S	Oral	12.5-5mg, Alternately/2 Days		Not Reported
	Prednisolone			S	Oral	15-5mg, Alternately/2 Days		Not Reported
	Prednisolone			S	Oral	20-5mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	5-17.5mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	5-15mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	5-12.5mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	5-20mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	5-15mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	25-5mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	5-15mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral	17.5-5mg, Alternately/2days		Not Reported
	Prednisolone			S	Oral			Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Prednisolone	S	Oral		Not Reported
Flomox (Cefcapene Pivoxil Hydrochloride)	S	Oral		Not Reported
Flomox (Cefcapene Pivoxil Hydrochloride)	S	Oral		Not Reported
Flomox (Cefcapene Pivoxil Hydrochloride)	S			Not Reported
Zithromac	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Cellcept /01275102/	S	Oral		Not Reported
Gaster	C	Oral		Not Reported
Baktar	C	Oral	2 Df, Twice Per Week	Not Reported
Baktar	C	Oral	2 Df, Thrice Per Week	Not Reported
Alfarol	C	Oral	0.25 Mcg, Once Daily	Not Reported
Persantin-L	C	Oral		Not Reported
Isodine Gargle	C	Topical	Unk Unk, Unknown Freq.	Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Juvela /00110502/	C	Oral		Not Reported
Juvela /00110502/	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Lutoral	C	Oral		Not Reported
Pariet	C	Oral	10-20 Mg Per Day	Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Pariet	C	Oral		Not Reported
Fosamac	C	Oral		Not Reported
Loxonin	C	Unknown		Not Reported
Loxonin	C			Not Reported
Selbex	C	Unknown		Not Reported
Selbex	C			Not Reported
Premarin	C	Oral		Not Reported
Glakay	C	Oral		Not Reported
Mevalotin	C	Oral		Not Reported
Myser /01249201/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Myser /01249201/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Ferromia	C	Oral		Not Reported
Incremin /00023544/	C	Oral		Not Reported
Incremin /00023544/	C			Not Reported
Restamin /00000401/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Restamin /00000401/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
PI	C	Oral		Not Reported
Cocarl	C	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cocarl	C	Oral		Not Reported
Biofermin R	C	Oral		Not Reported
Lac-B	C	Oral		Not Reported
Lac-B	C	Oral		Not Reported
Lopemin /00384302/	C	Oral		Not Reported
Onon	C	Oral		Not Reported
Buscopan	C	Oral		Not Reported
Propeto	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Epadel-S	C	Oral		Not Reported
Epadel-S	C	Oral		Not Reported
Edirol	C	Oral	0.75 Mcg, Once Daily	Not Reported
Imuran /00001501/	C	Oral		Not Reported
Juvela N	C	Oral		Not Reported
Juvela N	C	Oral		Not Reported
Bredinin	C	Oral		Not Reported
Bredinin	C	Oral		Not Reported
Bredinin	C	Oral		Not Reported
Bredinin	C	Oral		Not Reported
Bredinin	C	Oral		Not Reported
Indometacin	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Zetia	C	Oral		Not Reported
Kindavate	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Hirudoid /00723701/	C	Topical	Unk Unk, Unknown Freq.	Not Reported
Rinderon-Vg	C	Topical	Unk Unk, Unknown Freq.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	15894297	EXPEDITED (15-DAY)		HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-197612		31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Spontaneous;	Azithromycin	S	Unknown	Unk	Sun
Drug Ineffective; Exposure During Pregnancy	Ceftriaxone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Sep-2019	16763484	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2936660		35 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Maternal Exposure During Pregnancy; Ventilation Perfusion Mismatch	Bupivacaine Hcl			S		1.8 MI, Unk		Pfizer
	Fentanyl Citrate			S	Unknown	10 Ug, Unk		Unknown
	Morphine Sulfate			S		100 Ug		Unknown
	Ondansetron			S	Intravenous (not otherwise specified)	4.0 Mg, Unk		Unknown
	Phenylephrine Hcl			S	Intravenous (not otherwise specified)	650 Ug, Unk		Not Reported
	Oxytocin			S	Intravenous (not otherwise specified)	Unk		Unknown
	Fluticasone			S		Unk		Not Reported
	L-Thyroxine [Levothyroxine Sodium]			S		125 Ug, 1x/Day		Not Reported
	Omeprazole			S		40 Mg, 1x/Day		Not Reported
	Pms Azithromycin			S	Respiratory (inhalation)	Unk		Not Reported
	Salbutamol			S	Respiratory (inhalation)	Unk		Not Reported
	Serevent			S	Respiratory (inhalation)	Unk		Not Reported
	Tobramycin			S	Respiratory (inhalation)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	13497607	NON-EXPEDITED			US-PFIZER INC-2017181647			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Rash; Urticaria		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16765513	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2019-057762			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16766719	NON-EXPEDITED			US-PFIZER INC- 2019374596		69 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16767270	NON-EXPEDITED			US-PFIZER INC- 2019376654		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effective For Unapproved Indication; Off Label Use	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Sep-2019	16769175	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US- 1100974			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome; Thermal Burn	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	13377251	EXPEDITED (15-DAY)		OT	AU-MYLANLABS-2017M1018422			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumothorax	Azithromycin			S		Unk		Not Reported	
	Montelukast			S				Not Reported	
	Imatinib			S	Oral	100 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16759000	EXPEDITED (15-DAY)		OT	PHHY2019KR199979		22 YR	Female	KOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Eye; Dyspnoea; Forced Expiratory Volume Decreased; Graft Versus Host Disease; Obliterative Bronchiolitis	Imatinib			S	Unknown	Unk		Novartis	
	Ciclosporin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Cellcept			C	Unknown	Unk		Not Reported	
	Hydroxychloroquine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16769817	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-2907382-00		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Hypersensitivity; Intervertebral Disc Compression; Musculoskeletal Discomfort; Musculoskeletal Pain; Spinal Cord Compression; Urticaria; Urticaria; Vertebral Foraminal Stenosis	Biaxin			S	Oral			Not Reported	
	Gabapentin			S	Unknown			Not Reported	
	Gabapentin			S	Unknown			Not Reported	
	Gabapentin			S	Unknown			Not Reported	
	Zithromax			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16769826	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2909480-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Hypersensitivity; Gait Disturbance; Inflammation; Musculoskeletal Pain; Pain In Extremity; Thyroid Cancer	Humira			S	Subcutaneous			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Tetracycline			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ceftin			S	Unknown			Not Reported	
	Ibuprofen			C				Not Reported	
	Plaquenil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16770930	NON-EXPEDITED			PHEH2019US036499			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16770973	EXPEDITED (15-DAY)		DE, LT	US-PFIZER INC-2019368520		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Clozapine			S		Unk		Not Reported	
	Lamotrigine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16771519	EXPEDITED (15-DAY)		DS, HO, LT, OT	DE-PFIZER INC-2019379910		39 YR	Male	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure; Haemoglobin Decreased; Platelet Count Decreased	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Novalgin [Metamizole Sodium]			C	Oral	Maximum 4 Grams In 2 Receipts		Not Reported
	Ibuprofen			C	Oral	Maximal 4x400 Mg/D		Not Reported
	Paracetamol			C	Oral	1g, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16772142	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019348947		77 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Blood Pressure Increased; Cold Sweat; Confusional State; Decreased Appetite; Discomfort; Drug Interaction; Fear Of Death; Hallucination, Visual; Herpes Zoster; Malaise; Mobility Decreased; Nausea; Pain; Vertigo	Novatrex			S		Unk Unk, Weekly		Pfizer
	Valaciclovir Mylan			S		2 Df, 3x/Day		Not Reported
	Tramadol			S		Unk		Not Reported
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Sep-2019	16773271	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR131478		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Bronchiectasis; Cardiac Failure Congestive; Cardiac Failure Congestive; Chronic Obstructive Pulmonary Disease; Constipation; Diastolic Dysfunction; Dyspnoea;	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline
	Azithromycin			S		250 Mg, Qd		Glaxosmithkline
	Furosemide			S		20 Mg, Qd		Glaxosmithkline
	Calcium Carbonate			S		Unk Unk, Qd		Glaxosmithkline
	Salbutamol			S		Unk Unk, Qod		Glaxosmithkline
	Zenhale			S		2 Puff(S), Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ejection Fraction	Spiriva Respimat	S	2 Puff(S), Qd	Not Reported
Abnormal; Emphysema;	Citalopram	S	20 Mg, Unk, 20mg Daily	Not Reported
Lung Hyperinflation;	Hydromorphone	S	1 Mg, Prn	Not Reported
Obstructive Airways	Xarelto	S	20 Mg, Qd	Not Reported
Disorder; Oedema	Risedronate	S	35 Mg, Z, Monthly	Not Reported
Peripheral; Oedema	Bisoprolol	S	Unk, 5 Mg Qd	Not Reported
Peripheral; Oxygen	Atorvastatin	S	20 Mg, Qd	Not Reported
Saturation Abnormal;	Amlodipine	S	5 Mg, Qd	Not Reported
Productive Cough;	Docusate	S	100 Mg, Prn	Not Reported
Pulmonary Embolism;	Lasix	C	Unk	Not Reported
Respiratory Failure;				
Sputum Discoloured;				
Therapeutic Product Effect				
Incomplete; Ventricular				
Dysfunction; Ventricular				
Hypokinesia; Wheezing				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	14807692	EXPEDITED (15-DAY)		OT	AU-009507513-1804AUS009995			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For	Montelukast Sodium			S	Oral			Merck
Unapproved Indication;	Azithromycin			S				Not Reported
Graft Versus Host	Corticosteroids (Unspecified)			S				Not Reported
Disease; Pneumothorax;	Glivec			S	Oral	100 Mg, Qd		Not Reported
Product Use In								
Unapproved Indication;								
Subcutaneous								
Emphysema								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16334388	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2019PL112722		30 YR	Female	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Bone	Montelukast Sodium			S	Oral	Unk		Novartis
Neoplasm;	Montelukast Sodium			S				Novartis
Bronchopulmonary	Montelukast Sodium			S				Novartis
Aspergillosis; Death;	Azithromycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Device Related Infection;	Cytarabine	S	Unknown	Unk	Not Reported
Disease Progression;	Mitoxantrone	S	Unknown	Unk	Not Reported
Drug Ineffective;	Methylprednisolone	S	Unknown	2 Mg/Kg, Unk	Not Reported
Enterococcal Infection;	Methylprednisolone	S	Unknown	Unk	Not Reported
Graft Versus Host Disease	Daunorubicin	S	Unknown	Unk	Not Reported
In Gastrointestinal Tract;	Cladribine	S	Unknown	Unk	Not Reported
Graft Versus Host Disease	Voriconazole	C	Unknown	Unk	Not Reported
In Lung; Mucosal Toxicity;	Treosulfan	C	Unknown	Unk	Not Reported
Neutropenia; Product Use	Busulfan	C	Unknown	Unk	Not Reported
In Unapproved Indication;	Cyclophosphamide	C	Unknown	Unk	Not Reported
Pyrexia;	Fluconazole	C	Unknown	Unk	Not Reported
Stenotrophomonas	Amphotericinum B	C	Unknown	Unk	Not Reported
Infection	Posaconazole	C	Unknown	Unk	Not Reported
	Azacitidine	C	Unknown	Unk	Not Reported
	Tacrolimus	C	Unknown	Unk	Not Reported
	Fludarabine	C	Unknown	Unk	Not Reported
	Fluticasone	C	Unknown	Unk	Not Reported
	Fluticasone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16584899	EXPEDITED (15-DAY)		HO, OT	PHHY2019DO163448		5 YR	Female	DOM

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arterial Disorder;	Exjade			S	Unknown	500 Mg, Unk (From Monday To Thursday)		Novartis
Haemoglobin Decreased;	Exjade			S	Oral	500 Mg, 15mg / Kg / Day, 4 Tablets Weekly		Novartis
Inappropriate Schedule Of Product Administration;	Azithromycin			S	Unknown			Not Reported
Platelet Count Increased;	Amoxicillin			C	Unknown	250 Mg, Qd		Not Reported
Pneumonia Influenzal;	Hydroxyurea			C	Unknown	500 Mg, Unk (From Mondat Yo Thursday)		Not Reported
Pyrexia; Respiratory Tract Infection; Respiratory Tract Infection Viral;								
Serum Ferritin Increased								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Folic Acid	C	Unknown	(Satrted 8 Months Ago) 2.5 Ot, Unk (2.5 Cc) (Since Patient Was 5 Months Old)	Not Reported
Folic Acid	C	Unknown	5 Ug, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16755409	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-APOTEX- 2019AP021067		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Apotex	
	Lamotrigine			S	Unknown	Unk		Apotex	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Clozapine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16775909	NON-EXPEDITED			US-PFIZER INC- 2019382767		12 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16776132	NON-EXPEDITED			US-PFIZER INC- 2019382436		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Gabapentin			S		Unk		Pfizer	
	Hydroxyzine Pamoate			S		Unk		Pfizer	
	Metronidazole			S		Unk		Pfizer	
	Sulfasalazine			S		Unk		Pfizer	
	Verapamil Hcl			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ziprasidone Hcl	S	Unk	Pfizer
	Azithromycin	S	Unk	Pfizer
	Clindamycin	S	Unk	Pfizer
	Effexor Xr	S	Unk	Pfizer
	Morphine Sulfate	S	Unk	Unknown
	Pregabalin	S	Unk	Pfizer
	Sertraline Hcl	S	Unk	Pfizer
	Voriconazole	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Sep-2019	16776151	NON-EXPEDITED			US-PFIZER INC-2019384725		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	14559554	NON-EXPEDITED			US-PFIZER INC-2018074850		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16778690	NON-EXPEDITED		OT	US-STRIDES ARCOLAB LIMITED-2018SP008021			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication;	Tacrolimus			S	Unknown	Unk		Strides	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmonary Nocardiosis	Tacrolimus	S	Unknown	Unk	Strides
	Tacrolimus	S	Unknown	Unk	Strides
	Prednisolone	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Atovaquone	C	Unknown	1500 Mg Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16779351	NON-EXPEDITED			US-PFIZER INC-2019383404		39 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16780766	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-ALEMBIC PHARMACUETICALS LIMITED-2019SCAL000607			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Lamotrigine			S		Unk		Alembic
	Amoxicillin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Clozapine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16782074	EXPEDITED (15-DAY)		OT	PHHY2019CA205260			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Xolair			S	Subcutaneous	150 Mg, Unk		Not Reported
	Xolair			S	Subcutaneous	150 Mg, Unk		Not Reported
	Alendronate			S	Oral	35 Mg, Unk		Not Reported
	Alendronate			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	250 Mg, Unk	Novartis
Azithromycin	S			Novartis
Ventolin	S	Unknown	8 Df, Unk	Not Reported
Calcium Carbonate	C	Unknown	Unk	Not Reported
Ciclesonide	C	Unknown	Unk	Not Reported
Montelukast	C	Unknown	Unk	Not Reported
Spiriva	C	Unknown	Unk	Not Reported
Symbicort	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Sep-2019	16782156	EXPEDITED (15-DAY)		DE	PHHY2019US206778		27 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acanthamoeba Infection; Drug Ineffective For Unapproved Indication	Fluconazole			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Novartis
	Miltefosine			S	Unknown	Unk		Not Reported
	Pentamidine			S	Unknown	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported
	Flucytosine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16784950	EXPEDITED (15-DAY)		DS, HO, LT, OT	DE-TEVA-2019-DE-1103273		39 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Hepatic Failure	Azithromycin			S	Oral	250 Mg		Not Reported
	Novalgine Tropfen			C	Oral	Maximum 4 Grams In 2 Receipts		Not Reported
	Ibuprofen			C	Oral	Maximal 4x400 Mg/D		Not Reported
	Paracetamol			C	Oral	1 Gram		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16785830	NON-EXPEDITED			US-PFIZER INC-2019388944			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Cefuroxime			S		Unk		Unknown	
	Hydromorphone Hydrochloride			S		Unk		Unknown	
	Clarithromycin			S		Unk		Not Reported	
	Progesterone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16786114	EXPEDITED (15-DAY)		OT	AU-EPIC PHARMA LLC-2019EPC00237		64 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Glucose Increased; Cyanosis; Electrocardiogram Qt Prolonged; Hypotension; Oxygen Saturation Decreased; Tachypnoea; Unresponsive To Stimuli	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg		Epic Pharm	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 G		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16786134	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019386679			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Sep-2019	16786246	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019383688		22 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Urticaria; Urticaria	Zitromax			S		1 Df, Single		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	13054901	NON-EXPEDITED			US-PFIZER INC-2016577895		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	15858437	NON-EXPEDITED			US-PFIZER INC-2019029554		37 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Methocarbamol			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Ceclor			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16734045	EXPEDITED (15-DAY)		DE, LT, OT	PL-ACCORD-152775		30 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Neoplasm; Bronchopulmonary Aspergillosis; Device Related Infection; Disease	Montelukast			S	Oral			Not Reported	
	Methylprednisolone			S	Unknown			Not Reported	
	Azithromycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Progression; Drug	Fluticasone	C				Not Reported
Ineffective; Graft Versus	Cytarabine/Cytarabine	C		Unk		Not Reported
Host Disease In	Hydrochloride/Cytarabine					
Gastrointestinal Tract;	Ocfosfate					
Graft Versus Host Disease	Mitoxantrone	C		Unk		Not Reported
In Lung; Off Label Use;	Tacrolimus	C		Unk		Not Reported
Stenotrophomonas	Posaconazole	C		Unk		Not Reported
Infection	Cyclophosphamide/Cyclophosph	C		Unk		Not Reported
	amide Monohydrate					
	Voriconazole	C		Unk		Not Reported
	Amphotericin B/Amphotericin	C		Unk		Not Reported
	B/Liposome					
	Fludarabine	C		Unk		Not Reported
	Daunorubicin	C		Unk		Not Reported
	Cladribine	C		Unk		Not Reported
	Azacitidine	C		Unk		Not Reported
	Fluconazole	C		Unk		Not Reported
	Treosulfan	C		Unk		Not Reported
	Busulfan	C		Unk		Not Reported
	Montelukast	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16789226	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-219334		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown			Sun	
	Clindamycin			S	Unknown			Sun	
	Sulphamethoxazole/Trimethopri m			S	Unknown			Mutual	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16789843	EXPEDITED (15-DAY)		HO, LT, OT	AU-LUPIN		64 YR	Male	AUS

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

PHARMACEUTICALS
INC.-2019-05712

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Glucose Increased; Coma Scale Abnormal; Cyanosis; Electrocardiogram Qt Prolonged; Feeling Hot; Flushing; Hyperhidrosis; Hypotension; Liver Function Test Abnormal; Nausea; Tachypnoea; Unresponsive To Stimuli	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Lupin
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790278	EXPEDITED (15-DAY)		OT	PHHY2019US208559			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Low Birth Weight Baby	Azithromycin			S	Transplacental	Unk		Novartis
	Metronidazole			S	Transplacental	Unk		Not Reported
	Amoxicillin			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790429	NON-EXPEDITED			US-PFIZER INC-2019389158		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling; Urticaria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790678	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019389322		5 YR	Male	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Hypersensitivity; Product Use Issue; Urticaria	Zithromax			S	Intravenous drip	0.18 G, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Vitamin B6			C	Intravenous drip	0.1 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790760	NON-EXPEDITED			US-PFIZER INC-2019390809		10 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16790978	EXPEDITED (15-DAY)		HO	ES-MYLANLABS-2019M1083801		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coagulopathy; Hepatitis; Hyperbilirubinaemia	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Pazital			C	Oral	Unk		Mylan	
	Loratadina			C	Oral	Unk		Mylan	
	Algidol /00109201/			C	Oral	1 Dosage Form, Q8h		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16791002	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019387767		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Intervertebral Disc Compression; Musculoskeletal Discomfort; Musculoskeletal Pain; Spinal Cord Compression;	Zithromax			S		300 Mg, Unk		Pfizer	
	Gabapentin			S		1100 Mg, 3x/Day (Evrey 8 Hours)		Pfizer	
	Biaxin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urticaria; Vertebral
Foraminal Stenosis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Sep-2019	16791345	EXPEDITED (15-DAY)		HO, LT, OT	AU-MYLANLABS- 2019M1084949		64 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cyanosis; Electrocardiogram Qt Prolonged; Hypotension; Liver Function Test Abnormal; Tachypnoea	Azithromycin			S	Intravenous drip			Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16628712	NON-EXPEDITED			US-PFIZER INC- 2019316546			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Fosamax			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16791943	EXPEDITED (15-DAY)		OT	GB-JNJFOC- 20190901346		89 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Acetylcysteine			S	Unknown			Not Reported	
	Paracetamol/Codeine Phosphate			S	Unknown			Not Reported	
	Azitromycin			S	Unknown			Not Reported	
	Omeprazole			S	Unknown			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16794607	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2019M1084934		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Fluconazole			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Miltefosine			S	Unknown			Mylan	
	Flucytosine			S	Unknown			Mylan	
	Pentamidine			S	Unknown			Mylan	
	Sulfadiazine			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16794615	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2019M1084641		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
	Piperacillin/Tazobactam			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16794739	EXPEDITED (15-DAY)		HO, OT	PHHY2019FR206899		39 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Chlorhexidine+Chlorobutanol			S	Buccal	Unk Unk, Qd (Frequency-2 To 4 Time Daily)		Not Reported	
	Amoxicillin Trihydrate +Potassium Clavulanate			S	Oral	3 Df, Qd (3 Df,Qd; Dose:3 Unit(S))		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fluconazole	S	Oral	2 Df, Qd	Not Reported
Azithromycin	S	Oral	2 Df, Qd	Not Reported
Helicidine	S	Oral	3 Df, Qd	Not Reported
Biclotymol	S	Buccal	4 Df, Qd	Not Reported
Rulid	S	Oral	300 Mg, Qd	Not Reported
Prednisolone Metasulfobenzoate Sodium	S	Oral	60 Mg,Qd	Not Reported
Prednisolone Metasulfobenzoate Sodium	S	Oral	Unk	Not Reported
Exomuc	C	Unknown	Unk	Not Reported
Toplexil (Oxomemazine)	C	Unknown	Unk	Not Reported
Surgam	C	Unknown	Unk	Not Reported
Trimebutine	C	Unknown	Unk	Not Reported
Thalidomide	C	Unknown	Unk	Not Reported
Doliprane	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16795029	NON-EXPEDITED			US-PFIZER INC-2019391920		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16795593	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2074311		67 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Parosmia	Azithromycin			S	Oral			Wockhardt	
	Atorvastatin			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796051	EXPEDITED (15-DAY)		DE	US-FRESENIUS KABI-FK201909889		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Pentamidine Injection (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care	
	Pentamidine Injection (Manufacturer Unknown)			S				Fresenius Medical Care	
	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care	
	Azithromycin (Manufacturer Unknown)			S				Fresenius Medical Care	
	Fluconazole (Manufacturer Unknown)			S	Unknown	Unknown		Not Reported	
	Fluconazole (Manufacturer Unknown)			S				Not Reported	
	Flucytosine			S	Unknown	Unknown		Not Reported	
	Flucytosine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Sep-2019	16796308	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019AMR127742			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Salbutamol Sulphate			S		Unk		Glaxosmithkline	
	Advair			S		Unk		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Atrovent			S		Unk		Not Reported	
	Prednisone			S		10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	15439032	NON-EXPEDITED		OT	US-PFIZER INC-2018391053		57 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16483600	NON-EXPEDITED			US-PFIZER INC- 2019275796		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16768112	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US- 1102374		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Musculoskeletal Disorder; Mycobacterium Avium Complex Infection; Treatment Failure	Methotrexate			S	Unknown			Barr	
	Amikacin			S	Intravenous (not otherwise specified)			Teva	
	Azathioprine			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Ethambutol			S	Oral			Not Reported	
	Rituximab			S	Unknown			Not Reported	
	Rifabutin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16770860	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US- 1102373		23 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Musculoskeletal Disorder; Mycobacterial Infection; Nausea; Pyrexia; Renal Injury; Toxicity To Various Agents; Treatment Failure;	Hydroxychloroquine			S	Unknown			Teva	
	Mycophenolate Mofetil			S	Unknown			Teva	
	Amikacin			S	Intravenous (not otherwise specified)			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting	Amikacin	S	Unknown	Amikacin Containing Spacer	Teva
	Tigecycline	S	Intravenous (not otherwise specified)		Not Reported
	Tigecycline	S			Not Reported
	Clofazimine	S	Unknown		Not Reported
	Clofazimine	S			Not Reported
	Cefoxitin	S	Intravenous (not otherwise specified)		Not Reported
	Cefoxitin	S			Not Reported
	Linezolid	S	Intravenous (not otherwise specified)		Not Reported
	Linezolid	S	Oral		Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)		Not Reported
	Azithromycin	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16774708	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-057654		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased;	Atorvastatin Tablets			S	Unknown	Unk		Not Reported	
Coccydynia; Contusion;	Azithromycin			S	Unknown	Unk		Aurobindo	
Crying; Discomfort;	Montelukast			S	Unknown	Unk		Aurobindo	
Dizziness Exertional; Dry Skin; Dyspnoea;	Pantoprazole			S	Unknown	Unk		Aurobindo	
Dyspnoea Exertional; Ear Pain; Emotional Disorder;	Fentanyl			S	Unknown	Unk		Not Reported	
Fall; Fatigue; Feeling Abnormal; Headache;	Omalizumab			S	Subcutaneous	375 Milligram, Every 2 Weeks		Not Reported	
Heart Rate Increased;	Azithromycin Sandoz			S	Unknown	Unk		Not Reported	
Myalgia; Nausea; Oxygen Saturation Decreased;	Fentanyl Sandoz			S	Unknown	Unk		Not Reported	
Pain In Extremity;	Montelukast Sandoz			S	Unknown	Unk		Not Reported	
Respiratory Rate	Pantoprazole Sandoz			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Scratch; Vision Blurred	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	375 Milligram, 1 Every 2 Weeks	Not Reported
	Advair	C	Unknown	Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Spiriva	C	Unknown	Unk	Not Reported
	Ventolin	C	Intracardiac	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16790655	NON-EXPEDITED			US-PFIZER INC-2019391080		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16797741	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1104790			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Acetaminophene			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Actavis	
	Amoxicillin Trihydrate			S	Unknown			Teva	
	Atorvastatin			S	Unknown			Teva	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
	Betamethasone Dipropionate			S	Unknown			Actavis	
	Bisacodyl			S	Unknown			Not Reported	
	Clarithromycin			S	Unknown			Actavis	
	Diphenhydramine			S	Unknown			Barr	
	Metronidazole			S	Unknown			Actavis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nadolol	S	Unknown	Not Reported
Nicotine Polacrilex	S	Unknown	Actavis
Pantoprazole	S	Unknown	Teva
Prednisone	S	Unknown	Actavis
Pregabalin	S	Unknown	Teva
Sulfamethoxazole W/Trimethoprim	S	Unknown	Actavis
Sulfamethoxazole W/Trimethoprim	S	Unknown	Actavis
Apo Hydro	S	Unknown	Not Reported
Avamys	S	Unknown	Not Reported
Bactroban	S	Unknown	Not Reported
Betaderm	S	Unknown	Not Reported
Biaxin XI	S	Unknown	Not Reported
Calcium Carbonate/Magnesium Sulfate/Vitamin D3	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Cupric Oxide/DI-Alpha Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
Entocort	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Glycerine	S	Unknown	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown	Not Reported
Habitrol	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Kenalog	S	Unknown	Not Reported
	Lomotil	S	Oral	Not Reported
	Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride/Sodium Sulfate	S	Unknown	Not Reported
	Ms Ir	S	Unknown	Not Reported
	Mupirocin	S	Unknown	Not Reported
	Nicoderm	S	Unknown	Not Reported
	Pentasa	S	Unknown	Not Reported
	Pulmicort	S	Unknown	Not Reported
	Refresh Tears	S	Unknown	Not Reported
	Salinex [Sodium Chloride]	S	Unknown	Not Reported
	Sinus Rinse	S	Unknown	Not Reported
	Statex (Morphine Sulfate)	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Vitamin D3	S	Unknown	Not Reported
	Valsartan	C		Not Reported
	Calcium Carbonate/Vitamin D3	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16797963	NON-EXPEDITED			US-APOTEX-2019AP021173		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Vomiting	Azithromycin			S	Oral	1 G, Unk		Apotex
	Ceftriaxone			C	Intramuscular	1 G, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16798543	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1085080			Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment Failure	Azithromycin	S	Unknown	2 Gram	Not Reported
	Gentamicin	S	Unknown	240 Milligram	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799045	NON-EXPEDITED			US-ICU MEDICAL, INC.- ICU2019US00027			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Morphine Sulfate Injection			S	Intravenous (not otherwise specified)			Icu Medical
	0.25% Acetic Acid Irrigation			S	Unknown			Icu Medical
	Erythromycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Premarin			S	Vaginal	0.5 Gram Every Week		Not Reported
	Phenobarbital			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799127	NON-EXPEDITED			US-PFIZER INC- 2019393359		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pruritus; Rash	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799242	NON-EXPEDITED			US-PFIZER INC- 2019395130		54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Yellow Skin	Gabapentin			S	Oral	300 Mg, 1 Capsule Two Times Daily		Pfizer
	Atorvastatin Calcium			S	Oral	40 Mg, 1 Tablet At Bedtime		Pfizer
	Atorvastatin Calcium			S	Oral	80 Mg, 1 Tablet At Bedtime		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax		S		500 Mg, (2 Tablets Of 250 Mg) Today		Pfizer			
Zithromax		S		250 Mg, 1 Tablet Daily		Pfizer			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16799408	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019387542			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Bilirubin Increased; Diarrhoea; Feeling Abnormal; Gallbladder Disorder; Liver Disorder; Muscle Spasms; Nausea	Zithromac 250mg			S		250 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16801791	EXPEDITED (15-DAY)		DE, HO	CA-TEVA-2019-CA-1072339		19 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Metabolic Acidosis; Overdose; Toxicity To Various Agents	Azithromycin			S	Oral			Not Reported	
	Acetaminophen/Codeine Phosphate			S	Oral			Actavis	
	Amitriptyline			S	Oral			Not Reported	
	Caffeine			S	Oral			Not Reported	
	Caffeine			S	Oral			Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Codeine			S	Oral			Not Reported	
	Aerius (Desloratadine)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802768	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-058907		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amnesia; Asthma; Chest Discomfort; Cough; Depressed Mood; Dyspnoea; Insomnia; Laboratory Test Abnormal; Lower Respiratory Tract Infection; Productive Cough; Respiratory Tract Congestion; Sputum Discoloured; Wheezing	Azithromycin	S	Unknown	Unk	Aurobindo
	Montelukast	S	Unknown	Unk	Aurobindo
	Atrovent	S	Unknown	Unk	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Prednisone	S	Unknown	50.0 Milligram	Not Reported
	Prednisone	S	Unknown	10.0 Milligram, Daily	Not Reported
	Pulmicort	S	Unknown	2.0 Dosage Form, Two Times A Day	Not Reported
	Theophylline	S	Unknown	600.0 Milligram	Not Reported
	Ventolin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Sep-2019	16802769	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-058992		76 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bladder Discomfort; Blood Pressure Increased; Hot Flush; Urinary Tract Infection	Azithromycin			S	Unknown	250.0 Milligram		Aurobindo
	Montelukast			S	Unknown	1.0 Dosage Form, Daily		Aurobindo
	Tamsulosin Hydrochloride			S	Oral	1.0 Dosage Form, Daily		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	Unk	Not Reported
Xolair	S	Subcutaneous	300.0 Milligram	Not Reported
Prednisone	C	Oral	1.0 Dosage Form, Two Times A Day	Not Reported
Spiriva	C	Unknown	1.0 Dosage Form, Daily	Not Reported
Symbicort	C	Unknown	6.0 Dosage Form, Daily	Not Reported
Ventolin	C	Unknown	6.0 Dosage Form, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16215741	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039425		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Acyclovir			S	Transplacental			Teva
	Azithromycin			S	Transplacental			Not Reported
	Tenofovir			S	Transdermal			Teva
	Bactrim			S	Transplacental			Not Reported
	Intelence			S	Transplacental			Not Reported
	Lamivudine			S	Transplacental			Not Reported
	Prezista			S	Transplacental			Not Reported
	Raltegravir Potassium			S	Transplacental			Not Reported
	Ritonavir			S	Transplacental			Not Reported
	Zidovudine			S	Transplacental			Not Reported
	Abacavir			C	Transplacental			Not Reported
	Calcium			C				Not Reported
	Dpantothenate/Ergocalciferol/Nicotinamide/Pyridoxinehydrochlor							
	Folic Acid			C				Not Reported
	Iron			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Magnesium Gluconate			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16541605	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1072336		19 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Azithromycin			S	Unknown	2 Dosage Forms Daily;		Not Reported	
	Acyclovir			S	Unknown			Teva	
	Tenofovir			S	Unknown	300 Milligram Daily;		Teva	
	Abacavir			S	Unknown	600 Milligram Daily;		Not Reported	
	Bactrim			S	Unknown	800 Milligram Daily;		Not Reported	
	Intelence			S	Unknown	400 Milligram Daily;		Not Reported	
	Isentress			S	Oral	800 Milligram Daily;		Not Reported	
	Lamivudine			S	Unknown	300 Milligram Daily;		Not Reported	
	Prezista			S	Oral	1200 Milligram Daily;		Not Reported	
	Ritonavir			S	Unknown	200 Milligram Daily;		Not Reported	
	Zidovudine			S	Unknown	600 Milligram Daily;		Not Reported	
	Folic Acid			C	Unknown			Not Reported	
	Iron			C	Unknown			Not Reported	
	Magnesium Gluconate			C	Oral			Not Reported	
	Vitamins Nos			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16763770	EXPEDITED (15-DAY)		DE, LT	US-PFIZER INC-2019373017		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	250 Mg, Daily		Pfizer	
	Methylprednisolone Sodium Succinate			S				Pfizer	
	Methylprednisolone Sodium			S				Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Succinate Vancomycin Hcl	S	Unk	Pfizer
Vancomycin Hcl	S		Pfizer
Vancomycin Hcl	S		Pfizer
Piperacillin/Tazobactam	S	Unk	Unknown
Piperacillin/Tazobactam	S		Unknown
Piperacillin/Tazobactam	S		Unknown
Azithromycin	S	Unk	Pfizer
Azithromycin	S		Pfizer
Azithromycin	S		Pfizer
Oseltamivir	S	Unk	Not Reported
Oseltamivir	S		Not Reported
Oseltamivir	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16804797	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019373970		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Intolerance; Vomiting	Azithromycin			S	Oral	1 G, Unk		Pfizer
	Azithromycin			S				Pfizer
	Ceftriaxone			C	Intramuscular	1 G, Unk		Not Reported
	Ceftriaxone			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Trimethoprim Sulfamethoxazole			C		Unk, 2x/Day (160-800 Mg)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16804798	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019374803		83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia	Zithromax			S	Oral	Unk		Pfizer
	Entospletinib			S	Oral	200 Mg, Bid		Not Reported
	Entospletinib			S	Oral	200 Mg, Bid		Not Reported
	Entospletinib			S	Oral	200 Mg, Bid		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rocephin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Potassium Chloride	C			Not Reported
Atenolol	C			Not Reported
Potassium Bicarbonate/Citric Acid	C			Not Reported
Azithromycin	C			Not Reported
Albuterol Sulfate;Ipratropium Bromide	C			Not Reported
Calcium Gluconate And Sodium Chloride	C			Not Reported
Magnesium Sulfate	C			Not Reported
Dextrose In Water	C			Not Reported
Sodium Biphosphate	C			Not Reported
Apixaban	C			Not Reported
Phosphorus	C			Not Reported
Potassium Phosphates	C			Not Reported
Simvastatin	C		Unk	Not Reported
Hydralazine Hydrochloride	C			Not Reported
Rivastigmine	C			Not Reported
Tamsulosin	C			Not Reported
Coumadin	C			Not Reported
Doxepin	C		Unk	Not Reported
Exelon [Rivastigmine]	C		Unk	Not Reported
Prednisone	C		Unk	Not Reported
Eliouis	C		Unk	Not Reported
Z-Pak	C		Unk	Not Reported
Metoprolol Tartrate	C		Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	C		Unk	Not Reported
Aspirin [Acetylsalicylic Acid]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16805005	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019396824		71 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Erythema; Hypersensitivity	Zitromax		S	Oral	1 Df, 1x/Day		Pfizer		
	Zitromax		S				Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16805029	NON-EXPEDITED			US-PFIZER INC-2019396344		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Dilaudid			S		Unk		Not Reported	
	Gluten			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Zithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16806115	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019160512			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia; Breath Sounds Abnormal; Bronchitis; Conjunctivitis; Cough; Dysphonia; Eye Swelling; Inappropriate Schedule Of Product Administration; Product Dose Omission; Productive Cough; Wheezing; Wrong Technique In Device Usage Process	Anoro Ellipta Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), Qd		Glaxosmithkline	
	Trelegy Ellipta Inhalation Powder			S	Respiratory (inhalation)	1 Puff(S), (100/62.5/25 Mcg) Qd		Glaxosmithkline	
	Clindamycin			S	Unknown	Unk		Glaxosmithkline	
	Prednisone			S	Unknown	Unk		Not Reported	
	Z Pak			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2019	16806143	EXPEDITED (15-DAY)		OT	CN-BAXTER-2019BAX017794		3 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Eruption	Metronidazole And Sodium Chloride Injection	S	Intravenous (not otherwise specified)		Baxter	
	Azithromycin	S	Oral	Enteric-Coated Capsules	Not Reported	
	Azithromycin	S	Oral	Enteric-Coated Capsules	Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16807352	NON-EXPEDITED			PHEH2019US036842			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Nausea	Azithromycin			S	Unknown			Novartis
	Xanax			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16974453	DIRECT	N	HO, LT, OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Iatrogenic Injury; Stevens-Johnson Syndrome	Azithromycin 250 Mg			S				Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Sep-2019	16974618	DIRECT		HO, LT, OT			52 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Stevens-Johnson Syndrome	Azithromycin Tablets Usp 250mg			S	Oral	Quantity:2 Tablets;Other Frequency:Day 1 2tabs,Day 1;	7 DAY	Teva

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Sep-2019	16722295	EXPEDITED (15-DAY)		DE	US-TEVA-2019-US-1093616			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Clostridium Difficile	Azithromycin			S	Unknown			Teva

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection		Ceftriaxone		S	Unknown		Teva		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16808420	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1108412		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Photodermatosis; Solar Lentigo; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Atorvastatin			S	Oral			Teva	
	Azithromycin			S	Oral			Not Reported	
	Lansoprazole			S	Oral			Teva	
	Mycophenolate Mofetil			S	Oral			Teva	
	Pantoprazole			S	Oral			Teva	
	Prednisone			S	Oral			Actavis	
	Sulfamethoxazole And Trimethoprim			S	Oral			Actavis	
	Voriconazole			S	Oral			Teva	
	Tacrolimus			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16809247	EXPEDITED (15-DAY)		DE	PHHY2019US214126		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Clozapine			S	Unknown	Unk		Not Reported	
	Amoxicillin			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Lamotrigine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16810339	NON-EXPEDITED			US-PFIZER INC-2019398118		7 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16810615	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1085595		6 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Ecchymosis; Petechiae	Azithromycin			S	Oral	300 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Sep-2019	16810938	EXPEDITED (15-DAY)		DE, HO	US-MYLANLABS-2019M1087250		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Azithromycin			S	Unknown				Not Reported
	Clozapine			S	Unknown				Not Reported
	Lamotrigine			S	Unknown				Not Reported
	Amoxicillin			S	Unknown				Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	13993046	NON-EXPEDITED			US-PFIZER INC-2017403236		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Ibuprofen			S		Unk			Pfizer
	Morphine Sulfate			S		Unk			Unknown
	Zithromax			S		Unk			Pfizer
	Dilaudid			S		Unk			Not Reported
	Aleve			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16326525	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-BAXTER-2019BAX009687		61 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)			Baxter
	Amiodarone Hydrochloride			S	Unknown			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Diltiazem Hydrochloride			S	Oral			Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)			Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	Dosage Form: Not Specified		Not Reported
	Doxorubicin Hydrochloride			S	Intravenous (not otherwise specified)			Not Reported
	Doxorubicin Hydrochloride			S	Intravenous (not otherwise specified)	Dosage Form: Solution Intravenous		Not Reported
	Enoxaparin Sodium			S	Subcutaneous			Not Reported
	Furosemide			S	Oral	Dosage Form: Not Specified		Not Reported
	Hydralazine			S	Intravenous (not otherwise specified)			Not Reported
	Hydralazine			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorphone Hydrochloride	S	otherwise specified)		Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	Dosage Form: Not Specified	Not Reported
Metoprolol Tartrate	S	Intravenous (not otherwise specified)		Not Reported
Metoprolol Tartrate	S	Intravenous (not otherwise specified)		Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)		Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)		Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)		Not Reported
Trastuzumab	S	Unknown		Not Reported
Pms-Azithromycin	S	Intravenous (not otherwise specified)	Dosage Form: Not Specified	Not Reported
Aprepitant	C	Oral		Not Reported
Dexamethasone	C	Oral		Not Reported
Filgrastim	C	Subcutaneous		Not Reported
Gabapentin	C	Oral		Not Reported
Metoclopramide	C	Unknown		Not Reported
Metoclopramide	C	Oral		Not Reported
Ondansetron	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16611434	NON-EXPEDITED			US-PFIZER INC-2019310880		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16770743	EXPEDITED (15-DAY)		DS	FR-TEVA-2019-FR-1102841		40 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Dry Eye; Eye Pain; Eye Paraesthesia; Headache; Insomnia; Ocular Discomfort; Palpitations; Somnolence	Azithromycine Teva 250 Mg Imurel			S C	Unknown			Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16801655	NON-EXPEDITED			US-PFIZER INC-2019395101			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin Erythromycin Base			S S		Unk Unk		Pfizer Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16804685	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2019375028		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin Fluconazole Flucytosine Miltefosine Pentamidine Sulphadiazine [Sulfadiazine]			S S S S S S		Unk Unk Unk Unk Unk Unk		Pfizer Pfizer Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16813650	NON-EXPEDITED			FR-BEH-2019106289		58 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia	Privigen			S	Intravenous drip	30 Gram, Qd		Csl Behring
	Zithromax			S	Oral	2 Dosage Form, Qw		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16817235	EXPEDITED (15-DAY)		OT	NL-TEVA-2019-NL-1106354		6 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Neurosensory	Azitromycine (Azithromycin)			S		1dd 250mg		Not Reported
	Nutrini Creamy Fruit Multi Fibre - Diverse Smaken			C		3xdd		Not Reported
	Fresubin Drink Jucy - Diverse Smaken			C		1xdd		Not Reported
	Fantomalt			C		50 Gram, 1xdd		Not Reported
	Tigecycline			C		2dd 26 Mg		Not Reported
	Granisetron Tablet, 1 Mg			C		2xdd		Not Reported
	Omeprazol Tablet, 20 Mg			C		1xdd		Not Reported
	Imipenem/Cilastatine (500/500 Mg In 0.9% Nacl Infuus)			C		2dd 750/750 Mg (Voorheen 3dd 450/450 Mg)		Not Reported
	Clofazimine Capsule (Import)			C		50 Mg, 1xdd		Not Reported
	Salbutamol Aerosol 100mcg/Dosis			C		100 Mcg, Zn 4xdd		Not Reported
	Salmeterol/Fluticason Aerosol 25/250mcg/Dosis			C		1 Dose, 2xdd		Not Reported
	Mometason Neusspray 50mcg/Dosis			C		1 Dose, 1xdd		Not Reported
	Aprepitant Capsule, 80 Mg			C		1x Dd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16817440	NON-EXPEDITED			US-PFIZER INC-2019398907		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Doxycycline Hyclate	S	Unk	Pfizer
	Z-Pak	S	Unk	Not Reported
	Cimzia	S	Unk	Not Reported
	Percocet [Oxycodone Hydrochloride; Oxycodone Terephthalate; Paracetamol]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16817473	NON-EXPEDITED			US-PFIZER INC-2019399295		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16818675	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR165360			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Therapeutic Product Effect Incomplete	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline	
	Singulair			S		10 Mg, Qd		Glaxosmithkline	
	Azithromycin			S		250 Mg, Qd		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline	
	Zenhale			S		2 Puff(S), Tid		Not Reported	
	Spiriva-Respimat			S		2 Puff(S), Qd, 2.5mcg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16818798	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1108604		80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
	Oseltamivir			S	Unknown			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Piperacillin /Tazobactam	S	Unknown					Not Reported	
	Vancomycin	S	Unknown					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16818960	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1086838		47 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Laryngeal Oedema	Azithromycin			S	Oral	500 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16819000	NON-EXPEDITED			US-PFIZER INC-2019400927			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Sep-2019	16819354	EXPEDITED (15-DAY)		HO, LT, OT	DE-MYLANLABS-2019M1087537		49 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Hepatic Failure;	Paracetamol			S		Unk			Not Reported
Acute Kidney Injury;	Azithromycin			S	Oral	Unk			Not Reported
Blister; Drug Interaction;	Azithromycin			S					Not Reported
Livedo Reticularis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	15472937	NON-EXPEDITED			US-PFIZER INC-2018401696			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk			Pfizer
	Zithromax			S		Unk			Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Niaspan			S			Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16141371	NON-EXPEDITED			US-PFIZER INC-2019136586		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cefuroxime Axetil			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16497761	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR109340		78 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arteriosclerosis	Shingrix			S				Glaxosmithkline	
Coronary Artery; Back	Fluarix Quadrivalent 2017/2018			S				Glaxosmithkline	
Pain; Bradycardia;	Pneumococcal Vaccine			S				Glaxosmithkline	
Bronchitis; Cardiac Failure	Trelegy Ellipta			S		Unk		Glaxosmithkline	
Congestive; Chronic	Ceftriaxone			S		Unk		Glaxosmithkline	
Obstructive Pulmonary	Amoxicillin			S		Unk		Glaxosmithkline	
Disease; Coronary Artery	Azithromycine			S		Unk		Glaxosmithkline	
Disease; Cough;	Zoster VzV-Ge-As01b			S				Not Reported	
Diarrhoea; Dyslipidaemia;									
Dyspnoea Exertional;									
Epigastric Discomfort;									
Faeces Discoloured;									
Haemoglobin Decreased;									
Hip Arthroplasty;									
Hypercholesterolaemia;									
Hypertension;									
Intervertebral Disc									
Degeneration; Lung									
Disorder; Macule;									
Melaena; Oedema									
Peripheral; Osteoarthritis;									
Pneumonia; Pulmonary									
Fibrosis; Pulmonary Mass;									
Pulmonary Oedema;									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Rotator Cuff Syndrome;
Senile Dementia;
Wheezing

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16763754	EXPEDITED (15-DAY)		DE	BF-PFIZER INC-2019374659		21 DAY	Female	BFA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Distress	Azithromycin			S		1.45 MI, Daily		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16822611	NON-EXPEDITED			US-PFIZER INC-2019401798			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Impatience; Malaise; Rhinorrhoea; Sleep Disorder	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16822616	NON-EXPEDITED			US-PFIZER INC-2019401176			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma	Zithromax			S		250 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Sep-2019	16823082	NON-EXPEDITED			PHEH2019US038095			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Epigastric Discomfort; Ill-Defined Disorder	Azithromycin			S	Unknown	Unk		Novartis	
	Valsartan			C		Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Not Reported	
	Prolia			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Evista			C		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Sep-2019	16824050	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1086107		70 YR	Male	DEU	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hepatic Fibrosis; Hepatitis Acute; Jaundice	Azithromycin				S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Sep-2019	16824454	NON-EXPEDITED			PHEH2019US038615			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin				S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Sep-2019	16824899	EXPEDITED (15-DAY)		DE	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-220459		27 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin				S	Unknown	Unk		Sun	
	Fluconazole				S	Unknown	Unk		Ranbaxy	
	Miltefosine				S	Unknown	Unk		Not Reported	
	Flucytosine				S	Unknown	Unk		Not Reported	
	Pentamidine				S	Unknown	Unk		Not Reported	
	Sulfadiazine				S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
19-Sep-2019	14068614	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2017432605		55 YR	Female	USA	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Heart Rate Decreased	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	15626467	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-TEVA-2018-CA- 976409		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Amiodarone			S	Unknown			Teva	
	Amiodarone			S	Unknown			Teva	
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported	
	Diltiazem Cd			S	Oral			Teva	
	Diltiazem Cd			S	Oral			Teva	
	Doxorubicin			S	Intravenous (not otherwise specified)			Teva	
	Furosemide			S	Oral	40 Milligram Daily;		Ivax	
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported	
	Paclitaxel			S	Intravenous (not otherwise specified)			Not Reported	
	Paclitaxel			S	Intravenous (not otherwise specified)			Not Reported	
	Pantoprazole Sodium Anhydrous			S	Intravenous (not otherwise specified)			Teva	
	Pantoprazole Sodium Anhydrous			S	Intravenous (not otherwise specified)			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trastuzumab	S	Unknown	Not Reported
Procytox 2000mg/Vial	S	Intravenous (not otherwise specified)	Not Reported
Procytox 2000mg/Vial	S	Intravenous (not otherwise specified)	Not Reported
Procytox 2000mg/Vial	S	Intravenous (not otherwise specified)	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	Not Reported
Enoxaparin	S	Subcutaneous 40 Milligram Daily;	Not Reported
Enoxaparin	S	Subcutaneous 40 Milligram Daily;	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified) 500 Milligram Daily;	Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified) 500 Milligram Daily;	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified) 50 Milligram Daily;	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorphone	S	otherwise specified)	Intravenous (not otherwise specified)	Not Reported
Hydromorphone	S	Intravenous (not otherwise specified)	Intravenous (not otherwise specified)	Not Reported
Ondansetron	C	Oral	16 Gram Daily;	Not Reported
Metoclopramide	C	Oral	40 Milligram Daily;	Not Reported
Metoclopramide	C	Oral		Not Reported
Gabapentin	C	Oral	300 Milligram Daily;	Not Reported
Filgrastim	C	Subcutaneous	300 Microgram Daily;	Not Reported
Dexamethasone	C	Oral	20 Milligram Daily;	Not Reported
Aprepitant	C	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	15999316	NON-EXPEDITED			US-PFIZER INC-2019078764		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer
	Metformin			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16332763	NON-EXPEDITED			US-PFIZER INC-2019214356		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Dysphonia; Headache; Nausea	Azithromycin			S	Oral	500 Mg, First Day (Two 250mg Tablets)		Pfizer
	Azithromycin			S		250 Mg, 1x/Day (Next 4 Days)		Pfizer
	Fluticasone			C	Nasal	100 Ug, Unk (1 Spray In Each Nostril)		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azelastine Hcl			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16345749	EXPEDITED (15-DAY)		DE, LT, OT	PL-009507513-1905POL008958		30 YR	Female	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Neoplasm; Bronchopulmonary Aspergillosis; Device Related Infection; Disease Progression; Drug Ineffective; Graft Versus Host Disease In Gastrointestinal Tract; Graft Versus Host Disease In Lung; Product Use In Unapproved Indication; Stenotrophomonas Infection	Montelukast Sodium			S	Oral			Merck	
	Methylprednisolone			S	Unknown	2 Milligram/Kilogram, Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Voriconazole			C		Unk		Not Reported	
	Treosulfan			C		Unk		Not Reported	
	Cyclophosphamide			C		Unk		Not Reported	
	Mitoxantrone Hydrochloride			C		Unk		Not Reported	
	Amphotericin B			C		Unk		Not Reported	
	Cladribine			C		Unk		Not Reported	
	Busulfan			C		Unk		Not Reported	
	Posaconazole			C		Unk		Not Reported	
	Daunorubicin			C		Unk		Not Reported	
	Cytarabine			C		Unk		Not Reported	
	Tacrolimus			C		Unk		Not Reported	
	Fludarabine Phosphate			C		Unk		Not Reported	
	Azacitidine			C		Unk		Not Reported	
	Fluticasone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16648840	EXPEDITED (15-DAY)		OT	PHHY2019IT146930		34 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Pregnancy On Oral Contraceptive	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Azithromycin			S	Oral	500 Mg, Qd		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Klaira			S	Oral	1 Df, Qd			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16826405	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019397059		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acral Lentiginous Melanoma	Novatrex			S	Oral	Unk		Pfizer	
	Simponi			S	Subcutaneous	Unk		Not Reported	
	Apranax [Naproxen]			C		750 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16826892	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110410		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Azithromycin			S	Unknown			Not Reported	
	Caspofungin Acetate			S	Unknown			Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Montelukast			S	Oral			Teva	
	Mycophenolate Mofetil			S	Oral			Teva	
	Prednisone			S	Oral			Actavis	
	Pantoprazole			S	Oral			Teva	
	Voriconazole			S	Oral			Teva	
	Nifedipine			S	Oral			Not Reported	
	Sulfatrim			S	Oral			Not Reported	
	Tacrolimus			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16827610	NON-EXPEDITED			US-PFIZER INC-2019401111		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Eruption; Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Celecoxib	S	Unk	Pfizer
	Morphine Sulfate	S	Unk	Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16828687	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1086807		52 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Pruritus	Azithromycin			S	Oral	1 Dosage Form, Qd			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16828712	EXPEDITED (15-DAY)		OT	PL-MYLANLABS-2019M1086966		44 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Drug Interaction; Pharyngeal Swelling	Azithromycin			S	Unknown	Unk Unk, Unknown Freq.			Not Reported
	Unidox /00055701/			S	Unknown	Unk Unk, Twice Daily			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16829715	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110254		41 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthropathy;	Azithromycin			S	Unknown				Not Reported
Blister; Burning Sensation;	Azithromycin			S	Unknown				Not Reported
Chest Pain; Cough;	Azithromycin			S	Unknown				Not Reported
Dizziness; Drug	Azithromycin			S	Unknown				Not Reported
Ineffective; Fall; Feeling	Azithromycin			S	Unknown				Not Reported
Abnormal; Gait	Azithromycin			S	Unknown				Not Reported
Disturbance; Headache;	Pantoprazole			S	Unknown				Teva
Heart Rate Increased;	Pantoprazole			S	Unknown	40 Milligram Daily;			Teva
Hypertension; Incorrect	Omalizumab			S	Subcutaneous				Not Reported
Dose Administered;	Aluminium Hydroxide/			C	Unknown				Not Reported
Influenza Like Illness;									
Injection Site Rash;									
Insomnia; Lip Swelling;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Muscular Weakness; Nasopharyngitis; Painful Respiration; Peripheral Swelling; Product Storage Error; Pruritus; Rash; Respiratory Tract Congestion; Stress; Swelling; Tooth Fracture; Urticaria; Urticaria	Magnesium Carbonate Cetirizine Demulen /00040701/ Fusidate Sodium Hydroxyzine Metronidazole Nystatin Prednisone Reactine [Cetirizine Hydrochloride] Sertraline [Sertraline Hydrochloride] Singulair Ventolin	C C C C C C C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Sep-2019	16831754	DIRECT		DS, HO			30 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholelithiasis; Gallbladder Rupture	Prednisone Azithromycin Advil		Y	S S C	Oral			Hikma Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	15195783	NON-EXPEDITED			US-PFIZER INC- 2018299416		31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax Rocephin Lortab [Hydrocodone Bitartrate;Paracetamol] Vicodin			S S S S		Unk Unk Unk Unk		Pfizer Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Percocet [Oxycodone Hydrochloride; Oxycodone Terephthalate; Paracetamol]	S	Unk [7.5/325]	Not Reported
	Ultrame	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831487	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-060614		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Blood Pressure Increased; Cold Sweat; Confusional State; Decreased Appetite; Discomfort; Drug Interaction; Fear Of Death; Hallucination, Visual; Herpes Zoster; Malaise; Mobility Decreased; Nausea; Pain; Vertigo	Tramadol			S	Unknown	Unk		Aurobindo	
	Valaciclovir Mylan			S	Unknown	2 Dosage Form, 3 Times A Day		Not Reported	
	Methotrexate Sodium			S	Subcutaneous	Unk		Not Reported	
	Novatrex			S	Unknown	1 Unk, Weekly		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831540	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2019AP022109		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Rhabdomyolysis	Azithromycin			S	Oral	500 Mg, First Day		Apotex	
	Azithromycin			S	Oral	250 Mg, Daily For The Next 4 Days		Apotex	
	Simvastatin			S	Unknown	80 Mg, Qd		Not Reported	
	Simvastatin			S	Unknown	40 Mg, Qd		Not Reported	
	Simvastatin			S	Unknown	80 Mg, Qd		Not Reported	
	Allopurinol			C	Unknown	100 Mg, Qd		Not Reported	
	Prednisone			C	Unknown	5 Mg, Qd		Not Reported	
	Labetalol			C	Unknown	Unk		Not Reported	
	Bumetanide			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Amlodipine	C	Unknown	Unk				Not Reported	
	Insulin Glargine	C	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16831551	EXPEDITED (15-DAY)		LT	GB-TEVA-2019-GB-1109709		80 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Oral	500 Mg			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16833859	NON-EXPEDITED			US-PFIZER INC-2019405701			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk			Pfizer
	Erythromycin			S		Unk			Pfizer
	Seroquel			S		Unk			Not Reported
	Keflex [Cefalexin Monohydrate]			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16833931	NON-EXPEDITED			US-PFIZER INC-2017169114		80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block; Drug Hypersensitivity; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, Daily			Pfizer
	Zithromax			S					Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16834342	NON-EXPEDITED			PHEH2019US038728			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Nausea; Vomiting		Azithromycin		S	Unknown		250 Mg, Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Sep-2019	16834380	NON-EXPEDITED			PHEH2019US038554			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity	Azithromycin			S	Unknown			Novartis		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Sep-2019	16835188	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019404011		10 YR	Male	CHN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Distension; Abdominal Pain; Diarrhoea; Nausea; Vomiting	Zithromax			S	Oral	0.23 G, 1x/Day		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
20-Sep-2019	16835700	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1110723		10 YR	Male	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Azithromycin			S	Oral			Not Reported		
	Azithromycin			S	Oral			Not Reported		
	Caspofungin Acetate			S	Intravenous (not otherwise specified)			Not Reported		
	Caspofungin Acetate			S	Intravenous (not otherwise specified)			Not Reported		
	Pantoprazole Sodium Anhydrous			S	Oral			Teva		
	Pantoprazole Sodium Anhydrous			S	Intravenous (not otherwise specified)			Teva		
	Ciprofloxacin			S	Oral			Not Reported		
	Ciprofloxacin Hydrochloride			S	Oral			Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Montelukast Sodium	S	Oral	Teva
Montelukast Sodium	S	Oral	Teva
Mycophenolate Mofetil	S	Oral	Teva
Mycophenolate Mofetil	S	Oral	Teva
Pantoprazole	S	Oral	Teva
Prednisone	S	Oral	Actavis
Sulfamethoxazole And Trimethoprim	S	Oral	Teva
Sulfamethoxazole And Trimethoprim	S	Oral	Teva
Sulfamethoxazole/Trimethoprim	S	Oral	Teva
Sulfamethoxazole/Trimethoprim	S	Oral	Teva
Nifedipine	S	Oral	Not Reported
Tacrolimus	S	Oral	Not Reported
Voriconazole	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16835715	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019168899			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Cetirizine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Paracetamol			S	Unknown	Unk		Glaxosmithkline
	Nicotine			S	Unknown	Unk		Glaxosmithkline
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Glaxosmithkline
	Amoxicillin Trihydrate			S	Unknown	Unk		Glaxosmithkline
	Habitrol			S	Unknown	Unk		Glaxosmithkline
	Triamcinolone Acetonide			S	Unknown	Unk		Glaxosmithkline
	Vitamin D3			S	Unknown	Unk		Glaxosmithkline
	Avamys			S	Unknown	Metered Dose		Glaxosmithkline
	Azithromycin Dihydrate			S	Unknown	Unk		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactroban (Mupirocin)	S	Unknown	Unk	Glaxosmithkline
Betamethasone Dipropionate	S	Unknown	Unk	Glaxosmithkline
Betaderm	S	Unknown	Unk	Glaxosmithkline
Clotrimazole	S	Unknown		Glaxosmithkline
Entocort	S	Unknown	Unk	Glaxosmithkline
Mupirocin	S	Topical	Unk	Glaxosmithkline
Pantoprazole	S	Unknown	Unk	Glaxosmithkline
Metronidazole	S	Unknown	Unk	Glaxosmithkline
Bisacodyl	S	Unknown	Unk	Glaxosmithkline
Alprazolam	S	Unknown	Unk	Not Reported
Apo Hydro	S	Unknown	Unk	Not Reported
Atorvastatin	S	Unknown	Unk	Not Reported
Desonide	S	Unknown	Unk	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent (Fluticasone Propionate)	S	Unknown	Unk	Not Reported
Glycerine	S	Oral	Unk	Not Reported
Gramicidin + Neomycin + Polymyxin B Sulfate	S	Unknown	Unk	Not Reported
Kenalog	S	Intra-articular	Unk	Not Reported
Humira	S	Subcutaneous	Dosage Form: Solution Subcutaneous: 6.0 Year(S)	Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	S	Oral		Not Reported
Macrogol/Sodium Chloride	S	Nasal	Unk	Not Reported
Sinus Rinse	S	Nasal	Unk	Not Reported
Statex (Morphin)	S	Unknown		Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Biaxin XI	S	Unknown	Tablet (Extended Release)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Calcium Carbonate + Magnesium + Vitamin D	S	Unknown	Unk	Not Reported
Calcium Carbonate + Vitamin D3	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Moxalole (Macrogol 3350 + Potassium Chloride + Sodium Bicarbonate + So	S	Unknown	Unk	Not Reported
Ms Ir	S	Unknown	Unk	Not Reported
Nadolol	S	Unknown	Unk	Not Reported
Pentasa	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Pulmicort	S	Unknown	Unk	Not Reported
Refresh Tears	S	Ophthalmic	Unk	Not Reported
Nicoderm	S	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Glaxosmithkline
Calcium Carbonate + Vitamin D3	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2019	16835818	EXPEDITED (15-DAY)		HO, OT	CA-VIIV HEALTHCARE LIMITED-CA2019AMR166842		48 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterovirus Infection; Transplant Rejection	Azithromycin			S		250 Mg, Unk		Glaxosmithkline	
	Sulfamethoxazole			S		800 Mg, Unk		Glaxosmithkline	
	Tivicay			S		Unk		Viiv	
	Abacavir			S		Unk		Not Reported	
	Tacrolimus			S		Unk		Not Reported	
	Mycophenolic Acid			S		1 G, Bid		Not Reported	
	Prednisone			S		15 Mg, Qd		Not Reported	
	Trimethoprim			S		160 Mg, Unk		Not Reported	
	Valganciclovir			S		900 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Sep-2019	16836428	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-060975		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Bronchiectasis; Cardiac Murmur; Chronic Obstructive Pulmonary Disease; Gastroesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps; Oedema Peripheral; Rhinitis Allergic; Sarcoidosis; Total Lung Capacity Increased; Wheezing	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ciprofloxacin			S	Unknown	Unk		Aurobindo	
	Moxifloxacin			S	Unknown	Unk		Aurobindo	
	Advair			S	Unknown	Unk		Not Reported	
	Atrovent			S	Unknown	Unk		Not Reported	
	Avamys			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	Unk		Not Reported	
	Combivent			S	Unknown	Unk		Not Reported	
	Duaklir Genuair			S	Unknown	Unk		Not Reported	
	Inspiroto Respimat			S	Unknown	Unk		Not Reported	
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Milligram		Not Reported	
	Nasonex			S	Unknown	Unk		Not Reported	
	Omnaris			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Seebri			S	Unknown	Unk		Not Reported	
	Singulair			S	Unknown	Unk		Not Reported	
	Spiriva Respimat			S	Unknown	18 Microgram		Not Reported	
	Symbicort			S	Unknown	Unk		Not Reported	
	Tudorza Genuair			S	Unknown	Unk		Not Reported	
	Ultibro Breezhaler			S	Unknown	Unk		Not Reported	
	Umeclidinium Bromide			S	Unknown	Unk		Not Reported	
	Umeclidinium Bromide;Vilanterol Trifenatate			S	Unknown	Unk		Not Reported	
	Ventolin			S	Unknown	400 Microgram		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Xolair		S	Unknown	Unk			Not Reported	
	Zenhale		S	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	14576320	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP006769		76 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Ineffective; Dyspnoea; Malaise; Pneumonia; Throat Irritation	Amlodipine			S	Unknown	10 Mg, Qd		Apotex	
	Valsartan			S	Unknown	160 Mg, Qd		Apotex	
	Xolair			S	Subcutaneous	375 Mg, Once Every Two Weeks		Not Reported	
	Omalizumab			S	Subcutaneous	375 Mg, Unk		Not Reported	
	Azithro			S	Unknown	25 Mg, Unk		Not Reported	
	Alvesco			C	Unknown	2 Df, Bid		Not Reported	
	Claritin /00917501/			C	Unknown	1 Df, Qd		Not Reported	
	Spiriva			C	Unknown	1 Df, Qd		Not Reported	
	Symbicort Tu			C	Unknown	4 Df, Bid		Not Reported	
Budesonide			C	Unknown	4 Df, Qd		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	15572550	NON-EXPEDITED			US-PFIZER INC-2018438035			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	15743659	NON-EXPEDITED			US-PFIZER INC-2018524544		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Drug	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hypersensitivity; Nausea

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16081381	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-013248		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Ciprofloxacin			S	Oral	Unk		Aurobindo
	Montelukast			S	Oral	Unk		Aurobindo
	Montelukast Chewable Tablet			S	Oral	Unk		Aurobindo
	Azithromycin			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Voriconazole			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Candidas			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Nifedipine			S	Oral	Unk		Not Reported
	Pms Azithromycin			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Sulfamethoxazole;Trimethoprim			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16552307	NON-EXPEDITED			US-PFIZER INC- 2019294408			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Morphine Sulfate			S		Unk		Unknown
	Fentanyl Citrate			S		Unk		Unknown
	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amoxicillin	S	Unk	Pfizer
Erythromycin	S	Unk	Pfizer
Bactrim	S	Unk	Not Reported
Evista	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16837515	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1112016			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown				Not Reported
	Gentamicin			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16840040	NON-EXPEDITED			US-PFIZER INC-2019411302		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16840647	EXPEDITED (15-DAY)		HO	JP-PFIZER INC-2019403086			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Physical Deconditioning; Product Use Issue	Zithromac 250mg			S	Oral	Unk			Pfizer
	Zithromac 250mg			S	Oral	Unk			Pfizer
	Ceftriaxone			C	Oral	Unk			Not Reported
	Ceftriaxone			C	Oral	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16840655	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019402795			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bleeding Time Prolonged; Post Procedural Haemorrhage	Zithromac Norvasc		S S	Oral Oral	Unk Unk			Pfizer Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2019	16840671	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019390391			Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymph Gland Infection; Osteomyelitis; Therapeutic Product Effect Incomplete	Zithromac 250mg			S	Oral	Unk		Pfizer	
	Zithromac 250mg			S	Oral	2 Df, Daily		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	15839770	NON-EXPEDITED			US-PFIZER INC- 2019015751			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Demerol			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Effexor			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Betadine			S		Unk		Not Reported	
	Dilaudid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16113085	EXPEDITED (15-DAY)		OT	AU-009507513- 1903AUS009525			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Lung Disorder	Montelukast Sodium			S		10 Milligram, Qd		Merck	
	Methylprednisolone			S		10 Milligram/Kilogram/Day, 4 Days , Q2-3 Weeks		Not Reported	
	Azithromycin			S		250 Milligram 3x Per Week		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sirolimus	S	1 Milligram, Bid	Not Reported
Mycophenolate Mofetil	C	Unk	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16339695	EXPEDITED (15-DAY)		DE, OT	JP- ELI_LILLY_AND_COMP ANY-JP201905005722			Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Cholecystitis; Toxic Epidermal Necrolysis	Forteo 250ug/MI			S	Subcutaneous	20 Ug, Daily		Eli Lilly And Co
	Azithromycin			S	Oral	500 Mg, Daily		Not Reported
	Vegetamin A			C		Unk		Not Reported
	Rozerem			C	Oral	8 Mg, Daily		Not Reported
	Loxoprofen			C	Oral	60 Mg, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16542804	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-064737		69 YR	Male	DEU

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Autoimmune Hepatitis; Brain Abscess; Iris Adhesions; Multiple Allergies; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Nivolumab			S	Intravenous (not otherwise specified)	1 Milligram/Kilogram, Q3cycles		Bristol Myers Squibb
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q3cycles		Bristol Myers Squibb
	Novalgin [Metamizole Sodium]			S	Unknown	Unk		Not Reported
	Levetiracetam			S	Unknown	1000 Absent, Qd		Not Reported
	Azithromycin			S	Unknown			Not Reported
	Ranitidine			C	Unknown	300 Milligram, Qd		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Sep-2019	16792723	EXPEDITED (15-DAY)		OT	PHHY2019FR210347		13 YR	Female	FRA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nephritis; Product Use In Unapproved Indication; Tubulointerstitial Nephritis	Azithromycin	S	Unknown	Unk	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16842698	EXPEDITED (15-DAY)		HO	US-AUROBINDO-AUR-APL-2019-057645		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance; Hospitalisation; Vomiting	Azithromycin			S	Oral	1 Gram		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			C	Intramuscular	1 Gram		Not Reported	
	Ceftriaxone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16843070	EXPEDITED (15-DAY)		OT	US-ALLERGAN-1930328US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis	Escitalopram Oxalate Unk			S	Unknown			Allergan	
	Estradiol Unk			S	Unknown			Allergan	
	Genotropin Miniquik			S	Subcutaneous	0.6 Mg, Qd		Not Reported	
	Hizentra			S	Unknown			Not Reported	
	Hydrocortisone			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Tramadol			S	Unknown			Not Reported	
	Bupropion			S	Unknown			Not Reported	
	Nascobal			S	Unknown			Not Reported	
	Promethazine			S	Unknown			Not Reported	
	Montelukast Sodium			S	Unknown			Not Reported	
	Creon			S	Unknown			Not Reported	
	Acyclovir			S	Unknown			Not Reported	
	Meloxicam			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levetiracetam	S	Unknown	Not Reported
Diazepam	S	Unknown	Not Reported
Rizatriptan	S	Unknown	Not Reported
Levofloxacin	S	Unknown	Not Reported
Acetaminophen And Codeine	S	Unknown	Not Reported
Levoxyl	S	Unknown	Not Reported
Liothyronine Sodium	S	Unknown	Not Reported
Pantoprazole Sodium	S	Unknown	Not Reported
Proair Hfa	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16844947	NON-EXPEDITED			US-PFIZER INC-2019410569		48 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Headache	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16845409	DIRECT		OT			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Neck Pain	Azithromycin			S	Oral	Quantity:1 Tablet(S);		Sandoz	
	Lidocaine Ointment			C				Not Reported	
	Dicl/Gaba/Bacl/Doxe			C				Not Reported	
	2%6%2%5% Cre 120 Gms - Topical Compound								
	One-A Day Women'S Multivitamins			C				Not Reported	
	Calcium 600mg			C				Not Reported	
	D2 20 Mcg			C				Not Reported	
	Turmeric			C				Not Reported	
	Fish Oil			C				Not Reported	
	Tylenol			C				Not Reported	
	Ibuprofen			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16846341	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113343		16 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cerebrovascular Disorder; Chest X-Ray Abnormal; Gastrointestinal Haemorrhage; Hypoxia; Infection; Influenza Like Illness; Neuropathy Peripheral; Pancreatitis; Polyneuropathy; Premature Labour; Respiratory Acidosis; Respiratory Distress; Respiratory Failure; Tachypnoea	Amoxicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
	Betamethasone			S	Unknown			Actavis	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)			Not Reported	
	Levofloxacin			S	Unknown			Teva	
	Heparin Sodium			S	Intravenous (not otherwise specified)			Not Reported	
	Oseltamivir Phosphate			S	Oral	150 Milligram Daily;		Not Reported	
	Vancomycin Hydrochloride			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16846473	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1112282		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Amoxicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
	Clozapine			S	Unknown			Ivax	
	Lamotrigine			S	Unknown			Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Sep-2019	16846762	NON-EXPEDITED			PHEH2019US039079			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Azithromycin			S	Oral	250 Mg, Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	12972889	NON-EXPEDITED			US-PFIZER INC-2016540772		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Erythromycin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	15505851	NON-EXPEDITED			US-PFIZER INC-2018419604		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Dizziness; Drug Hypersensitivity; Vomiting	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Demerol			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16346050	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-027572			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo	
	Lamivudine			S	Transplacental	150 Milligram		Aurobindo	
	Zidovudine			S	Transplacental	300 Milligram		Aurobindo	
	Abacavir			S	Transplacental	300 Milligram, Daily		Not Reported	
	Acyclovir			S	Transplacental	Unk		Not Reported	
	Bactrim			S	Transplacental	Unk		Not Reported	
	Intelence			S	Transplacental	200 Milligram, Daily		Not Reported	
	Prezista			S	Transplacental	600 Milligram, Daily		Not Reported	
	Raltegravir Potassium			S	Transplacental	400 Milligram		Not Reported	
	Ritonavir			S	Transplacental	100 Milligram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Viread			S	Transplacental	300 Milligram, Daily			Not Reported
	Folic Acid			C	Unknown	Unk			Not Reported
	Iron			C	Intracardiac	Unk			Not Reported
	Magnesium Gluconate			C	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16540036	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1072131		34 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Pregnancy On Oral Contraceptive	Azithromycin			S		Oral			Not Reported
	Klaira			S		Oral			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16848275	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1111536		18 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Throat Tightness	Azithromycin Dihydrate			S		Oral			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16848397	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1113104		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptococcosis; Drug Ineffective; Drug Intolerance; Drug Resistance; Enterocolitis; Multiple Organ Dysfunction Syndrome; Mycobacterium Avium Complex Infection; Nosocomial Infection	Clarithromycin			S		Oral			Actavis
	Fluconazole			S		Oral			Not Reported
	Moxifloxacin			S		Unknown			Teva
	Mycophenolate Sodium			S		Unknown			Teva
	Prednisone			S		Unknown			Actavis
	Amikacin			S		Parenteral			Not Reported
	Azithromycin			S		Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ethambutol	S	Oral	Not Reported
	Rifabutin	S	Oral	Not Reported
	Rifampin	S	Intravenous (not otherwise specified)	Not Reported
	Tacrolimus	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849004	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-061753		81 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Acute Kidney Injury; Adjustment Disorder; Anaemia; Angina Pectoris; Atrophy; Back Pain; Bundle Branch Block Left; Death; Drug Hypersensitivity; Drug Intolerance; Hepatic Steatosis; Hypercalcaemia; Hypertension; Monoclonal Gammopathy; Musculoskeletal Pain; Osteoarthritis; Palmar Erythema; Plasma Cell Myeloma; Sacroiliitis; Spinal Disorder; Toxicity To Various Agents	Risedronate			S	Unknown	Unk		Aurobindo
	Aclasta			S	Intravenous drip	Unk		Not Reported
	Codeine			S	Unknown	Unk		Not Reported
	Amoxil			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Dilaudid			C	Unknown	1.0 Milligram		Not Reported
	Esomeprazole Sodium			C	Unknown	40 Milligram, Once A Day		Not Reported
	Nitroglycerin			C	Oral	1 Dosage Form		Not Reported
	Propranolol Hydrochloride			C	Unknown	80 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849211	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2019-062322		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Blood Lactic Acid Increased; Blood Potassium Decreased;	Azithromycin			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Breath Sounds Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Cough; Dyspnoea; Ear Pruritus; Eosinophilia; Eye Pruritus; Lacrimation Increased; Loss Of Personal Independence In Daily Activities; Nasal Congestion; Nasal Polyps; Platelet Count Increased; Pulmonary Function Test Abnormal; Rhinitis Allergic; Rhinorrhoea; Sneezing; Upper-Airway Cough Syndrome; Urticaria; Vasculitis; Wheezing	Nucala	S	Intravenous (not otherwise specified)	100.0 Milligram	Not Reported
	Omalizumab	S	Unknown	150.0 Milligram	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Pulmicort	S	Unknown	Unk	Not Reported
	Pulmicort	S	Unknown	Unk	Not Reported
	Rupatadine	S	Oral	10.0 Milligram	Not Reported
	Rupatadine Fumarate	S	Unknown	Unk	Not Reported
	Salbutamol	S	Unknown	Unk	Not Reported
	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	10.0 Milligram	Not Reported
	Symbicort	S	Unknown	2.0 Dosage Form, Two Times A Day	Not Reported
	Tamiflu	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16849849	DIRECT		OT				Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapy Non-Responder	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851083	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC- 2019409339		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Diarrhoea;	Azithromycin			S	Unknown	Unk		Pfizer
Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension;	Ciprofloxacin			S	Unknown	Unk		Unknown
Infection; Nausea;	Ciprofloxacin			S	Oral	500 Mg, 1x/Day		Unknown Not Reported
Obesity; Renal Disorder;	Ciprofloxacin			S				Not Reported
Renal Impairment	Quetiapine			S	Oral	Unk Unk, 2x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Quetiapine	S	Oral	100 Mg, 1x/Day	Not Reported
Amoxicillin	C		Unk	Not Reported
Risperidone	C		Unk	Not Reported
Valproate Semisodium	C		Unk	Not Reported
Zyprexa	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851209	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019409678		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Biopsy	Azithromycin			S	Unknown	Unk		Pfizer
Colon Abnormal; Blood	Azithromycin			S				Pfizer
Pressure Decreased; C-Reactive Protein	Cefixime			S	Unknown	Unk		Not Reported
Increased; Diarrhoea;	Ciprofloxacin			S	Oral	Unk		Not Reported
Dysbiosis; Enteritis;	Moxifloxacin			S	Unknown	Unk		Not Reported
Frequent Bowel	Pms Azithromycin			S	Unknown	Unk		Not Reported
Movements;	Pms Azithromycin			S				Not Reported
Gastroenteritis								
Staphylococcal;								
Gastrointestinal Mucosa								
Hyperaemia;								
Haematochezia; Heart								
Rate Increased; Nausea;								
Purulence; Staphylococcal								
Infection; Weight								
Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851321	EXPEDITED (15-DAY)		DS, OT	CA-PFIZER INC-2019409736		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine	Azithromycin			S		Unk		Pfizer
Increased; Diarrhoea;	Cipro [Ciprofloxacin]			S	Oral	500 Mg, Once A Day (1 Every 1 Day)		Not Reported
Flank Pain; Haematocrit								
Decreased; Haemoglobin								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Cipro [Ciprofloxacin]	S		Unk	Not Reported
	Quetiapine Fumarate	S	Oral	25 Mg, Twice A Day (2 Every 1 Day)	Not Reported
	Quetiapine Fumarate	S	Oral	100 Mg, Once A Day (1 Every 1 Day)	Not Reported
	Amoxicillin	C	Unknown	Unk	Not Reported
	Risperidone	C	Unknown	Unk	Not Reported
	Valproate Semisodium	C	Unknown	Unk	Not Reported
	Zyprexa	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851494	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2019409835		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Oesophageal Ulcer; Oesophagitis; Rash; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Pfizer
	Ciprofloxacin			S	Oral	500 Mg, 2x/Day		Not Reported
	Tiotropium Bromide			C		Unk		Not Reported
	Fluticasone			C		Unk		Not Reported
	Ipratropium			C		Unk		Not Reported
	Quetiapine			C		Unk		Not Reported
	Risedronate Sodium			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851532	EXPEDITED (15-DAY)		OT	MY-PFIZER INC- 2019409312			Unknown	MYS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Thermal Burn	Zithromax			S	Intravenous (not otherwise specified)	Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16851635	EXPEDITED (15-DAY)		DS, OT	NO-BAYER-200514433GDS		25 YR	Male	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abnormal Dreams; Alopecia; Amnesia; Amnesia; Anal Haemorrhage; Anal Incontinence; Arrhythmia; Asthenia; Asthenia; Chronic Fatigue Syndrome; Depressed Mood; Diarrhoea; Disturbance In Attention; Dizziness; Epistaxis; Fatigue; Flatulence; Gastrointestinal Disorder; Headache; Muscle Spasms; Nasopharyngitis; Nausea; Night Sweats; Palpitations; Pollakiuria; Prostatitis; Sleep Disorder; Tension Headache; Tinnitus; Tremor; Vision Blurred	Ciprofloxacin			S	Oral	1000 Mg (Daily Dose), Bid, Oral		Bayer	
	Azitromax			S	Oral	500 Mg, Qd		Not Reported	
	Carduran			S	Oral	400 Mg, Once		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16852654	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1088849			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Oral	2 G, Single		Not Reported	
	Gentamicin Sulfate			S	Intramuscular	240 Mg, Single		Mylan	
	Ceftriaxone Sodium			S	Intramuscular	1 G, Single		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Sep-2019	16853301	NON-EXPEDITED			PHEH2019US039472			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Flatulence	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	8573249	NON-EXPEDITED		OT	US-PFIZER INC-2012119612		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Stevens-Johnson Syndrome	Zithromax			S		Unk		Pfizer	
	Rifampin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	11538627	EXPEDITED (15-DAY)		DE, HO, OT	PHHO2015US009360		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Anticoagulation Drug Level Below Therapeutic; Cardiac Failure; Hyperkalaemia; Hyperkalaemia; Hypotension; Respiratory Failure; Spinal Fracture; Subdural Haematoma; Thoracic Vertebral Fracture	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Diovan			S	Oral	160 Mg, Bid		Novartis	
	Diovan			S	Oral	160 Mg, Bid		Novartis	
	Diovan			S	Oral	160 Mg, Bid		Novartis	
	Placebo			S	Oral	Unk		Not Reported	
	Placebo			S	Oral	Unk		Not Reported	
	Placebo			S	Oral	Unk		Not Reported	
	Coumadin//Warfarin Sodium			S	Oral	5 Mg, Qd		Not Reported	
	Coumadin//Warfarin Sodium			S	Oral	Dose Varis Based On Inr		Not Reported	
	K-Dur			S	Oral	80 Meq, Qd		Not Reported	
	Lasix			S	Oral	120 Mg, Qd (80 Mg Am And 40 Mg Pm)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metoprolol	C	Oral	50 Mg, Qd	Not Reported
Metoprolol	C			Not Reported
Metoprolol	C			Not Reported
Gabapentin	C	Unknown		Not Reported
Oxygen	C		Unk	Not Reported
Oxygen	C		Unk	Not Reported
Albuterol Sulfate	C	Respiratory (inhalation)	1 Df, Prn (Q4h)	Not Reported
Duoneb	C	Respiratory (inhalation)	1 Df, Prn (Q4h)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16538884	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-038037		34 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction;	Azithromycin			S	Oral	500 Milligram, Daily		Aurobindo	
Pregnancy On Oral Contraceptive	Klaira			S	Oral	1 Dosage Form, Daily		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16555475	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019287164		34 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous;	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
Drug Interaction;	Klaira			S	Oral	1 Df, 1x/Day		Not Reported	
Pregnancy On Oral Contraceptive									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16854182	EXPEDITED (15-DAY)		OT	AU-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-093049		79 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure Acute;	Eliquis			S	Unknown	5 Milligram, Bid		Bristol Myers Squibb	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chronic Obstructive Pulmonary Disease	Amoxicillin Clavulanic Acid	S	Unknown	Unk	Not Reported
	Atenolol	S	Unknown	50 Milligram, Qd	Not Reported
	Azithromycin Alphapharm	S	Oral	Unk	Not Reported
	Doxycycline	S	Unknown	Unk	Not Reported
	Furosemide	S	Unknown	40 Milligram, Qd	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Seretide	S	Unknown	1 Dosage Form, Bid	Not Reported
	Telmisartan	S	Unknown	80 Milligram	Not Reported
	Tiotropium	S	Unknown	18 Microgram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16854966	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1112463		81 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Loss Of Consciousness; Torsade De Pointes	Sotalol			S	Oral	80 Mg		Teva	
	Zitromax			S		500 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16855622	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1111753		33 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Prednisolone			S	Oral	Unk Unk,Unk		Actavis	
	Metasulphobenzoate Sodium			S	Oral	60 Mg,Qd		Actavis	
	Prednisolone			S	Oral	300 Milligram		Not Reported	
	Metasulphobenzoate Sodium			S	Buccal	Dose:4 Unit(S)		Not Reported	
	Rulid 150 Mg, Comprimé Enrobé			S	Buccal	Frequency- 2 To 4 Time Daily		Not Reported	
	Hexaspray			S	Oral	Dose:2 Unit(S)		Not Reported	
	Eludril (Chlorhexidine Gluconate\Chlorobutanol)			S	Oral	Dose:2 Unit(S)		Not Reported	
	Triflucan 100 Mg, Gélule			S	Oral	Dose:2 Unit(S)		Not Reported	
	Zithromax 250 Mg, Comprime Pellicule			S	Oral	Dose:2 Unit(S)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Solupred (Prednisolone Sodium Sulfobenzoate)	S	Oral		Not Reported
	Solupred (Prednisolone Sodium Sulfobenzoate)	S	Oral		Not Reported
	Helicidine	S	Oral	Dose:3 Unit(S)	Not Reported
	Augmentin	S	Oral	Dose:3 Unit(S)	Not Reported
	Thalidomide	C			Not Reported
	Doliprane	C			Not Reported
	Exomuc	C			Not Reported
	Surgam	C			Not Reported
	Trimebutine	C			Not Reported
	Toplexil	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16855779	NON-EXPEDITED			PHEH2019US039486			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16856356	NON-EXPEDITED			US-PFIZER INC-2019415275		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pruritus	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16857348	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019410637		67 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Blood Creatinine Increased;	Azithromycin			S	Unknown	250 Mg, 1x/Day		Pfizer
Blood Test Abnormal;	Ciprofloxacin			S	Oral	750 Mg, 2x/Day		Unknown
Cough; Distal Intestinal Obstruction Syndrome;	Ciprofloxacin			S	Oral	500 Mg, 2x/Day		Unknown

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea; Eosinophil Count Increased; Glucose Tolerance Impaired; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Obstructive Airways Disorder; Pancreatic Failure; Productive Cough; Renal Failure; Therapeutic Product Effect Incomplete	Ceftazidime	S	Unknown	2 G, 2x/Day	Not Reported
	Fluticasone	S	Unknown	1 Df, 2x/Day	Not Reported
	Propionate/Salmeterol Xinafoate	S	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Nucala	S	Unknown	Unk Unk, 4x/Day	Not Reported
	Nystatin	S	Unknown	45 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	2 Df, 2x/Day	Not Reported
	Pulmicort	S	Unknown	2 Df, 2x/Day	Not Reported
	Septra	S	Oral	2 Df, 2x/Day	Not Reported
	Singulair	S	Unknown	10 Mg, 1x/Day	Not Reported
	Spiriva	S	Unknown	18 Mg, 1x/Day	Not Reported
	Ventolin [Salbutamol]	S	Unknown	2 Df, Unk	Not Reported
	Zopiclone	S	Unknown	7.5 Mg, Unk	Not Reported
	Causton	C	Unknown	75 Mg, 3x/Day	Not Reported
	Pulmozyme	C	Unknown	2.5 Mg, 1x/Day	Not Reported
	Vitamin D [Ergocalciferol]	C	Unknown	Unk Unk, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16857472	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019411358		81 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Loss Of Consciousness; Torsade De Pointes	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Sotalol			S	Oral	80 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2019	16857838	NON-EXPEDITED			US-PFIZER INC-2019415543		51 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	15678851	EXPEDITED (15-DAY)		DE, HO, OT	PHHY2018CZ170991		68 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Cardiac Failure; Cardiomegaly; Circulatory Collapse; Drug-Induced Liver Injury; Hepatorenal Syndrome; Hepatotoxicity; Hypercatabolism; Multiple Organ Dysfunction Syndrome; Pneumonia; Pulmonary Fibrosis; Pulmonary Hypertension; Pyrexia; Respiratory Disorder; Sepsis; Tachypnoea	Azithromycin			S	Unknown	Unk		Novartis
	Azithromycin			S				Novartis
	Azithromycin			S				Novartis
	Azithromycin			S				Novartis
	Voriconazole			S	Unknown	Unk (Discontinued On Day4)		Not Reported
	Voriconazole			S				Not Reported
	Amiodarone			S	Intravenous drip	1800 Mg, Qd		Not Reported
	Amiodarone			S	Intravenous drip	600 Mg, Qd		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	600 Mg, Unk		Not Reported
	Amiodarone			S	Intravenous (not otherwise specified)	1800 Mg, After 36h, The Dose Of Amiodarone Was Reduced		Not Reported
	Moxifloxacin			S	Unknown	Unk (Discontinued On Day4)		Not Reported
	Co-Trimoxazole			S	Unknown	Unk (Discontinued Day 4)		Not Reported
	Meropenem			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Biseptol			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			C	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Piperacillin/Tazobactam			C				Not Reported
	Gliclazide			C	Unknown	Unk		Not Reported
	Metformin			C	Unknown	Unk		Not Reported
Nitrendipine			C	Unknown	Unk		Not Reported	
Metoprolol			C	Unknown	Unk		Not Reported	
Hydrochlorothiazide			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Esmolol	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Adrenaline	C	Unknown		Not Reported
Atorvastatin	C	Unknown	Unk	Not Reported
Fenofibrate	C	Unknown	Unk	Not Reported
Fenofibrate	C			Not Reported
Acetylsalicylic Acid	C	Unknown	Unk	Not Reported
Acetylsalicylic Acid	C			Not Reported
Nitrous Oxide	C	Respiratory (inhalation)		Not Reported
Noradrenaline	C	Unknown		Not Reported
Dexmedetomidine	C	Unknown	Unk	Not Reported
Dexmedetomidine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16859964	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2019SP006990		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure During Pregnancy	Oseltamivir			S	Unknown	Unk		Strides
	Oseltamivir			S				Strides
	Prednisolone			S	Unknown	Unk		Not Reported
	Prednisolone			S	Unknown	Unk, Taper		Not Reported
	Vancomycin			S	Unknown	Unk		Strides
	Vancomycin			S	Unknown	Unk		Strides
	Salbutamol			S	Unknown	Unk, Every 2 Hrs		Not Reported
	Salbutamol			S	Unknown	20 Mg, Every Hour		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	60 Mg, Bid		Not Reported
	Methylprednisolone			S	Intravenous (not otherwise specified)	80 Mg, Every 6 Hrs		Not Reported
	Ipratropium Bromide			S	Unknown	Unk, Every 6 Hrs		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Ipratropium Bromide		S					Not Reported
		Azithromycin		S	Unknown	Unk			Not Reported
		Cefepime		S	Unknown	Unk			Not Reported
		Ceftriaxone		S	Unknown	Unk			Not Reported
		Duoneb		S	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16859993	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1113205		70 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cerebrovascular Accident; Loss Of Consciousness	Azithromycin			S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16860627	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019413768		66 YR	Male	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dyspnoea	Azithromycin			S		Unk			Pfizer
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16861755	EXPEDITED (15-DAY)		HO	GR-MYLANLABS-2019M1040390		49 YR	Female	GRC
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Resistance; Off Label Use; Product Use In Unapproved Indication	Azithromycin Mylan			S		Unk			Mylan
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Sep-2019	16862002	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2019M1089325			Female	DEU
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Swollen Tongue	Azithromycin	S	Oral	Unk	Not Reported
	Azithromycin	S			Not Reported
	Cosentyx	S	Unknown	150 Milligram, Once	Mylan
	Prednisolone	C	Oral	20 Milligram, Qd	Mylan
	Methotrexate	C	Subcutaneous	15 Milligram, Qw	Mylan
	Folic Acid	C	Oral	5 Milligram, Qw	Mylan
	Ramipril	C	Oral	5 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16862188	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2019171994		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Blood Pressure Decreased; Drug Interaction; Heart Rate Decreased; Tremor	Flonase Allergy Relief Otc Nasal Spray			S		Unk		Glaxosmithkline
	Azithromycin			S		200 Mg, Unk		Glaxosmithkline
	Azithromycin			S				Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16862590	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2019413808		61 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematuria	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2019	16863935	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019411507		25 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia;	Azithromycin			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Diphenhydramine Hydrochloride			S		Unk		Not Reported
	Diphenhydramine Hydrochloride			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Seasonal Allergy; Skin Reaction; Throat Irritation	Diphenhydramine Hydrochloride	S		Unk	Not Reported
	Diphenhydramine Hydrochloride	S		Unk	Not Reported
	Omalizumab	S		Unk	Not Reported
	Omalizumab	S		Unk	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Every 2 Weeks	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Every 2 Weeks	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Every 2 Weeks	Not Reported
	Omalizumab	S	Subcutaneous	150 Mg, Unk	Not Reported
	Omalizumab	S	Subcutaneous	150 Mg, Unk	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Every 2 Weeks	Not Reported
	Pms Azithromycin	S		Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S		20 Mg, 2x/Day	Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Mg, Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S		10 Mg, Unk	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	20 Mg, 2x/Day	Not Reported
	Rifadin [Rifampicin]	S		Unk	Not Reported
	Rifampin	S		Unk	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 2 Weeks	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Every 2 Weeks	Not Reported
	Xolair	S	Subcutaneous	150 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Sep-2019	16739460	EXPEDITED (15-DAY)		HO	CZ-AXELLIA-002648		68 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Hepatorenal Syndrome	Voriconazole			S	Unknown	Discontinued On Day4		Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Moxifloxacin/Moxifloxacin Hydrochloride	S	Unknown	Discontinued On Day4	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown		Not Reported
Amiodarone	S	Intravenous drip	After 36 Hours The Dose Was Reduced To 600 Mg/24 Hours Continuously	Not Reported
Acetylsalicylic Acid	C	Unknown		Not Reported
Fenofibrate	C	Unknown		Not Reported
Metoprolol	C	Unknown		Not Reported
Nitrous Oxide	C	Respiratory (inhalation)		Not Reported
Esmolol	C	Unknown		Not Reported
Ciprofloxacin	C	Unknown		Not Reported
Atorvastatin	C	Unknown		Not Reported
Meropenem	C	Unknown		Not Reported
Nitrendipine	C	Unknown		Not Reported
Norepinephrine	C	Unknown	Low Dose	Not Reported
Metformin	C	Unknown		Not Reported
Piperacillin/Tazobactam	C	Unknown		Not Reported
Hydrochlorothiazide	C	Unknown		Not Reported
Gliclazide	C	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported
Morphine	C			Not Reported
Dexmedetomidine/Dexmedetomidine Hydrochloride	C			Not Reported
Propofol	C			Not Reported
Piperacillin/Tazobactam	C	Unknown		Not Reported
Amiodarone	S	Intravenous drip		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16115750	EXPEDITED (15-DAY)		OT	PHHY2019AU054773		9 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Chronic Graft Versus Host Disease; Dyspnoea Exertional; Obliterative Bronchiolitis	Ciclosporin	S	Unknown	Unk	Novartis
	Mycophenolate Mofetil	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	250 Mg, P	Not Reported
	Montelukast Sodium	S	Unknown	10 Mg, Qd	Not Reported
	Prednisolone	S	Unknown	2 Mg/Kg, Qmo	Not Reported
	Methylprednisolone	S	Unknown	10 Mg/Kg, Qd	Not Reported
	Sirolimus	S	Unknown	1 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16864846	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1113366			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Azathioprine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Methotrexate			S	Unknown			Barr
	Metoprolol			S	Unknown			Not Reported
	Naproxen			S	Unknown			Teva
	Plaquenil			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Xeljanz			S	Unknown	10 Milligram Daily;		Not Reported
	Humira			S	Subcutaneous			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16864876	EXPEDITED (15-DAY)		OT	PHHY2019CA225922		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous	Azithromycin			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Oral	Unk		Novartis
	Montelukast Sodium			S	Oral	Unk		Not Reported
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cell Carcinoma Of Skin	Pantoprazole	S	Oral	Unk	Not Reported
	Pantoprazole	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tacrolimus	S	Oral	Unk	Not Reported
	Voriconazole	S	Oral	Unk	Not Reported
	Apo Mycophenolate	S	Oral	Unk	Not Reported
	Apo-Sulfatrim	S	Oral	Unk	Not Reported
	Apo-Voriconazole	S	Oral	Unk	Not Reported
	Candidas	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Caspofungin Acetate	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Nifedipine	S	Oral	Unk	Not Reported
	Prednisone	S	Oral	Unk	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Oral	Unk	Not Reported
	Apo Azithromycin	S	Oral	Unk	Not Reported
	Apo Montelukast	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Sep-2019	16864998	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2019-062772		27 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acanthamoeba Infection; Amoebic Brain Abscess; Condition Aggravated; Drug Ineffective; Encephalitis; Haemophagocytic Lymphohistiocytosis; Nervous System Disorder; Somnolence	Azithromycin			S	Unknown	Unk		Aurobindo
	Fluconazole			S	Unknown	Unk		Aurobindo
	Miltefosine			S	Unknown	Unk		Not Reported
	Flucytosine			S	Unknown	Unk		Not Reported
	Pentamidine			S	Unknown	Unk		Not Reported
	Sulfadiazine			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	13735449	NON-EXPEDITED			US-PFIZER INC-2017294290		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Prozac			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	15255300	NON-EXPEDITED			US-PFIZER INC-2018313705		43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
	Benadryl			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	15423554	NON-EXPEDITED			US-PFIZER INC-2018380790		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Unknown	
	Sertraline Hcl			S		Unk		Pfizer	
	Testosterone Cipionate			S		Unk		Unknown	
	Zoloft			S		Unk		Pfizer	
	Amoxicillin And Clavulanate			S		Unk		Not Reported	
	Potassium								
	Bupropion			S		Unk		Not Reported	
	Wellbutrin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Copolymer 1 (Glatiramer Acetate)	S	Unk	Not Reported
	Copaxone	S	Unk	Not Reported
	Drospirenone And Ethinyl Estradiol	S	Unk	Not Reported
	Duloxetine	S	Unk	Not Reported
	Cymbalta	S	Unk	Not Reported
	Ocrelizumab	S	Unk	Not Reported
	Teriflunomide	S	Unk	Not Reported
	Trazodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	15856279	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1002437			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16212479	NON-EXPEDITED			US-PFIZER INC-2019164767		12 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16215720	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039423		68 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Cardiac Failure; Emphysema	Azithromycin			S	Unknown			Not Reported	
	Fluticasone			S	Unknown	4 Dosage Forms Daily;		Teva	
	Rabeprazole			S	Unknown			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Salbutamol	S	Unknown		Barr
Olodaterol Hydrochloride/Tiotropium Bromide	C	Other	2 Dosage Forms Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16536029	NON-EXPEDITED			US-PFIZER INC- 2019273692		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Contusion; Drug Hypersensitivity; Rash Macular; Skin Discolouration; Skin Disorder	Azithromycin			S		250 Mg, Unk		Pfizer
	Estradiol			C	Vaginal	Unk		Not Reported
	Estradiol			C		Unk		Not Reported
	Hydrocodone Bitartrate And Chlorpheniramine Maleate			C		Unk		Not Reported
	Fluticasone			C		50 Ug, Unk		Not Reported
	Fluconazole			C		150 Mg, Unk		Not Reported
	Amoxicillin And Clavulanate Potassium			C		Unk (875-125 Mg)		Not Reported
	Amoxicillin And Clavulanate Potassium			C		Unk (875-125 Mg)		Not Reported
	Amoxicillin And Clavulanate Potassium			C		Unk (875-125 Mg)		Not Reported
	Naproxen			C		500 Mg, Unk		Not Reported
	Naproxen			C		500 Mg, Unk		Not Reported
	Naproxen			C		500 Mg, Unk		Not Reported
	Benzonatate			C		100 Mg, Unk		Not Reported
	Amoxicillin			C		500 Mg, Unk		Not Reported
	Doxycycline Monohydrate			C		100 Mg, Unk		Not Reported
	Ventolin Hfa			C		90 Ug, Unk (Mdi)		Not Reported
	Estrace Vaginal			C		Unk		Not Reported
	Estrace Vaginal			C		Unk		Not Reported
	Estrace Vaginal			C		Unk		Not Reported
	Estrace Vaginal			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Premarin	C	Unk	Not Reported
Topiramate	C	25 Mg, Unk	Not Reported
Banophen	C	Unk (12.5 Mg/5ml)	Not Reported
Alendronate Sodium	C	70 Mg, Unk	Not Reported
Estradiol	C	0.5 Mg, Unk	Not Reported
Estradiol	C	0.5 Mg, Unk	Not Reported
Mi Acid	C	Unk [Suspension]	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16829982	EXPEDITED (15-DAY)		HO, OT	US-GILEAD-2019-0426681		82 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pneumonia; Rash; Stevens-Johnson Syndrome	Idelalisib			S	Oral	150 Mg, Bid		Gilead	
	Azithromycin			S	Unknown			Not Reported	
	Brimonidine Tartrate			C		Unknown		Not Reported	
	Xopenex			C				Not Reported	
	Symbicort			C				Not Reported	
	Xanax			C				Not Reported	
	Dorzolamide Hydrochloride			C				Not Reported	
	Latanoprost			C				Not Reported	
	Pantoprazole Sodium			C				Not Reported	
	Stool Softener			C				Not Reported	
	Triamcinolone Acetonide			C				Not Reported	
	Ambien			C				Not Reported	
	Albuterol			C				Not Reported	
	Brimonidine			C				Not Reported	
	Dorzolamide			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Albuterol Sulfate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16867477	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2019421834		79 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardiac Failure Acute; Chronic Obstructive Pulmonary Disease	Eliquis	S	Unknown	5 Milligram, Bid	Not Reported
	Atenolol	S	Unknown	50 Milligram, Qd	Pfizer
	Doxycycline Hyclate	S	Unknown	Unk	Pfizer
	Furosemide	S	Unknown	40 Milligram, Qd	Unknown
	Ibuprofen	S	Unknown	Unk	Pfizer
	Amoxicillin Clavulanic Acid	S	Unknown	Unk	Not Reported
	Azithromycin Alphapharm	S	Oral	Unk	Not Reported
	Seretide	S	Unknown	1 Dosage Form, Bid (250/25 Microgram, Bid)	Not Reported
	Telmisartan	S	Unknown	80 Milligram	Not Reported
	Tiotropium	S	Unknown	18 Microgram, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16868651	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2019413988		3 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematochezia; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	125 Mg, 1x/Day		Pfizer
	Zithromax			S				Pfizer
	Zithromax			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869024	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2019419552		50 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Temperature Intolerance; Tremor	Zithromax			S	Intravenous drip	500 Mg, 1x/Day		Pfizer
	Lentinan			S	Intravenous drip	2 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869555	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA- 1114855		68 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Cardiac Failure; Emphysema	Azithromycin	S	Unknown					Not Reported
	Fluticasone	S	Unknown	4 Dosage Forms Daily;				Teva
	Rabeprazole	S	Unknown					Teva
	Salbutamol	S	Unknown					Barr
	Bi 1744+Tiotropium Bromide	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16869787	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1090253		212 DAY	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Medication Error	Azithromycin			S	Oral	320 Milligram, Qd			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Sep-2019	16871101	NON-EXPEDITED			US-BAXTER-2019BAX019157			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Administration Site Pain; Incorrect Route Of Product Administration	0.9% Sodium Chloride Injection			S	Subcutaneous				Baxter
	Azithromycin			S	Subcutaneous	Injectable Solution			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16871850	EXPEDITED (15-DAY)		OT	NL-TEVA-2019-NL-1113968			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Coordination Abnormal; Depersonalisation/Derealisation Disorder; Dysarthria; Sensory Disturbance	Azithromycin Tablet, 250 Mg (Milligram)			S		3 Times Per Week 1 Tablet, 250 Mg Per 2 Days			Not Reported
	Zopiclon Pch 7,5 Mg Tablet			C		1 Dd 1 For The Night, 7 Mg Per Day			Not Reported
	Calci Chew 500 Mg Kauwtablet			C		1 Dd 1			Not Reported
	Gabapentine Pch 300 Mg Caps			C		3 Dd 1 Capsule, 30 Mg Per Hrs			Not Reported
	Diclofenac /Misosdz 50/0,2 Mg			C					Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mometason Fur Cf 50 Mcg/Di 140	C	1 Dd 2 Spray In Both Nostrils	Not Reported
Diclofenac Na Cf 50 Mg T Msr	C	3 Dd 1, 50 Mg Per 8 Hrs	Not Reported
Miconazol/Hc Pch 20/10 Mg Creme	C	2 Dd Crème, 2 Dosage Forms	Not Reported
Omecat 20 Mg Capsule Msr	C	1 Dd 1, 20 Mg Per Day	Not Reported
Bumetanide Pch 1 Mg Tablet	C	1 Dd 1, 1 Mg Per Day	Not Reported
Foster Aer 100/6 Mcg/Do 120 Do	C	3 Dd 2 Inhalaties, 2 Dosage Forms	Not Reported
Prednisolon Pch 5 Mg Tablet	C	Vv Arts	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16874346	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1115076		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury	Spironolactone			S	Oral	50 Milligram Daily;		Actavis
	Mavik			S	Oral	2 Milligram Daily;		Not Reported
	Pms-Azithromycin			S	Oral			Not Reported
	Amlodipine			C				Not Reported
	Furosemide			C				Not Reported
	Humalog			C				Not Reported
	Insulin Isophane, Human Biosynthetic			C				Not Reported
	Levetiracetam			C				Not Reported
	Rosuvastatin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Oct-2019	16875889	DIRECT	N	HO			30 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cystic Fibrosis	Azithromycin			S	Oral			Teva
	Prednisone			C				Not Reported
	Protonix			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877347	NON-EXPEDITED			US-PFIZER INC-2019425405		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Indomethacin			S		Unk		Unknown	
	Hydrocodone			S		Unk		Not Reported	
	Cefixime			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877472	NON-EXPEDITED			US-PFIZER INC-2019425178			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Cipro			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877538	NON-EXPEDITED			US-PFIZER INC-2019424288			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877560	NON-EXPEDITED			US-PFIZER INC-2019424314		56 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin			S			Unk		Pfizer	
	Doxycycline Hyclate			S			Unk		Pfizer	
	Erythromycin			S			Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877637	NON-EXPEDITED				US-PFIZER INC-2019424735		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax				S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877644	NON-EXPEDITED				US-PFIZER INC-2019423960			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Zithromax				S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16877735	NON-EXPEDITED				US-AKRON, INC.-2075187			Male	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite Opt Solution				S	Ophthalmic				Akorn
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Oct-2019	16878482	NON-EXPEDITED				US-PFIZER INC-2019423339		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin				S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	12079041	NON-EXPEDITED				US-PFIZER INC-2016033683		64 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Eructation	Azithromycin			S	Oral	250 Mg, Unk (Monday, Wednesday, And Friday)		Pfizer
	Prednisone			S	Oral	60 Mg, Daily (3 Tablets Daily For 3 Days)		Not Reported
	Prednisone			S	Oral	40 Mg, Daily (2 Tablets Daily For 3 Days)		Not Reported
	Prednisone			S	Oral	20 Mg, Daily (1 Tablets Daily For 3 Days)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	15757864	EXPEDITED (15-DAY)		DE, HO, OT	CZ-AUROBINDO-AUR-APL-2018-061765		68 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Atrial Fibrillation; Cardiac Failure; Cardiomegaly; Circulatory Collapse; Drug-Induced Liver Injury; Hepatorenal Syndrome; Hepatotoxicity; Hypercatabolism; Multiple Organ Dysfunction Syndrome; Pneumonia; Pulmonary Fibrosis; Pulmonary Hypertension; Pyrexia; Respiratory Disorder; Sepsis; Tachypnoea	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Azithromycin			S				Aurobindo
	Azithromycin			S				Aurobindo
	Moxifloxacin			S	Unknown	Unk, Discontinued On Day4		Aurobindo
	Co-Trimoxazole			S	Unknown	Unk, Discontinued On Day4		Not Reported
	Voriconazole			S	Unknown	Unk, Discontinued On Day4		Not Reported
	Voriconazole			S				Not Reported
	Biseptol			S	Unknown	Unk		Not Reported
	Ciprofloxacin			S	Unknown	Unk		Not Reported
	Atorvastatin			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Acetylsalicylic Acid			C				Not Reported
	Metoprolol			C	Unknown	Unk		Not Reported
	Hydrochlorothiazide			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem	C	Unknown	Unk	Not Reported
Gliclazide	C	Unknown	Unk	Not Reported
Fenofibrate	C	Unknown	Unk	Not Reported
Nitrendipine	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Piperacillin;Tazobactam	C	Unknown	Unk	Not Reported
Piperacillin;Tazobactam	C			Not Reported
Esmolol	C	Unknown	Unk	Not Reported
Piperacillin	C	Unknown	Unk	Not Reported
Tazobactam	C	Unknown	Unk	Not Reported
Dexmedetomidine	C	Unknown	Unk	Not Reported
Dexmedetomidine	C			Not Reported
Morphine	C	Unknown	Unk	Not Reported
Morphine	C			Not Reported
Propofol	C	Unknown	Unk	Not Reported
Dobutamine	C	Unknown	Unk	Not Reported
Adrenaline	C	Unknown	Unk	Not Reported
Nitrous Oxide	C	Respiratory (inhalation)	Unk	Not Reported
Norepinephrine	C	Unknown	Unk, Low Dose	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16197723	EXPEDITED (15-DAY)		OT	US-NEOPHARMA INC-000122			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Angioedema; Drug Hypersensitivity	Amoxil			S				Not Reported
	Z-Pack			S				Not Reported
	Keflex			S				Not Reported
	Codeine			S				Not Reported
	Omnicef			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16444194	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-033702		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oesophageal Ulcer; Oesophagitis; Rash; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ciprofloxacin			S	Oral	500 Milligram, Two Times A Day		Aurobindo	
	Tiotropium Bromide			C	Unknown	Unk		Not Reported	
	Fluticasone			C	Unknown	Unk		Not Reported	
	Ipratropium			C	Unknown	Unk		Not Reported	
	Quetiapine			C	Unknown	Unk		Not Reported	
	Risedronate Sodium			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Fluticasone;Salmeterol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16444197	EXPEDITED (15-DAY)		DE, HO, OT	CA-AUROBINDO-AUR-APL-2019-033693		19 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bipolar Disorder; Metabolic Acidosis; Overdose; Toxicity To Various Agents	Azithromycin			S	Oral	Unk		Aurobindo	
	Ciprofloxacin			S	Oral	Unk		Aurobindo	
	Acetaminophen And Codeine			S	Oral	Unk		Not Reported	
	Aerius (Desloratadine)			S	Oral	Unk		Not Reported	
	Amitriptyline			S	Oral	Unk		Not Reported	
	Caffeine			S	Oral	Unk		Not Reported	
	Codeine			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16563879	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-		34 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2019RR-213508

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Pregnancy On Oral Contraceptive	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Klaira			S	Oral	1 Dosage Form, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16661341	NON-EXPEDITED			US-PFIZER INC- 2019330248		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Keflex			S		Unk		Not Reported
	Cipro [Ciprofloxacin]			S		Unk		Not Reported
	Robinul			S		Unk		Not Reported
	Levothyroxine			C		175 Ug, 1x/Day (Every Am)		Not Reported
	Levothyroxine			C		50 Ug, Unk (On Sun & Thurs Only)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16756492	EXPEDITED (15-DAY)		DE, HO, LT	JP-DSJP-DSJ-2019- 132877			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Interstitial Lung Disease; Pneumonia; Pneumonia Bacterial	Lixiana Od Tablets 30mg			S	Oral	30 Mg, Qd		Daiichi
	Hanp For Injection 1000			S	Other	Unk		Not Reported
	Hanp For Injection 1000			S	Other	3000 Ug, Qd		Not Reported
	Bayaspirin			S	Oral	100 Mg, Qd		Not Reported
	Lansoprazole			S	Oral	15 Mg, Qd		Not Reported
	Verapamil /00014302/			S	Oral	40 Mg, Bid		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Atorvastatin /01326102/	S	Oral	10 Mg, Qd	Not Reported
Biseno	S	Other	4 Mg, Qd	Not Reported
Spironolactone	S	Oral	25 Mg, Qd	Not Reported
Ceftriaxone /00672202/	S	Other	2 G, Qd	Not Reported
Ceftriaxone /00672202/	S	Other	2 G, Qd	Not Reported
Lasix /00032601/	S	Other	Unk	Not Reported
Lasix /00032601/	S	Other	10 Mg, Bid	Not Reported
Heparin	S	Unknown	Unk	Not Reported
Azithromycin Hydrate	S		Unk	Not Reported
Methylprednisolone Na Succinate	S		125mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16795253	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019390748		71 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Bone Pain; Chest Discomfort; Decreased Appetite; Dizziness; Dysentery; Fatigue; Headache; Hyperhidrosis; Insomnia; Pyrexia; Swelling Face; Taste Disorder; Weight Decreased	Zitromax			S		500 Mg, Every 12 Hours		Pfizer
	Giasion			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16868721	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019415899		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective; Dysphagia; Intentional Product Misuse;	Zithromax			S		3 Df, Daily(Took Two Of The Pills In The Morning And Another One At 01:00 Am)		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oropharyngeal Pain; Pharyngeal Swelling; Pharyngitis	Xeljanz	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16879820	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2019420349		71 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperhidrosis; Hypersensitivity; Malaise; Nausea	Zitromax			S	Intravenous (not otherwise specified)	500 Mg, Total		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16880865	NON-EXPEDITED			US-PFIZER INC- 2019426262		67 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16881761	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2012103135		84 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Alveolar Haemorrhage	Novatrex			S	Oral	10 Mg, Weekly		Pfizer
	Novonorm			S	Oral	Unk		Not Reported
	Cortancyl			S	Oral	5 Mg, 1x/Day (5mg, Qd)		Not Reported
	Lasilix			S	Oral	40 Mg Twice Daily (Bid)		Not Reported
	Lasilix			S	Oral	80 Mg, 1x/Day		Not Reported
	Nitriderm Tts			S	Transdermal	10 Mg, 1x/Day (Qd)		Not Reported
	Xatral			S	Oral	Unk		Not Reported
	Forlax			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2019	16882318	DIRECT					22 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Gastric Ulcer	Azithromycin Tablets, Usp Zantac	Y		S C	Oral	Quantity:6 Tablet(S);	5 DAY	Sandoz Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	15275068	NON-EXPEDITED			US-PFIZER INC- 2018325502			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Azithromycin Amitriptyline			S S		Unk Unk		Pfizer Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	15497386	NON-EXPEDITED			US-PFIZER INC- 2018416746			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	15500906	NON-EXPEDITED			US-PFIZER INC- 2018416752			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	15731126	EXPEDITED (15-DAY)		OT	CA-SA-2018SA339535			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol	S		Unk Unk, Unk	Sanofi
	Arava	S		Unk	Sanofi
	Plaquenil	S		Unk	Sanofi
	Diphenhydramine Hydrochloride	S		Unk	Sanofi
	Celecoxib	S	Oral	Unk, Unk	Not Reported
	Levofloxacin	S		Unk, Unk	Not Reported
	Cyclophosphamide	S		Unk Unk, Unk	Not Reported
	Methotrexate	S		Unk Unk, Unk	Not Reported
	Azithromycin	S		250 Mg, Qd	Not Reported
	Cimzia	S		Unk, Unk	Not Reported
	Enbrel	S		Unk, Unk	Not Reported
	Humira	S		Unk, Unk	Not Reported
	Imuran [Azathioprine Sodium]	S		Unk	Not Reported
	Simponi	S		Unk, Unk	Not Reported
	Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Unk	Not Reported
	Xeljanz	S	Oral	5 Unk	Not Reported
	Ezetrol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16422034	EXPEDITED (15-DAY)		OT	CA-VIIV HEALTHCARE LIMITED- CA2019GSK098191			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Exposure During Pregnancy	Acyclovir			S	Transplacental	Unk		Glaxosmithkline
	Abacavir			S	Transplacental	300 Mg, Qd		Viiv
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline
	Bactrim			S	Transplacental	Unk		Glaxosmithkline
	Lamivudine			S		150 Mg, Unk		Viiv

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Viread	S	Transdermal	200 Mg, Qd	Glaxosmithkline
Zidovudine	S		300 Mg, Unk	Viiv
Intelence	S		200 Mg, Qd	Not Reported
Prezista	S		600 Mg, Unk	Not Reported
Raltegravir Potassium	S	Transplacental	400 Mg, Unk	Not Reported
Ritonavir	S	Transplacental	100 Mg, Unk	Not Reported
Iron	C		Unk	Not Reported
Magnesium Gluconate	C		Unk	Not Reported
Folic Acid	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16422089	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK098191			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Exposure During Pregnancy	Acyclovir			S	Transplacental	Unk		Glaxosmithkline
	Abacavir			S	Transplacental	300 Mg, Qd		Viiv
	Azithromycin			S	Transplacental	Unk		Glaxosmithkline
	Bactrim			S	Transplacental	Unk		Glaxosmithkline
	Lamivudine			S		150 Mg, Unk		Viiv
	Viread			S	Transdermal	200 Mg, Qd		Glaxosmithkline
	Zidovudine			S		300 Mg, Unk		Viiv
	Intelence			S		200 Mg, Qd		Not Reported
	Prezista			S		600 Mg, Unk		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Mg, Unk		Not Reported
	Ritonavir			S	Transplacental	100 Mg, Unk		Not Reported
	Iron			C		Unk		Not Reported
	Magnesium Gluconate			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16884219	EXPEDITED (15-DAY)		HO, OT	GB-TEVA-2019-GB-1117933			Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Azithromycin			S	Unknown			Not Reported	
Alanine Aminotransferase	Losartan 50mg			C				Not Reported	
Increased; Drug-Induced	Omeprazole			C				Not Reported	
Liver Injury; Serum Ferritin	Flixotide 250mg			C				Not Reported	
Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16886041	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2019-28500			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	5-Asa			S	Unknown	Unknown		Not Reported	
	Asacol			S	Unknown	Unknown		Not Reported	
	Azathioprine			S	Unknown	Unknown		Not Reported	
	Azithromycin			S	Unknown	Unknown		Not Reported	
	Ethinyl Estradiol/Levonorge Strel			S	Unknown	Unknown		Not Reported	
	Mercaptopurine			S	Unknown	Unknown		Not Reported	
	Mezavant			S	Unknown	Unknown		Not Reported	
	Para-Aminosalicylic Acid			S	Unknown	Unknown		Not Reported	
	Prednisone			C	Oral	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16886513	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1115532		70 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Pressure Systolic Increased; Cough;	Amlodipine	S	Oral	10 Milligram Daily;	Teva
Dizziness; Drug Ineffective; Dyspnoea;	Amlodipine	S	Oral	1 Dosage Forms Daily;	Teva
Epistaxis; Forced Vital Capacity Decreased;	Azithromycin	S	Oral		Not Reported
Headache; Lung Disorder;	Azithromycin	S	Oral		Not Reported
Malaise; Nasopharyngitis;	Xolair	S	Subcutaneous		Not Reported
Oxygen Saturation Decreased; Sputum Discoloured	Advair	C			Not Reported
	Asa	C			Not Reported
	Brilinta	C			Not Reported
	Hydrochlorothiazide	C			Not Reported
	Pantoprazole	C			Not Reported
	Singulair	C			Not Reported
	Spiriva	C			Not Reported
	Ventolin	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2019	16887078	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-PFIZER INC-2019426885			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis;	Azithromycin			S				Pfizer
Brain Abscess; Iris Adhesions; Multiple Allergies; Pancytopenia;	Novalgine [Metamizole Sodium]			S		Unk		Not Reported
Pneumonia; Rash; Sepsis;	Levetiracetam			S		1000 Absent, Qd		Not Reported
Toxic Epidermal Necrolysis	Nivolumab			S	Intravenous (not otherwise specified)	1 Milligram/Kilogram, Q3cycles		Not Reported
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Q3cycles		Not Reported
	Ranitidine			C	Unknown	300 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	10290135	NON-EXPEDITED			US-PFIZER INC-2014188558			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Septra	S	Unk	Pfizer
Sulfamethoxazole/Trimethoprim	S	Unk	Pfizer
Augmentin	S	Unk	Not Reported
Keflex	S	Unk	Not Reported
Macrobid	S	Unk	Not Reported
Amoxicillin/Clavulanate	S	Unk	Not Reported
Potassium Cephalexin [Cefalexin]	S	Unk	Not Reported
Nitrofurantoin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	15225746	NON-EXPEDITED			US-PFIZER INC-2018307479		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Keflex			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	15320129	NON-EXPEDITED			US-PFIZER INC-2018343951		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Micardis			S		Unk		Not Reported	
	Zyrtec Allergy			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16439526	NON-EXPEDITED			US-PFIZER INC-2019255491		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Gastrointestinal Disorder;
Nausea; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16682428	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019334056		26 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dermatitis Allergic;	Zitromax			S	Oral	1 Df, Total		Pfizer	
Dysphonia; Lip Oedema;	Rocefin			S	Intramuscular	1 Df, Total		Not Reported	
Pruritus									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16889538	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP023151		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Cyclosporine			S	Unknown	Unk		Apotex	
Mycobacterium Avium	Prednisone			S	Unknown	Unk		Not Reported	
Complex Infection	Azithromycin			S	Unknown	625 Mg, Qd		Apotex	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	800 Mg, Qd		Not Reported	
	Rifampin			S	Unknown	300 Mg, Qd		Not Reported	
	Insulin			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16889663	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2019425004		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product	Zitromax			S	Oral	500 Mg, Single		Pfizer	
Use In Unapproved									
Indication; Tachycardia									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16890585	NON-EXPEDITED			US-PFIZER INC-2019427642		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Zithromax			S	Oral	250 Mg, (Took Two The 1st Day And Then One Tablet Over The Next Four Days By Mouth Till Gone)		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16890740	EXPEDITED (15-DAY)		OT	CA-BAYER-2019-177650			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	Levonorgestrel			S	Unknown			Bayer	
	Azithromycin			S	Unknown			Not Reported	
	Mercaptopurine			S	Unknown			Not Reported	
	Azathioprine			S	Unknown			Not Reported	
	Asacol			S	Unknown			Not Reported	
	Infliximab			S	Unknown	50 Mg/Kg, Unk		Not Reported	
	5-Asa			S	Unknown			Not Reported	
	Para-Aminosalicylic Acid			S	Unknown			Not Reported	
	Mezavant			S	Unknown			Not Reported	
	Prednisone			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16891572	EXPEDITED (15-DAY)		DE, HO	AU-MYLANLABS-2019M1094130		55 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Piperacillin/Tazobactam			S	Unknown			Not Reported	
	Doxycycline			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Vancomycin	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Meropenem	S	Unknown	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2019	16892656	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2019M1092356		67 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Confusional State; Delirium	Azithromycin			S	Oral	Monday, Wednesday, Friday		Not Reported	
	Avamys			C	Nasal	In Each Nostril		Mylan	
	Carbocisteine			C		1500 Milligram, Qd		Mylan	
	Fostair			C	Respiratory (inhalation)	200micrograms/Dose / 6micrograms/Dose		Mylan	
	Salbutamol			C	Respiratory (inhalation)	Unk Unk, Prn		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Oct-2019	16875606	EXPEDITED (15-DAY)		OT	CN-ROCHE-2414880		68 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Marrow Failure; Cardiac Dysfunction; Cough; Extrasystoles; Gastrointestinal Haemorrhage; Haematemesis; Haematochezia; Pyrexia	Mabthera			S	Unknown			Not Reported	
	Cyclophosphamide			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Vincristine			S	Unknown			Not Reported	
	Prednisolone			S	Unknown			Not Reported	
	Etoposide			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	15692332	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08285			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16212904	NON-EXPEDITED			US-PFIZER INC-2019162596		47 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Benzylpenicillin Potassium			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	
	Celecoxib			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Clarithromycin			S		Unk		Not Reported	
	Oxycodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16642266	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-04493		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Swollen Tongue	Azithromycin Tablets Usp, 250 Mg			S	Oral	2 Dosage Form, Qd (2 Tabs P.. Day 1)		Lupin	
	Azithromycin Tablets Usp, 250 Mg			S	Oral	1 Dosage Form, Qd (One Daily For 5 Days)		Lupin	
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897073	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06296		38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anxiety; Dry Mouth	Azithromycin Tablets Usp, 250 Mg	S	Oral	250 Mg, Qd	Lupin
	Carvedil	C	Unknown	12.5 Mg, Bid	Not Reported
	Amlodipine	C	Unknown	5 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897074	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06621		13 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
No Adverse Event; Underdose	Azithromycin Tablets Usp, 250 Mg			S	Oral	Unk, Bid		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897075	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06169		14 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pain In Extremity; Vomiting	Azithromycin Tablets, 250 Mg			S	Oral	250 Mg, Bid		Lupin
	Azithromycin Tablets, 250 Mg			S	Oral	250 Mg, Qd		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897076	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-06267		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Pain; Headache; Pruritus	Azithromycin			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897122	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08250		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dermatitis Allergic; Feeling Hot	Azithromycin Tablets Usp, 250 Mg	S	Oral	2 Df, Unk	Lupin
	Azithromycin Tablets Usp, 250 Mg	S	Oral	1 Df, Qd	Lupin
	Levothyroxine	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897123	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-08293			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Duloxetine			S	Unknown	Unk		Lupin
	Azithromycin			S	Unknown	Unk		Lupin
	Gabapentin			C	Oral	600 Mg, Tid		Not Reported
	Gabapentin			C	Oral	600 Mg, Tid		Not Reported
	Hydrocodone Bitartrate And Acetaminophen			C	Unknown	10/325 G, 6 Hours, Prn		Not Reported
	Diazepam			C	Oral	5 Mg, Prn, 1-2, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897125	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01148			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Suspected Product Quality Issue	Azithromycin Tablets Usp, 250 Mg			S	Oral	Unk (2 Tablet By Mouth Today And Then Take One Tablet Daily For 4 Days)		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897126	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2018-07744			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Sinusitis		Azitromed 500 Mg Tablets		S	Unknown		1 Tablet On Day For 6 Days		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897127	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2018-08973			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Burning Sensation; Mouth Swelling; Pharyngeal Swelling; Speech Disorder	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Bid		Lupin		
	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Mg, Qd		Lupin		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897128	NON-EXPEDITED			CA-LUPIN PHARMACEUTICALS INC.-2018-07920			Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Rash	Azithromycin			S	Unknown	Unk		Lupin		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897129	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-00136			Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Faeces Discoloured	Azithromycin Tablets			S	Unknown	Unk		Lupin		
	Eliquis			C	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897130	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-00850			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Myasthenia Gravis	Azithromycin Tablets Usp, 250			S	Unknown	Unk		Lupin		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mg

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897131	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2018-09135		86 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea; Insomnia	Azithromycin Tablets Usp, 250 Mg Lipitor			S	Oral	250 Mg, 2df, Qd		Lupin	
				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897133	NON-EXPEDITED			BR-LUPIN PHARMACEUTICALS INC.-2018-07317			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azitromed 500 Mg Tablets			S	Unknown	1 Df, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897134	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-00963			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Azithromycin Tablets			S	Unknown	Unk		Lupin	
	Morphine Sulphate			S	Unknown	Unk		Novel Labs	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897135	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01009			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Azithromycin Tablets, 250 Mg			S	Oral	250 Milligram, Bid		Lupin	
	Azithromycin Tablets, 250 Mg			S	Oral	250 Milligram, Qd (One Dose Per Day For The		Lupin	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Methylphenidate			C	Unknown	Next Four Days)		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897136	NON-EXPEDITED			US-LUPIN HEALTHCARE (UK) LIMITED-2019-00664			Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Product Package Associated Injury; Product Packaging Difficult To Open	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin		
	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897137	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-00338			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Acne; Rash	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk (3 Doses)		Lupin		
	Advil /00044201/			C	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897142	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01389			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Discomfort; Abdominal Pain; Nausea	Azithromycin Tablets			S	Unknown	Unk		Lupin		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
09-Oct-2019	16897446	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02268		81 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pruritus; Urticaria	Azithromycin Tablets Usp, 250 Mg	S	Oral	2 Dosage Form, Qd	Lupin
	Pravastatin	C	Unknown	Unk	Not Reported
	Diphenhydramine Hcl	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897452	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-03421		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dizziness; Headache	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Milligram, Qd		Lupin
	Phenobarbital			C	Unknown	Unk		Not Reported
	Vitamin D [Colecalciferol]			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897453	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02260			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nausea; Pyrexia; Vomiting	Azithromycin			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897455	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02302			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vomiting	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897456	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02897			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897458	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01731		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous; Skin Warm; Swelling	Azithromycin Tablets, 250 Mg			S	Oral	Unk Unk, Qd, 2 Tablets		Lupin	
	Azithromycin Tablets, 250 Mg			S	Oral	Unk, 1 Tablet		Lupin	
	Azithromycin Tablets, 250 Mg			S	Oral	Unk Unk, Qd, 1 Tablet		Lupin	
	Azithromycin Tablets, 250 Mg			S	Oral	Unk Unk, Qd, 1 Tablet		Lupin	
	Tessalon Perle			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897459	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-03306			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pyrexia	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897461	NON-EXPEDITED			PT-LUPIN PHARMACEUTICALS INC.-2019-02294		83 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Symmetrical Drug-Related Intertriginous And Flexural Exanthema	Amoxicillin And Clavulanic Acid			S	Unknown	Unk (8 Years Ago)		Not Reported	
	Azithromycin			S	Unknown	Unk (8 Years Before)		Lupin	
	Azithromycin			S	Unknown	Unk (Current Dose)		Lupin	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897462	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-05272			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Hyperhidrosis; Malaise	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897463	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02528		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Nausea	Azithromycin Tablets Usp, 250 Mg			S	Oral	1 Dosage Form, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897464	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-03130		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chills; Cough; Headache; Pain; Pyrexia	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Milligram, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897465	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-02076			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache	Azithromycin Tablets Usp, 250 Mg			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16897467	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-01959		86 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Milligram, 250 Mg Bid On Day 1 And 250 Mg Daily		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16898705	NON-EXPEDITED			US-PFIZER INC-2019430580		78 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16899187	NON-EXPEDITED			US-PFIZER INC-2019432725			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amlodipine Besilate			S		Unk		Pfizer	
	Dilantin			S		Unk		Pfizer	
	Fluconazole			S		Unk		Pfizer	
	Cerebyx			S		Unk		Pfizer	
	Fosphenytoin Sodium			S		Unk		Unknown	
	Ibuprofen			S		Unk		Pfizer	
	Phenobarbital			S		Unk		Unknown	
	Phenytoin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Acyclovir			S		Unk		Not Reported	
	Allopurinol			S		Unk		Not Reported	
	Carbamazepine			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Carbatrol	S	Unk	Not Reported
Tegretol	S	Unk	Not Reported
Cilostazol	S	Unk	Not Reported
Lunesta	S	Unk	Not Reported
Isovue	S	Unk	Not Reported
Phenytek	S	Unk	Not Reported
Propafenone	S	Unk	Not Reported
Rifadin	S	Unk	Not Reported
Rifampin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16899502	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- SLTR-AE-19-105		64 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Cyanosis; Depressed Level Of Consciousness; Electrocardiogram Qt Prolonged; Feeling Hot; Flushing; Hyperglycaemia; Hyperhidrosis; Hypotension; Hypoxia; Liver Function Test Abnormal; Nausea; Tachypnoea	Ceftriaxone 70436-019-82 Azithromycin For Injection Dry Vial Usp 500 Mg			C S	Intravenous (not otherwise specified)			Not Reported Hainan Poly Pharmaceuticals	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16900445	NON-EXPEDITED			US-PFIZER INC- 2019429917			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16900920	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1119178			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Exposure During Pregnancy	Acyclovir			S	Transplacental			Teva
	Azithromycin			S	Transplacental			Not Reported
	Abacavir			S	Transplacental	300 Milligram Daily;		Not Reported
	Bactrim			S	Transplacental			Not Reported
	Intelence			S	Unknown	200 Milligram Daily;		Not Reported
	Lamivudine			S	Unknown			Not Reported
	Prezista			S	Unknown			Not Reported
	Raltegravir Potassium			S	Transplacental			Not Reported
	Ritonavir			S	Transplacental			Not Reported
	Viread			S	Transdermal	200 Milligram Daily;		Not Reported
	Zidovudine			S	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Magnesium Gluconate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Oct-2019	16901523	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2019-065226		59 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Aplasia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Soliris			S	Intravenous (not otherwise specified)	1200 Milligram For 21 Days		Not Reported
	Cellcept			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2019	15497882	NON-EXPEDITED			US-PFIZER INC-2018409159			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2019	16030875	NON-EXPEDITED			US-PFIZER INC-2016228347		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Cephalexin			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Repatha			S		Unk		Not Reported	
	Metformin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2019	16902196	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-065523		77 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin Film-Coated Tablets			S	Unknown	250 Milligram, Unk		Aurobindo	
	Enoxaparin			C	Unknown	40 Milligram, Unk		Not Reported	
	Lidocaine			C	Unknown	1 Dosage Form, Unk		Not Reported	
	Lorazepam			C	Unknown	0.5 Milligram, Unk		Not Reported	
	Ranitidine			C	Unknown	150 Milligram, Unk		Not Reported	
	Diazepam			C	Unknown	2 Milligram, Unk		Not Reported	
	Codeine Phosphate			C	Unknown	15-30 Mg		Not Reported	
	Docusate Sodium			C	Unknown	200 Milligram, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ibuprofen	C	Unknown	200 Milligram, Unk	Not Reported
Oxygen	C	Unknown	1-2 Litres/Minute Unchecked Units	Not Reported
Biotene Dry Mouth	C	Unknown	1-2 Application(S) Unchecked Units	Not Reported
Paracetamol	C	Unknown	500 Milligram, Unk	Not Reported
Omeprazole	C	Unknown	10 Milligram, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2019	16904801	EXPEDITED (15-DAY)		HO, LT	GB-MYLANLABS- 2019M1095530		78 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenic Sepsis	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Amitriptyline Hydrochloride			C		Unk		Mylan
	Salbutamol			C		Unk		Mylan
	Ethambutol			C		Unk		Mylan
	Seretide			C		Unk		Mylan
	Accrete D3			C		Unk		Mylan
	Rifampicin			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Oct-2019	16905789	NON-EXPEDITED			US-TEVA-2019-US- 1120310			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	13421858	NON-EXPEDITED			US-PFIZER INC- 2017148716			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Rash	Zithromax	S	Unk	Pfizer
	Bactrim	S	Unk	Not Reported
	Keflex	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16285085	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2019-02801		14 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Anxiety; Blood Pressure Increased; Malaise; Nervousness; Paranoia; Tremor	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Milligram, Bid (500 Mg, Two Tablets)		Lupin
	Azithromycin Tablets Usp, 250 Mg			S				Lupin
	Azithromycin Tablets Usp, 250 Mg			S				Lupin
	Azithromycin Tablets Usp, 250 Mg			S				Lupin

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16862127	EXPEDITED (15-DAY)		DE	US-AUROBINDO-AUR- APL-2019-062637		80 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo
	Piperacillin+Tazobactam			S	Unknown	Unk		Aurobindo
	Vancomycin			S	Unknown	Unk		Aurobindo
	Oseltamivir			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16906646	EXPEDITED (15-DAY)		OT	US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-096605		19 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Pneumonia	Eliquis			S	Oral	5 Milligram, Bid		Bristol Myers Squibb

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax	S	Unknown	Unk	Not Reported
Zofran [Ondansetron Hydrochloride]	C	Unknown	Unk	Not Reported
Nucala	C	Unknown	100 Milligram, Q4wk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16906810	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-TEVA-2019-CA-1119311		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Amiodarone			S	Unknown			Teva
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported
	Diltiazem			S	Oral			Teva
	Furosemide			S	Oral	40 Milligram Daily;		Ivax
	Hydromorphone			S	Intravenous (not otherwise specified)			Actavis
	Methylprednisolone			S	Intravenous (not otherwise specified)			Not Reported
	Paclitaxel			S	Intravenous (not otherwise specified)			Not Reported
	Adriamycin			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram Daily;		Not Reported
	Hydralazine			S	Intravenous (not otherwise specified)			Not Reported
	Metoprolol			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metoprolol	S	Intravenous (not otherwise specified)	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified)	Not Reported
Procytox	S	Intravenous (not otherwise specified) 1060 Milligram Daily;	Not Reported
Trastuzumab	S	Unknown	Not Reported
Dexamethasone	C	Unknown	Not Reported
Emend	C	Unknown	Not Reported
Filgrastim	C	Unknown	Not Reported
Gabapentin	C	Unknown	Not Reported
Metoclopramide	C	Unknown	Not Reported
Ondansetron	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16907046	EXPEDITED (15-DAY)		CA, HO	FR-TEVA-2019-FR-1120026		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia	Azithromycine Anhydre			S	Oral	500 Mg, 1 Day		Not Reported	
	Soliris			S	Intravenous (not otherwise specified)	1200 Mg Per 21 Days		Not Reported	
	Cellcept 500 Mg, Poudre Pour Solution A Diluer Pour Perfusion			S	Intravenous (not otherwise specified)	2 Gram Per 24 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16907710	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-065818		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urethral Stenosis	Azithromycin	S	Oral	250 Milligram, Once A Day	Aurobindo				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Oct-2019	16908483	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2019435754		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Soliris			S	Intravenous (not otherwise specified)	1200 Mg, (1 Injection/21 Days)		Not Reported	
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S	Intravenous (not otherwise specified)	2 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2019	16910653	EXPEDITED (15-DAY)	HO		FR-ROCHE-2432554		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia	Cellcept [Mycophenolate Mofetil]			S	Intravenous (not otherwise specified)			Not Reported	
	Soliris			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycine			S	Oral	Recent Dose On 01/Sep/2019		Not Reported	
	Cortancyl			C	Unknown			Not Reported	
	Pantoprazole			C	Unknown			Not Reported	
	Oracilline [Phenoxymethylpenicillin]			C	Unknown			Not Reported	
	Ramipril			C	Unknown			Not Reported	
	Lasilix [Furosemide]			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2019	16911012	EXPEDITED (15-DAY)	OT		FR-ACCORD-157501		68 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Lamprene			S	Oral	Strength: 100 Mg		Not Reported	
	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported	
	Amiklin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	15749369	NON-EXPEDITED			US-PFIZER INC-2018525879		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16383550	EXPEDITED (15-DAY)		DE, HO, OT	CZ-BAYER-2019-106620		68 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Hepatotoxicity; Multiple Organ Dysfunction Syndrome	Avelox			S		Unk		Bayer	
	Voriconazole			S		Unk		Not Reported	
	Amiodarone			S	Intravenous (not otherwise specified)	1800 Mg, Qd		Not Reported	
	Amiodarone			S	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Cotrimoxazole			S		Unk		Not Reported	
	Atorvastatin			C		Unk		Not Reported	
	Meropenem			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nitric Oxide	C	Unk	Not Reported
Esmolol	C	Unk	Not Reported
Metoprolol	C	Unk	Not Reported
Valsartan	C	Unk	Not Reported
Hydrochlorothiazide	C	Unk	Not Reported
Metformin	C	Unk	Not Reported
Gliclazide	C	Unk	Not Reported
Acetylsalicylic Acid	C	Unk	Not Reported
Dexmedetomidine	C	Unk	Not Reported
Piperacillin/Tazobactam	C	Unk	Not Reported
Propofol	C	Unk	Not Reported
Nitrendipine	C	Unk	Not Reported
Fenofibrate	C	Unk	Not Reported
Morphine	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16863535	NON-EXPEDITED			US-PFIZER INC-2019419351		49 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Influenza Vaccine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16913913	NON-EXPEDITED			US-PFIZER INC-2019439778			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16915157	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019439323		21 DAY	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Decreased; Oxygen Saturation Decreased; Pallor	Azithromycin Glucose			S C	Intravenous drip Intravenous drip	0.017 G, 1x/Day 17 MI, 1x/Day		Pfizer Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16915929	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2019M1096426		78 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Cough; Delirium; Febrile Neutropenia; Malaise; Night Sweats; Pyrexia; Skin Abrasion; Urticaria	Azithromycin Meropenem Enoxaparin Rifampicin Oilatum /01690401/ Fexofenadine Salbutamol Ethambutol Amitriptyline Adcal D3 Paracetamol Seretide Cetraben /01690401/ Betnovate C			S C C C C C C C C C C C C C	Oral	250 Milligram, Qd Unk Unk Unk (Stopped Last Week) Unk Unk Unk Unk (Stopped Last Week) Unk Unk Unk Unk Unk Unk		Not Reported Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Oct-2019	16919303	DIRECT		OT			8 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Swelling; Urticaria	Azithromycin For Oral Suspension	Y		S	Oral			Zydus Pharm
	Xyzol			C				Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	15238185	EXPEDITED (15-DAY)		HO, OT	NL-AUROBINDO-AUR-APL-2018-038971		65 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Appetite Disorder; Back Pain; Bone Pain; Chronic Obstructive Pulmonary Disease; Dehydration; Dizziness; Fatigue; Headache; Hypersensitivity; Malaise; Myalgia; Nausea; Pneumonia; Sense Of Oppression; Vomiting; Weight Decreased	Azithromycin			S	Oral	3 Unk, Once A Day		Aurobindo
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported
	Teriparatide			S	Subcutaneous	20 Ug, Qd		Not Reported
	Adenuric			S	Unknown	Unk, Unknown		Not Reported
	Nebusal			S	Respiratory (inhalation)	2 Df, Qd, Nebuliser Solution		Not Reported
	Spironolacton			C	Oral	1 Df, Qd		Not Reported
	Beclometasone Dipropionate W/Formoterol Fumar			C	Oral	2 Df, Tid, Aerosol (Spray And Inhalation)		Not Reported
	Budesonide			C	Oral	Unk, Inhaler		Not Reported
	Pantoprazol /01263201/			C	Oral	1 Df, Bid		Not Reported
	Itraconazol			C	Oral	1 Df, Bid		Not Reported
	Macrogol			C	Oral	Unk ()		Not Reported
	Benzbromaron			C	Oral	1 Df, Daily		Not Reported
	Benzbromaron			C	Oral	0.5 Df, Qd		Not Reported
	Levothyroxine			C	Oral	3 Df, Qd		Not Reported
	Levothyroxine			C		1 Df, Qd		Not Reported
	Paracetamol			C	Oral	1 Df, Qid		Not Reported
	Paracetamol			C	Oral	1 Df, Tid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hidroxocobalamina	C	Subcutaneous	Unk	Not Reported
Kaliumchloride	C	Oral	3d1t	Not Reported
Oxicodona	C	Oral	2 Df, Qid	Not Reported
Colchicine	C	Oral	1 Df, Bid	Not Reported
Codeine	C	Oral	1 Df, Tid	Not Reported
Sodium Chloride	C	Subcutaneous	1 Df, Monthly (1/M)	Not Reported
Paracetamol Codeine	C	Rectal	Unk	Not Reported
Acetylcysteine	C	Oral	1 Df, Daily	Not Reported
Calciumcarbonaat	C	Oral	2 Df, Qd, Chewable Tablet	Not Reported
Ipratropium W/Salbutamol	C	Oral	Unk	Not Reported
Algeldrate W/Magnesium Hydroxide	C	Oral	15 MI, Bid, Suspension	Not Reported
Fentanyl	C	Topical	Unk	Not Reported
Oxycodon	C	Oral	Unk	Not Reported
Labetalol	C	Oral	1 Df, Daily	Not Reported
Sumatriptan	C	Oral	Unk	Not Reported
Desloratadine	C	Oral	1 Df, Bid	Not Reported
Metoclopramide	C	Oral	1 Df, Prn, Suppository	Not Reported
Metoclopramide	C	Rectal	Unk	Not Reported
Colistine /00013201/	C	Oral	1 Df, Bid	Not Reported
Ezetimibe W/Simvastatin	C	Oral	1 Df, Qd	Not Reported
Pregabalin	C	Oral	3 Df, Bid	Not Reported
Salbutamol	C	Respiratory (inhalation)	Unk, Respiratory	Not Reported
Nystatine	C	Oral	5 MI, Qid	Not Reported
Colecalciferol	C	Oral	2 Df, Unk, Liquid	Not Reported
Moxifloxacin	C	Oral	1 Df, Qd	Not Reported
Carbasalaatcalcium	C	Oral	1 Df, Qd	Not Reported
Metformine /00082701/	C	Oral	1 Df, Bid	Not Reported
Prednisolon /00016201/	C	Unknown	1 Df, Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tiotropium	C	Oral	2 Df, Qd	Not Reported
Nortriptyline	C	Oral	Unk	Not Reported
Bumetanide	C	Oral	1 Df, Bid	Not Reported
Fluticasone Furoate	C	Nasal	2 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	15770675	NON-EXPEDITED			US-PFIZER INC-2018534059		90 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Diclofenac Sodium			S		Unk		Pfizer
	Ketorolac Tromethamine			S		Unk		Pfizer
	Piperacillin			S		Unk		Unknown
	Topiramate			S		Unk		Not Reported
	Divalproex Sodium			S		Unk		Not Reported
	Simvastatin			S		Unk		Not Reported
	Tazobactam Sodium			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16449263	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033865		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chapped Lips; Cough; Dry Mouth; Dysphagia; Eczema; Eye Pruritus; Eye Swelling; Fatigue; Formication; Hypoaesthesia; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Mouth Swelling; Oral Pruritus; Peripheral Swelling; Pruritus; Psoriasis;	Azithromycin			S	Unknown	250 Milligram		Aurobindo
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	300 Milligram		Not Reported
	Benadryl			C	Oral	1 Dosage Form		Not Reported
	Cetirizine Hydrochloride			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Prednisone			C	Oral	1 Dosage Form		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Respiratory Tract Infection; Skin Exfoliation; Speech Disorder; Stomatitis; Stress; Swelling; Therapeutic Response Shortened; Urticaria	Singulair Singulair Cetirizine Diphenhydramine Hydrochloride	C C C C	Unknown Oral Oral Oral	Unk 10 Milligram, Once A Day 1 Dosage Form, Once A Day 1 Dosage Form	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16823572	NON-EXPEDITED			US-PFIZER INC-2019399718			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16916976	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019444647		20 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Pneumonia	Eliquis			S	Oral	5 Milligram, Bid		Not Reported	
	Zithromax			S	Unknown	Unk		Pfizer	
	Zofran [Ondansetron Hydrochloride]			C	Unknown	Unk		Not Reported	
	Nucala			C	Unknown	100 Milligram, Q4wk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16917718	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-066566			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Exposure During Pregnancy; Maternal Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo	
	Lamivudine			S	Transplacental	150.0 Milligram		Aurobindo	
	Zidovudine			S	Transplacental	300.0 Milligram		Aurobindo	
	Acyclovir			S	Transplacental	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bactrim	S	Unknown	Unk	Not Reported
Intelence	S	Transplacental	1.0 Dosage Form, Once A Day	Not Reported
Intelence	S	Unknown	200 Milligram, Once A Day	Not Reported
Prezista	S	Transplacental	600.0 Milligram	Not Reported
Raltegravir Potassium	S	Transplacental	400.0 Milligram	Not Reported
Sulfamethoxazole;Trimethoprim	S	Transplacental	Unk	Not Reported
Ritonavir	S	Transplacental	100.0 Milligram	Not Reported
Viread	S	Transdermal	300.0 Milligram	Not Reported
Abacavir	C	Transplacental	300.0 Milligram	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16917722	EXPEDITED (15-DAY)	OT		CA-AUROBINDO-AUR- APL-2019-066570			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Exposure During Pregnancy	Azithromycin			S	Transplacental	Unk		Aurobindo	
	Lamivudine			S	Unknown	150.0 Milligram		Aurobindo	
	Zidovudine			S	Unknown	300.0 Milligram		Aurobindo	
	Abacavir			S	Transplacental	300.0 Milligram, Once A Day		Not Reported	
	Acyclovir			S	Transplacental	Unk		Not Reported	
	Bactrim			S	Transplacental	Unk		Not Reported	
	Intelence			S	Unknown	200.0 Milligram, Once A Day		Not Reported	
	Prezista			S	Unknown	600.0 Milligram		Not Reported	
	Raltegravir Potassium			S	Transplacental	400.0 Milligram		Not Reported	
	Ritonavir			S	Transplacental	100.0 Milligram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Viread	S	Transdermal	200.0 Milligram, Once A Day	Not Reported
Folic Acid	C	Unknown	Unk	Not Reported
Iron	C	Unknown	Unk	Not Reported
Magnesium Gluconate	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16917798	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-066782		60 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis	Azithromycin			S	Unknown	Unk		Aurobindo	
	Breo Ellipta			S	Unknown	Unk, Once A Day		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Salbutamol			S	Unknown	Unk		Not Reported	
	Spiriva			S	Unknown	Unk, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16918324	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019435795		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Tigecycline			S	Intravenous (not otherwise specified)	100 Mg, 1x/Day		Pfizer	
	Lamprene [Clofazimine]			S	Oral	1 Df, 1x/Day		Not Reported	
	Cefoxitine			S	Intravenous (not otherwise specified)	12 G, 1x/Day		Not Reported	
	Amiklin [Amikacin]			C	Intravenous (not otherwise specified)	Unk (Inconnue)		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16918632	EXPEDITED (15-DAY)		HO	GB-MYLANLABS-2019M1095564		33 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Pain; Chest Discomfort; Condition Aggravated; Cough; Decreased Appetite; Dry Throat; Hypersomnia; Influenza; Nasopharyngitis	Azithromycin			S	Oral	250 Milligram, Qd (Each Morning 28 Days)		Not Reported	
	Creon			S	Oral	10000 Milligram (5 Capsule Three Times A Day With Food 07:00, 12:00, 17:00)		Mylan	
	Omeprazole			S	Oral	40 Milligram		Not Reported	
	Colecalciferol			S	Oral	800 Dosage Form, Qd (Capsules/Tablets, 800 Unit Each Morning 28 Days)		Not Reported	
	Salbutamol			S	Unknown	100 Microgram, Prn (2 Puff(S) Prn 28 Days) (Inhalant)		Not Reported	
	Montelukast			S	Oral	10 Milligram, Qd (Each Night 28 Days)		Not Reported	
	Zopiclone			S	Oral	3.75 Milligram, Qd (Each Night 28 Days)		Not Reported	
	Docusate Sodium			S	Oral	200 Milligram, Qd (200 Milligram Daily)		Mylan	
	Macrogol			S	Oral	1sachet Twice Daily At Loam And 10pm 10 Days		Mylan	
	Paracetamol			S	Oral	Max 4g Daily 1000 Mg Four Times A Day Prn 7 Days		Mylan	
	Paracetamol			S		Unk		Mylan	
	Multivitamins /00116001/			S	Oral	1 Dosage Form, Qd (Tablets/Capsules - 1 Tablet Each Morning 28 Days)		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ciclesonide	S	Unknown	160 Microgram, Qd (Each Morning) (Inhalant)	Mylan
Sodium Chloride	S	Unknown	4 Milliliter, Qd (4 MI Every Morning At 6 A.M., Mucolytic)	Mylan
Tocopheryl Acetate-D-Alpha	S	Oral	134 Milligram, Qd (Every Morning At 6 A.M.)	Mylan
Fluticasone	S	Unknown	27.5 Microgram, Qd (Each Morning)	Mylan
Colobreathe	S		Unk	Mylan
Dornase Alfa	S	Unknown	2.5 Milligram, Qd (2.5 Mg Each Morning 2~ Days, Mucolytic)	Mylan
Vitamin A & D /00343801/	S	Oral	2 Dosage Form, Qd (2 Capsules Every Morning At 6 A.M.)	Mylan
Colobreathe	S	Respiratory (inhalation)	2 Dosage Form, Qd (1,662,500 Iu; Twice Daily.)	Mylan
Sodium Chloride	S	Oral	600 Milligram, Tid (1800 Mg Three Times A Day)	Mylan
Symbicort	S	Unknown	Budesonide 200mcg I Formetrol6mcg, 2 Puff(S) Twice Daily Morning	Mylan
Carbocisteine	S	Oral	750 Mg Three Times A Day, Mucolytic	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16918808	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019443603			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pulmonary Fibrosis	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16919213	NON-EXPEDITED			US-PFIZER INC- 2019441786			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Reaction To Excipient	Azithromycin			S		Unk		Pfizer	
	Gluten			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Oct-2019	16920471	EXPEDITED (15-DAY)		DE, HO	US-TARO PHARMACEUTICALS USA.,INC- 2019SUN00533		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Multiple Organ Dysfunction Syndrome; Toxic Epidermal Necrolysis	Lamotrigine			S	Unknown	Unk		Taro	
	Amoxicillin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Clozapine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16904707	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019430937		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Toxicity; Neurotoxicity; Off Label Use; Product Use Issue; Toxicity To Various Agents	Azithromycin			S		Unk		Pfizer	
	Tigecycline			S		Unk		Pfizer	
	Amikacin Sulfate			S	Respiratory (inhalation)	Unk (Inhaled)		Unknown	
	Clofazimine			S		Unk		Not Reported	
	Basiliximab			C		Unk		Not Reported	
	Methylprednisolone			C		Unk		Not Reported	
	Mycophenolate Mofetil			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tacrolimus	C	Unk	Not Reported
Prednisone	C	Unk	Not Reported
Trimethoprim Sulfamethoxazole	C	Unk	Not Reported
Valganciclovir	C	Unk	Not Reported
Posaconazole	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16922952	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1121403		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urethral Stenosis	Azithromycine Anhydre			S	Oral	250 Mg 1 Days		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16923209	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-066380		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Toxicity; Neurotoxicity; Toxicity To Various Agents	Azithromycin			S	Unknown	Unk		Aurobindo	
	Tigecycline			S	Unknown	Unk		Aurobindo	
	Amikacin			S	Respiratory (inhalation)	Unk		Not Reported	
	Clofazimine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16923392	EXPEDITED (15-DAY)		OT	US-APOTEX-2019AP023572		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Toxicity; Mycobacterium Abscessus Infection; Neurotoxicity	Mycophenolate			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Tigecycline			S	Unknown	Unk		Apotex	
	Clofazimine			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amikacin	S	Unknown	Unk	Not Reported
Basiliximab	S	Unknown	Unk	Not Reported
Methylprednisolone	S	Unknown	Unk	Not Reported
Tacrolimus	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Trimethoprim Sulfamethoxazole	C	Unknown	Unk	Not Reported
Valganciclovir	C	Unknown	Unk	Not Reported
Posaconazole	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924011	EXPEDITED (15-DAY)		OT	NVSC2019ES001321			Unknown	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Gentamicin			S	Transplacental	Unk		Novartis
	Dexamethasone			S	Transplacental	Unk		Not Reported
	Azithromycin Dihydrate			S	Transplacental	Unk Unk, Once/Single		Not Reported
	Propamidine Isetionate			S	Transplacental	Unk Unk, Qh		Not Reported
	Chlorhexidin			S	Transplacental	Unk (Every Two Hours)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924012	EXPEDITED (15-DAY)		HO	NVSC2019US001089			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924234	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019440390		64 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Off Label Use; Product Use In Unapproved Indication; Urethral Stenosis	Azithromycin	S	Oral	250 Mg, 1x/Day	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924276	EXPEDITED (15-DAY)		HO	FR-ZYDUS-042032		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia	Azithromycin			S	Oral			Zydus Pharm	
	Soliris			S	Intravenous (not otherwise specified)			Not Reported	
	Cellcept			S	Intravenous (not otherwise specified)	Powder For Concentrate For Solution For Infusion		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924361	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019444928		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Atorvastatin Calcium			S	Oral	20 Mg, Unk		Pfizer	
	Apo Azithromycin			S	Oral	250 Mg, 2x/Day		Not Reported	
	Seebri Breezhaler			S		50 Mg, 1x/Day		Not Reported	
	Calcium Carbonate			C		Unk		Not Reported	
	Dexilant			C		Unk (Delayed Release)		Not Reported	
	Fosamax			C		Unk		Not Reported	
	Montelukast			C		Unk		Not Reported	
	Pulmicort			C		Unk (Suspension Inhalation)		Not Reported	
	Qvar			C		Unk (Inhalation)		Not Reported	
	Remicade			C		Unk (Powder For Solution Intravenous)		Not Reported	
	Salbutamol			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924435	EXPEDITED (15-DAY)		OT	FR-ZYDUS-042112		64 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urethral Stenosis	Azithromycin			S	Oral			Zyduz Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924524	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2019M1097668		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Toxicity; Neurotoxicity	Azithromycin			S	Unknown	Unk		Not Reported
	Amikacin			S		Unk		Mylan
	Clofazimine			S	Unknown	Unk		Mylan
	Tigecycline			S	Unknown	Unk		Mylan
	Mycophenolate Mofetil			C	Unknown	Unk		Mylan
	Tacrolimus			C	Unknown			Mylan
	Prednisone			C	Unknown	Unk		Mylan
	Trimethoprim Sulfamethoxazole			C	Unknown	Unk		Mylan
	Posaconazole			C	Unknown	Unk		Mylan
	Valganciclovir			C	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924558	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1097730		2 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Not Reported
	Clindamycin			S	Unknown	Unk		Not Reported
	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Cefotaxime		S	Unknown	Unk			Mylan	
	Ceftriaxone		S	Unknown	Unk			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924746	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019446213		23 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain; Nausea; Syncope	Zithromax			S	Oral	0.25 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924871	NON-EXPEDITED			US-PFIZER INC-2019445985		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk [5 Day Dose Pack]		Pfizer	
	Codeine			S		Unk		Not Reported	
	Hydralazine			S		Unk		Not Reported	
	Hydrochlorothiazide			S		Unk		Not Reported	
	Povidone Iodine			S	Topical	Unk		Not Reported	
	Rocephin			S		Unk		Not Reported	
	Phenergan [Promethazine]			S		Unk		Not Reported	
	Augmentine [Amoxicillin Sodium;Clavulanate Potassium]			S		Unk		Not Reported	
	Betadine [Povidone-Iodine]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16924910	NON-EXPEDITED			US-PFIZER INC-2019446360			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levaquin	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Oct-2019	16925633	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019442489		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased; Coccydynia; Contusion; Crying; Discomfort; Dizziness Exertional; Dry Skin; Dyspnoea; Dyspnoea Exertional; Ear Pain; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Headache; Headache; Heart Rate Increased; Myalgia; Nausea; Oxygen Saturation Decreased; Pain In Extremity; Respiratory Rate Increased; Scratch; Vision Blurred	Atorvastatin Calcium			S	Unknown	Unk		Pfizer
	Azithromycin Sandoz			S	Unknown	Unk		Not Reported
	Fentanyl Sandoz			S	Unknown	Unk		Not Reported
	Montelukast Sandoz			S	Unknown	Unk		Not Reported
	Pantoprazole Sandoz			S	Unknown	Unk		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	375 Mg, Cyclic 1 Every 2 Weeks		Not Reported
	Advair			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Reactine [Cetirizine Hydrochloride]			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Ventolin [Salbutamol]			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16928502	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2019AP023415		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Ear Discomfort; Granulomatosis With Polyangiitis; Haemoptysis	Azithromycin			S	Unknown	Unk		Apotex
	Amikacin			S	Unknown	Unk		Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16929092	EXPEDITED (15-DAY)		HO	US-GLAND PHARMA LIMITED-2075767		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ecchymosis; Petechiae; Thrombocytopenia	Azithromycin Monohydrate			S				Gland Pharma

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16929683	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2019445007		67 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Atorvastatin Calcium			S	Oral	20 Mg, Unk		Pfizer
	Apo Azithromycin			S	Oral	250 Mg, 2x/Day		Not Reported
	Seebri Breezhaler			S	Respiratory (inhalation)	50 Mg, 1x/Day (1 Every 24 Hour)		Not Reported
	Alendronate Sodium			C		Unk		Not Reported
	Calcium Carbonate			C		Unk		Not Reported
	Dexilant			C		Unk		Not Reported
	Montelukast			C		Unk		Not Reported
	Pulmicort			C		Unk		Not Reported
	Qvar			C		Unk		Not Reported
	Remicade			C		Unk		Not Reported
	Salbutamol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16930021	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019448833			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Azithromycin			S	Oral	250 Mg, Unk		Pfizer
	Azithromycin			S				Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alendronate	S	Oral	35 Mg, Unk	Not Reported
Alendronate	S			Not Reported
Ventolin [Salbutamol]	S	Unknown	8 Df, Unk	Not Reported
Xolair	S	Subcutaneous	150.0 Mg, Unk	Not Reported
Xolair	S	Subcutaneous	150.0 Mg, Unk	Not Reported
Calcium Carbonate	C		Unk	Not Reported
Ciclesonide	C		Unk	Not Reported
Montelukast	C		Unk	Not Reported
Spiriva	C		Unk	Not Reported
Symbicort	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16930025	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449208		86 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypotension; Oxygen Saturation Decreased	Zithromax			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer
	Asa			C		Unk		Not Reported
	Atrovent Hfa			C		Unk		Not Reported
	Enalapril			C		Unk		Not Reported
	Gravol			C		Unk		Not Reported
	Ondansetron			C		Unk		Not Reported
	Tylenol [Paracetamol]			C		Unk		Not Reported
	Ventolin [Salbutamol]			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16930704	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019444824		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E	Atorvastatin Calcium			S	Oral	20 Mg, Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use In Unapproved Indication	Azithromycin	S	Oral	250 Mg, 3x/Day	Pfizer
	Glycopyrronium Bromide/Indacaterol Maleate	S	Respiratory (inhalation)	1 Df, Unk	Not Reported
	Seebri Breezhaler	S	Respiratory (inhalation)	50 Ug, 1x/Day	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Montelukast	C	Unknown	Unk	Not Reported
	Pulmicort	C	Unknown	Unk	Not Reported
	Qvar	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported
	Salbutamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16931023	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI- FK201911292		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Granulomatosis With Polyangiitis	Azithromycin (Manufacturer Unknown)			S	Unknown	Unk		Fresenius Medical Care
	Amikacin (Manufacturer Unknown)			S	Unknown	Unk		Not Reported
	Imipenem			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16931810	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019449692		50 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Alanine Aminotransferase	Codeine			S		Unk		Not Reported
Increased; Antisocial Behaviour; Arthralgia;	Morphine Sulfate			S	Oral	120 Mg, 1x/Day		Unknown
Aspartate	Zithromax			S		Unk		Pfizer
Aminotransferase	Cocaine			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Blood Albumin Increased; Blood Alkaline Phosphatase Increased; Chest Pain; Depression; Drug Dependence; Drug Withdrawal Syndrome; Hyperhidrosis; Insomnia; Nausea; Night Sweats; Rhinorrhoea; Substance Abuse; Vomiting	Marijuana	S	Respiratory (inhalation)	Unk	Not Reported
	Methadone	S	Oral	Unk	Not Reported
	Oxycodone And Acetaminophen	S	Oral	8 Df, Unk (8 Every 1 Day(S))	Not Reported
	Oxycontin	S	Oral	80 Mg, 1x/Day	Not Reported
	Statex [Morphine Sulfate]	S	Oral	25 Mg, Unk	Not Reported
	Alprazolam	C		Unk	Not Reported
	Amitriptyline	C		Unk	Not Reported
	Ativan	C		Unk	Not Reported
	Cephalexin Monohydrate	C		Unk	Not Reported
	Ciprofloxacin	C		Unk	Not Reported
	Clonazepam	C		Unk	Not Reported
	Demerol	C		Unk	Not Reported
	Gravol	C		Unk	Not Reported
	Imovane	C		Unk	Not Reported
	Influenza Vaccine/Tetanus Vaccine	C		Unk	Not Reported
	Paroxetine Hydrochloride	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2019	16932577	EXPEDITED (15-DAY)		OT	NVSC2019US001131		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea; Granulomatosis With Polyangiitis; Influenza Like Illness; Malaise; Night Sweats; Polyarthritis; Product Use In Unapproved Indication; Pyrexia; Renal Tubular Necrosis; Urine Abnormality	Azithromycin			S	Unknown			Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16868233	NON-EXPEDITED			US-PFIZER INC-2019417241		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16932785	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019445040		48 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Feeling Hot; Palpitations; Throat Tightness	Zitromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16934130	EXPEDITED (15-DAY)		OT	US-ACCORD-157980		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Toxicity; Neurotoxicity	Tigecycline			S				Not Reported	
	Azithromycin			S				Not Reported	
	Amikacin			S	Respiratory (inhalation)			Not Reported	
	Clofazimine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16934729	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1097686		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Granulomatosis With Polyangiitis; Renal Tubular Necrosis	Azithromycin			S	Unknown			Not Reported	
	Amikacin			S	Unknown			Mylan	
	Imipenem			S	Unknown			Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16935892	EXPEDITED (15-DAY)		DS, HO	US-INSMED, INC.-US-INS-19-03361		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Arikayce			S				Insmmed	
Device Dependence;	Lamira Nebulizer System			S				Insmmed	
Granulomatosis With	Azithromycin			S				Not Reported	
Polyangiitis; Product Use	Imipenem			S				Not Reported	
In Unapproved Indication									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936327	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC-2019449278		59 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Decreased	Zithromax			S		Unk		Pfizer	
Activity; Dyspnoea;	Alvesco			S		2 Df, 1x/Day		Not Reported	
Eosinophil Count	Salbutamol Sulfate			S		100 Ug, Unk		Not Reported	
Abnormal; Oesophageal	Spiriva			S		2 Df, 2x/Day		Not Reported	
Carcinoma; Therapeutic	Zenhale			S		2 Df, 2x/Day		Not Reported	
Product Effect Incomplete;	Prednisone			C		Unk		Not Reported	
Wheezing									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936328	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449455		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal;	Azithromycin			S	Oral	250.0 Mg, Unk		Pfizer	
Blood Pressure Increased;	Advair			S		1 Df, 2x/Day		Not Reported	
Body Temperature	Prednisone			S	Oral	8.0 Mg, 1x/Day		Not Reported	
Increased; Cataract;	Salbutamol			S		Unk		Not Reported	
Cough; Drug Dependence;	Spiriva			S		18 Ug, 1x/Day		Not Reported	
Heart Rate Increased;	Zenhale			S		1 Df, 2x/Day		Not Reported	
Lung Diffusion Test									
Decreased; Nasal									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Nasopharyngitis; Obstructive Airways	Cetirizine	C	Unknown	20.0 Mg, 1x/Day	Not Reported
Disorder; Pyrexia; Restrictive Pulmonary Disease; Therapeutic Response Decreased; Type 2 Diabetes Mellitus	Pariet	C	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936335	EXPEDITED (15-DAY)		HO	CA-PFIZER INC- 2019449917		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma	Zithromax			S		Unk		Pfizer
	Atrovent			S		20 Ug, Unk		Not Reported
	Ciclesonide			S		200 Ug, 2x/Day		Not Reported
	Rupatadine Fumarate			S		Unk		Not Reported
	Salbutamol			S	Respiratory (inhalation)	100 Ug, Unk		Not Reported
	Salbutamol Sulfate			S		Unk		Not Reported
	Symbicort Turbohaler			S		2 Df, 2x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936336	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2019450287		1 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Allergic; Rash; Rash Maculo-Papular; Urticaria	Zithromax			S	Oral	0.1 G, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936350	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2019449143		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Zithromax	S	Unk	Pfizer
	Alvesco	S	2.0 Df, 1x/Day	Not Reported
	Salbutamol Sulfate	S	100 Ug, 1x/Day	Not Reported
	Salbutamol	S	100 Ug, Unk	Not Reported
	Spiriva	S	2.0 Df, 2x/Day	Not Reported
	Zenhale	S	2.0 Df, 2x/Day	Not Reported
	Prednisone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936352	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019448972		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Zithromax			S		250 Ug, Unk		Pfizer
Alopecia; Asthenia;	Zithromax			S		Unk		Pfizer
Asthma; Balance Disorder;	Zithromax			S		Unk		Pfizer
Bladder Disorder; Blood Glucose Abnormal; Blood Pressure Systolic Increased; Body Temperature Decreased;	Diltiazem			S		1 Df, 1x/Day		Not Reported
Brain Hypoxia; Breath Odour; Breath Sounds Abnormal; Bronchitis;	Omalizumab			S	Subcutaneous	Unk		Not Reported
Carbon Dioxide Increased; Chest Discomfort; Chest Pain; Cough; Crepitations;	Prednisone			S		Unk		Not Reported
Diarrhoea; Drug Ineffective; Dyspepsia;	Prednisone			S		Unk		Not Reported
Dyspnoea; Dyspnoea Exertional; Fall; Fatigue;	Prednisone			S		Unk		Not Reported
Feeling Abnormal; Forced Expiratory Volume Decreased; Frustration Tolerance Decreased;	Ventolin [Salbutamol]			S		Unk		Not Reported
Gait Disturbance; Gastrooesophageal Reflux Disease; General Physical	Ventolin [Salbutamol]			S	Respiratory (inhalation)	Unk		Not Reported
	Ventolin [Salbutamol]			S		Unk		Not Reported
	Ventolin [Salbutamol]			S		Unk		Not Reported
	Ventolin [Salbutamol]			S		Unk		Not Reported
	Advair			C	Respiratory (inhalation)	1 Df, 2x/Day		Not Reported
	Alvesco			C	Unknown	2 Df, 4x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Health Deterioration; Haemarthrosis; Headache; Heart Rate Increased; Humidity Intolerance; Hypersensitivity; Hypoventilation; Infection; Injury; Insomnia; Joint Swelling; Lung Disorder; Malaise; Memory Impairment; Muscle Disorder; Muscle Spasms; Musculoskeletal Discomfort; Nasopharyngitis; Odynophagia; Oral Candidiasis; Oropharyngeal Pain; Pain In Extremity; Paraesthesia; Peak Expiratory Flow Rate Abnormal; Peak Expiratory Flow Rate Decreased; Peripheral Swelling; Pneumonia; Pollakiuria; Poor Quality Sleep; Productive Cough; Pulmonary Function Test Decreased; Pyrexia; Respiratory Rate Increased; Respiratory Tract Congestion; Rhinorrhoea; Seasonal Allergy; Sputum Discoloured; Stress; Tendonitis; Tremor; Viral Infection; Vomiting; Weight Decreased; Wheezing	Atrovent Dexilant Ipratropium Bromide And Salbutamol Sulfate Spiriva Tums [Calcium Carbonate;Magnesium Carbonate;Magnesium Trisilicate] Zenhale	C C C C C C C	Unknown Unknown Unknown Unknown Unknown Unknown Unknown	2 Df, 4x/Day 1 Df, 1x/Day 20 Ug, Unk 2 Df, 1x/Day 1 Df, Unk Unk	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936357	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019448859		46 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Bronchitis; Fatigue; Nausea; Pneumonia; Pruritus; Urticaria	Zithromax			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Aubagio			S	Oral	14 Mg, 1x/Day		Not Reported
	Aubagio			S	Oral	14 Mg, 1x/Day		Not Reported
	Cymbalta			C	Oral	30 Mg, 1x/Day		Not Reported
	Ergocalciferol			C	Oral	4000 Iu, 1x/Day		Not Reported
	Gabapentin			C	Oral	1200 Mg, 1x/Day		Not Reported
	Levothyroxine			C	Oral	Unk		Not Reported
	Vitamin B12 [Cyanocobalamin]			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936358	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449115		53 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dactylitis; Drug Ineffective; Incorrect Dose Administered; Joint Swelling; Malaise; Musculoskeletal Stiffness; Psoriatic Arthropathy	Azithromycin			S	Unknown	Unk		Pfizer
	Methotrexate Sodium			S	Subcutaneous	25 Mg, Weekly		Unknown
	Cosentyx			S	Subcutaneous	300 Mg, Weekly		Not Reported
	Cosentyx			S	Subcutaneous	300 Mg, Weekly		Not Reported
	Cosentyx			S	Subcutaneous	450 Mg, Monthly		Not Reported
	Cosentyx			S	Unknown	150 Mg, Unk		Not Reported
	Folic Acid			S	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Enbrel			C	Unknown	Unk		Not Reported
	Simponi			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936360	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019449274		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Dyspnoea; Gait Disturbance; Headache; Influenza Like Illness; Malaise; Musculoskeletal Pain; Nasopharyngitis; Neck Pain; Pneumonia; Pyrexia; Seasonal Allergy	Azithromycin	S	Oral	250 Mg, Unk	Pfizer
	Omalizumab	S	Subcutaneous	300 Mg, Unk (1 Every 2 Week(S))	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Unk (1 Every 2 Week(S))	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Unk (1 Every 2 Week(S))	Not Reported
	Omalizumab	S	Subcutaneous	300 Mg, Unk (1 Every 2 Week(S))	Not Reported
	Advair	C	Respiratory (inhalation)	1 Df, 2x/Day	Not Reported
	Atrovent	C	Unknown	1 Df, Unk	Not Reported
	Clarithromycin	C	Oral	500 Mg, Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Spiriva	C	Respiratory (inhalation)	1 Df, 2x/Day	Not Reported
	Symbicort Turbohaler	C	Respiratory (inhalation)	Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Ventolin [Salbutamol]	C	Unknown	Unk	Not Reported
	Ventolin [Salbutamol]	C	Respiratory (inhalation)	2 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936587	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449007		69 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Dyspnoea; Exercise Tolerance Decreased; Lymphoma; Quality Of Life Decreased	Azithromycin			S	Oral	1 Df, Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Alendronate			S	Oral	1 Df, Unk		Not Reported	
	Alendronate			S				Not Reported	
	Omalizumab			S	Subcutaneous	150 Mg, Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alvesco	C	Respiratory (inhalation)	2 Df, 2x/Day	Not Reported
Calcium	C	Oral	1 Df, 2x/Day	Not Reported
Calcium	C			Not Reported
Singulair	C	Oral	1 Df, 1x/Day	Not Reported
Spiriva	C	Respiratory (inhalation)	1 Df, 1x/Day	Not Reported
Symbicort Turbohaler	C	Respiratory (inhalation)	2 Df, 2x/Day	Not Reported
Ventolin [Salbutamol]	C	Respiratory (inhalation)	8 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16936848	EXPEDITED (15-DAY)		DE, HO	ES-FRESENIUS KABI-FK201911179		77 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Colitis	Levofloxacin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Oct-2019	16938169	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1123910		24 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Gonorrhoea	Azithromycin			S	Unknown			Not Reported
	Ceftriaxone Sodium For Injection Bp			S	Unknown			Not Reported
	Remicade			S	Intravenous (not otherwise specified)			Not Reported
	Keppra			C				Not Reported
	Prednisone			C				Not Reported
	Ventolin			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2019	16937684	EXPEDITED (15-DAY)		HO, OT	US-EMCURE PHARMACEUTICALS LTD-2019-EPL-0941		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Granulomatosis With Polyangiitis	Amikacin Sulfate			S		Unk		Emcure	
	Azithromycin			S		Unk		Not Reported	
	Imipenem			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	15156494	EXPEDITED (15-DAY)		LT	CA-TEVA-2018-CA- 924442		62 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Atrial Flutter; Cardiac Arrest; Cardioversion; Hyperbaric Oxygen Therapy; Resuscitation; Torsade De Pointes	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram Daily;		Not Reported	
	Atorvastatin Calcium			C				Not Reported	
	Bisoprolol			C				Not Reported	
	Enoxaparin			C				Not Reported	
	Ferrous Gluconate			C				Not Reported	
	Ipratropium/Salbutamol			C				Not Reported	
	Prednisone			C				Not Reported	
	Thyroxine			C				Not Reported	
	Zopiclone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	15704784	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2018-CA- 985146		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Death; Decreased Appetite; Drug Ineffective; Fatigue; Malignant Neoplasm Progression; Pancreatic	Azithromycin			S	Unknown			Not Reported	
	Ciprofloxacin			S	Unknown			Not Reported	
	Octreotide Acetate			S	Subcutaneous			Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Neuroendocrine Tumour;	Afinitor	S	Oral	5 Milligram Daily;	Not Reported
Platelet Count Decreased;	Sandostatin	S	Unknown		Not Reported
Rash; Somnolence;	Trimethoprim	S	Unknown		Not Reported
Weight Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16215722	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039415		25 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection;	Azithromycin			S	Unknown			Not Reported	
Headache	Cefixime			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	Powder For Solution Intravenous		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16215747	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2019-CA-1039371		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Mental Status Changes; Product Use In Unapproved Indication	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Minocycline			S	Unknown			Actavis	
	Tigecycline			S	Unknown			Not Reported	
	Tigecycline			S	Unknown			Not Reported	
	Cilastatin Sodium/Imipenem			S	Unknown			Not Reported	
	Cilastatin Sodium/Imipenem			S	Unknown			Not Reported	
	Cilastatin Sodium/Imipenem			S	Unknown			Not Reported	
	Rifampin			S	Unknown			Not Reported	
	Rifampin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16215938	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039391		66 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic Increased; Stress	Azithromycin			S	Oral			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Salbutamol Sulfate			C	Respiratory (inhalation)			Not Reported	
	Spiriva			C	Respiratory (inhalation)	1 Dosage Forms Daily;		Not Reported	
	Symbicort Turbuhaler			C	Respiratory (inhalation)	6 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16221731	EXPEDITED (15-DAY)		HO, LT	CA-TEVA-2019-CA-1039327		80 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acid Fast Bacilli Infection; Respiratory Failure	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	
	Tobramycin			S	Respiratory (inhalation)			Teva	
	Adalat XI - Srt			C		Extended Release		Not Reported	
	Primidone			C				Not Reported	
	Synthroid			C				Not Reported	
	Ventolin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16226713	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039367			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cognitive Disorder; Depression; Dizziness; Drug Intolerance; Fatigue; Feeling Hot; Ill-Defined Disorder; Impaired Gastric	Azithromycin			S	Unknown			Not Reported	
	Ocrevus Single-Use Vial			S	Intravenous (not otherwise specified)	Solution Intravenous, 300milligram, 1every 2weeks		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Emptying; Pain In
Extremity

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16939254	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1123898			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	5-Asa			S	Unknown			Teva	
	Azathioprine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ethinylestradiol/Levonorgestrel			S	Unknown			Teva	
	Mercaptopurine			S	Unknown			Not Reported	
	Asacol			S	Unknown			Not Reported	
	Infliximab			S	Intravenous (not otherwise specified)			Not Reported	
	Mezavant Also Known As Mesalamine			S	Unknown			Not Reported	
	Para-Aminosalicylic Acid			S	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16939517	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-224216		59 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aplasia	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Soliris			S	Intravenous (not otherwise specified)	1200 Milligram, Daily		Not Reported	
	Cellcept [Mycophenolate Mofetil Hydrochloride]			S	Intravenous (not otherwise specified)	2 Gram, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16939612	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124622		25 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Headache	Azithromycin			S	Unknown			Not Reported	
	Cefixime			S	Unknown			Not Reported	
	Remicade			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16940445	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449838			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect Decreased	Celebrex			S	Unknown	Unk		Pfizer	
	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Zithromax			S	Unknown	Unk		Pfizer	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown	Unk		Not Reported	
	Tylenol [Paracetamol]			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16940961	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019450968		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Off Label Use; Product Use Issue; Serum Sickness; Therapeutic Product Effect Incomplete	Azithromycin			S	Respiratory (inhalation)	Unk		Pfizer	
	Arnuity Ellipta			S	Respiratory (inhalation)	Unk		Not Reported	
	Flovent			S	Respiratory	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

			(inhalation)		
	Fluticasone Furoate/Vilanterol Trifenatate	S	Respiratory (inhalation)	Unk	Not Reported
	Omalizumab	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	10 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16940995	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019449344		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cystic Fibrosis; Ill-Defined Disorder	Zithromax			S		Unk		Pfizer	
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16941008	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019449712		22 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pharyngitis Streptococcal; Psoriasis; Weight Increased	Zithromax			S		Unk		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	300 Mg, Unk (1 Every 8 Week(S))		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16941012	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019449968		50 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Alopecia; Asthenia; Asthma; Balance Disorder;	Zithromax			S	Unknown	250 Mg, Every 3 Weeks		Pfizer	
	Zithromax			S				Pfizer	



Detailed Report

Bladder Disorder; Blood Glucose Abnormal; Blood Pressure Systolic Increased; Body Temperature Decreased; Brain Hypoxia; Breath Odour; Breath Sounds Abnormal; Bronchitis; Carbon Dioxide Increased; Chest Discomfort; Chest Pain; Cough; Crepitations; Diarrhoea; Dizziness; Drug Ineffective; Dyspepsia; Dyspnoea; Dyspnoea Exertional; Fall; Fatigue; Feeling Abnormal; Forced Expiratory Volume Decreased; Frustration Tolerance Decreased; Gait Disturbance; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Haemarthrosis; Headache; Heart Rate Increased; Humidity Intolerance; Hypersensitivity; Hypoventilation; Infection; Injury; Insomnia; Joint Swelling; Malaise; Memory Impairment; Muscle Disorder; Muscle Spasms; Musculoskeletal Discomfort; Nasopharyngitis; Odynophagia; Oral Candidiasis; Oropharyngeal Pain; Pain In Extremity; Palpitations; Paraesthesia; Peak Expiratory Flow Rate	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk(1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Omalizumab	S	Subcutaneous	375 Mg, Unk (1 Every 2 Weeks)	Not Reported
	Prednisone	S	Unknown	40 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	15 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, 1x/Day	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Peak Expiratory Flow Rate Decreased; Peripheral Swelling; Pneumonia; Pollakiuria; Poor Quality Sleep; Productive Cough; Pulmonary Function Test Decreased; Pyrexia; Respiratory Rate Increased; Respiratory Tract Congestion; Rhinorrhoea; Seasonal Allergy; Sputum Discoloured; Stress; Tendonitis; Tremor; Viral Infection; Vomiting; Weight Decreased; Wheezing	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	50 Mg, 1x/Day	Not Reported
	Ventolin [Salbutamol]	S	Unknown	2 Df, 4x/Day	Not Reported
	Ventolin [Salbutamol]	S	Unknown	60 Df, Unk	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Unk, 1x/Day	Not Reported
	Ventolin [Salbutamol]	S	Respiratory (inhalation)	8 Df, 1x/Day	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Unk, 1x/Day	Not Reported
	Ventolin [Salbutamol]	S	Unknown	40 Df, 1x/Day	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Unk	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Unk, 1x/Day	Not Reported
	Advair	C	Respiratory (inhalation)	Unk, 2x/Day	Not Reported
	Advair	C	Respiratory (inhalation)	1 Df, 2x/Day	Not Reported
	Alvesco	C	Unknown	2 Df, 4x/Day	Not Reported
	Atrovent	C	Unknown	2 Df, 4x/Day	Not Reported
	Calcium Carbonate/Sodium Alginate	C	Oral	1 Df, 4x/Day	Not Reported
	Calcium Carbonate/Sodium Alginate	C	Oral	1 Df, 2x/Day	Not Reported
	Dexilant	C	Unknown	1 Df, 1x/Day	Not Reported
	Diltiazem	C	Unknown	Unk, 1x/Day	Not Reported
	Ipratropium Bromide And Salbutamol Sulfate	C	Unknown	20 Ug, Unk	Not Reported
	Spiriva	C	Unknown	2 Df, 1x/Day	Not Reported
	Tums [Calcium Carbonate]	C	Unknown	1 Df, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zenhale			C		Unknown	Unk	Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16941751	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1124586		74 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported	
Asthma; Blood Pressure	Xolair			S	Subcutaneous			Not Reported	
Increased; Decreased	Xolair			S	Subcutaneous			Not Reported	
Appetite; Dyspnoea;	Xolair			S	Subcutaneous			Not Reported	
Forced Expiratory Volume	Xolair			S	Subcutaneous			Not Reported	
Decreased; Forced Vital									
Capacity Decreased;									
Heart Rate Increased;									
Inappropriate Schedule Of									
Product Administration;									
Influenza; Malaise;									
Obstructive Airways									
Disorder; Off Label Use;									
Oxygen Saturation									
Decreased; Product Use									
In Unapproved Indication									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16941753	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124619		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Systolic	Azithromycin			S	Oral			Not Reported	
Increased; Off Label Use;	Xolair			S	Subcutaneous			Not Reported	
Stress	Prednisone			C				Not Reported	
	Salbutamol			C				Not Reported	
	Spiriva			C				Not Reported	
	Symbicort 200/6			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16942039	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124703		22 YR	Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Feeling Of Body Temperature Change; Nausea; Vertigo	Azithromycin			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16942127	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124623		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal;	Azithromycin			S	Oral			Not Reported	
Blood Pressure Increased;	Salbutamol			S	Unknown			Barr	
Body Temperature Increased; Cataract;	Advair			S	Unknown	2 Dosage Forms Daily;		Not Reported	
Cough; Drug Dependence;	Prednisone (Mah Unknown)			S	Oral	8 Milligram Daily;		Not Reported	
Heart Rate Increased;	Spiriva			S	Unknown			Not Reported	
Lung Diffusion Test Decreased; Nasal	Zenhale			S		4 Dosage Forms Daily;		Not Reported	
Disorder; Nasopharyngitis;	Cetirizine			C				Not Reported	
Obstructive Airways Disorder; Pyrexia;	Pariet			C				Not Reported	
Restrictive Pulmonary Disease; Therapeutic Response Decreased;	Rosuvastatin			C				Not Reported	
Type 2 Diabetes Mellitus									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2019	16942523	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124669		85 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug	Azithromycin			S	Unknown			Not Reported	
Level Above Therapeutic;	Cefuroxime Axetil			S	Unknown			Not Reported	
Drug Interaction; Peripheral Swelling	Warfarin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	15156487	EXPEDITED (15-DAY)		HO	CA-TEVA-2018-CA-924447		79 YR	Male	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Pruritus	Azithromycin			S	Oral	Frequency: Once		Not Reported
	Cefazolin			S	Intraperitoneal			Not Reported
	Alfacalcidol			C				Not Reported
	Amlodipine			C				Not Reported
	Asa			C				Not Reported
	Bisoprolol			C				Not Reported
	Eprex Sterile Solution			C	Intravenous (not otherwise specified)			Not Reported
	Fluticasone			C				Not Reported
	Kayexalate			C				Not Reported
	Megestrol			C				Not Reported
	Pantoprazole			C				Not Reported
	Salbutamol			C				Not Reported
	Sevelamer			C				Not Reported
	Vit D 1000			C				Not Reported
	Docusate			C				Not Reported
	One Alpha			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	15156490	EXPEDITED (15-DAY)		HO	CA-TEVA-2018-CA-924441		50 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Blood Bilirubin Increased; Drug Hypersensitivity; Transaminases Increased	Azithromycin			S	Oral			Not Reported
	Allopurinol			S	Oral			Not Reported
	Cholestyramine			C				Not Reported
	Diphenhydramine			C				Not Reported
	Hydroxyzine			C				Not Reported
	Lispro 50lis50npl			C				Not Reported
	Valsartan			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	15654987	EXPEDITED (15-DAY)		OT	CA-TEVA-2018-CA-979434		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Azithromycin	S	Unknown	Not Reported
	Ciprofloxacin	S	Oral	Not Reported
	Montelukast	S	Oral	Teva
	Mycophenolate Mofetil	S	Oral	Teva
	Mycophenolate Mofetil	S		Teva
	Pantoprazole	S	Oral	Teva
	Pantoprazole	S	Intravenous (not otherwise specified)	Teva
	Prednisone	S	Oral	Actavis
	Caspofungin Acetate	S	Intravenous (not otherwise specified)	Not Reported
	Caspofungin Acetate	S	Intravenous (not otherwise specified)	Not Reported
	Sulfamethoxazole W/Trimethoprim	S	Oral	Not Reported
	Voriconazole	S	Oral	Teva
	Voriconazole	S		Teva
	Candidas	S	Unknown	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Tacrolimus	S		Not Reported
	Apo-Azithromycin	S	Oral	Not Reported
	Apo-Montelukast	S	Oral	Not Reported
	Apo-Mycophenolate	S	Oral	Not Reported
	Apo-Sulfatrim	S	Oral	Not Reported
	Apo-Voriconazole	S	Oral	Not Reported
	Nifedipine	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16215744	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039386		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal;	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Pressure Increased; Body Temperature Increased; Cataract; Cough; Drug Dependence; Heart Rate Increased; Lung Diffusion Test Decreased; Nasal Disorder; Nasopharyngitis; Obstructive Airways Disorder; Pyrexia; Restrictive Pulmonary Disease; Therapeutic Response Decreased; Type 2 Diabetes Mellitus	Azithromycin Salbutamol Sulfate Advair Prednisone Spiriva Zenhale Cetirizine Pariet Rosuvastatin Calcium	S S S S S S C C C	Oral Unknown Unknown Oral Unknown Unknown Unknown Unknown Unknown	250 Milligram Daily; 2 Dosage Forms Daily; 8 Milligram Daily; 18 Microgram Daily; 2 Dosage Forms Daily; Aerosol, Metered Dose 20 Milligram Daily;	Not Reported Barr Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16215977	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039351		12 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia; Rash Pustular; Staphylococcal Infection; Syncope	Azithromycin Fluoxetine Xolair Avamys Intuniv Xr Prozac Quetiapine			S S S C C C C	Oral Unknown Unknown Unknown Unknown	1 Dosage Forms Daily; Powder For Solution Subcutaneous Tablet (Extendedrelease) Powder For Solution Subcutaneous		Not Reported Barr Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16226634	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039410		34 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product; Chapped Lips; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder; Stomatitis; Urticaria	Azithromycin			S	Unknown			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Benadryl /00000402/			C	Oral			Not Reported
	Cetirizine Hydrochloride			C	Oral	1 Dosage Forms Daily;		Not Reported
	Prednisone			C	Oral			Not Reported
	Singular			C	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16226712	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1039362		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported
	Ipratropium Bromide/Salbutamolsulfate			S	Unknown			Teva
	Prednisone			S	Oral			Actavis
	Salbutamol Sulfate			S	Unknown			Barr
	Theophylline			S	Oral	450 Milligram Daily;		Barr
	Atrovent			S	Unknown			Not Reported
	Breo Ellipta			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported
	Seebri Breezhaler			S	Unknown	1 Dosage Forms Daily;		Not Reported
	Singular			S	Oral	10 Milligram Daily;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16284840	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK081490			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Dyspnoea; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Malaise; Sleep Disorder Due To A General Medical Condition; Wheezing	Salbutamol Sulphate	S	Intravenous (not otherwise specified)	100 ?G, Prn	Glaxosmithkline
	Nucala	S		100 Mg, Z; Monthly	Glaxosmithkline
	Incruse Ellipta	S		62.5 ?G, Qd	Glaxosmithkline
	Breo Ellipta	S		25 ?G, Qd	Glaxosmithkline
	Azithromycine	S		250 Mg, Qd	Glaxosmithkline
	Ventolin Nebules	S		2.5 MI, Prn	Glaxosmithkline

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16530668	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1072319		85 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anticoagulation Drug Level Above Therapeutic; Drug Interaction; Peripheral Swelling	Azithromycin			S	Unknown			Not Reported	
	Cefuroxime			S	Unknown			Not Reported	
	Warfarin Sodium			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16534540	EXPEDITED (15-DAY)		CA, OT	CA-TEVA-2019-CA-1071647		25 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Azithromycin			S	Unknown			Not Reported	
	Diphenhydramine Hydrochloride			S	Unknown			Barr	
	Diphenhydramine Hydrochloride			S	Unknown			Barr	
	Diphenhydramine Hydrochloride			S	Unknown			Barr	
	Diphenhydramine Hydrochloride			S	Unknown			Barr	
	Levofloxacin			S	Unknown			Teva	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Xolair	S	Subcutaneous		Not Reported
	Xolair	S	Subcutaneous		Not Reported
	Xolair	S	Subcutaneous		Not Reported
	Xolair	S	Subcutaneous		Not Reported
	Reactine [Cetirizine]	S	Unknown	40 Milligram Daily;	Not Reported
	Reactine [Cetirizine]	S	Unknown		Not Reported
	Reactine [Cetirizine]	S	Unknown		Not Reported
	Reactine [Cetirizine]	S	Unknown	40 Milligram Daily;	Not Reported
	Rifampin	S	Unknown		Not Reported
	Diphenhydramine Hydrochloride	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16535767	EXPEDITED (15-DAY)		HO, LT, OT	CA-TEVA-2019-CA-1072323		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dysphagia; Dysuria;	Azithromycin			S	Unknown			Not Reported
Epidermal Necrosis;	Ciprofloxacin Hydrochloride			S	Oral	1000 Milligram Daily;		Not Reported
Hypophagia; Nikolsky'S	Ciprofloxacin			S	Oral			Not Reported
Sign; Odynophagia;	Fluticasone W/Salmeterol			C	Unknown			Not Reported
Oesophageal Ulcer;	Quetiapine			C	Unknown			Not Reported
Oesophagitis; Oral Pain;	Risedronate			C	Unknown			Not Reported
Pyrexia; Rash; Stevens-	Salbutamol			C	Unknown			Not Reported
Johnson Syndrome; Toxic	Tiotropium			C	Unknown			Not Reported
Epidermal Necrolysis;	Ipratropium			C	Unknown			Not Reported
Ulcer; Urinary Tract	Fluticasone			C	Unknown			Not Reported
Infection	Propionate;Salmeterol							
	Fluticasone Propionate			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16779666	EXPEDITED (15-DAY)		HO, OT	DE-009507513-1908DEU010547		32 YR	Female	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ovarian Hyperstimulation Syndrome	Puregon Pen			S	Subcutaneous	150 Iu International Unit(S), Qd		Merck	
	Puregon Pen			S	Subcutaneous	150 Iu International Unit(S), Qd		Merck	
	Orgalutran			S	Subcutaneous	0.25 Mg, Daily		Merck	
	Ovitrelle			S	Subcutaneous	250 Iu, Once/Single		Not Reported	
	Zithromax			S	Oral	1000 Mg And 500 Mg For Two Days		Not Reported	
	Zithromax Progesterone			S	S	Vaginal	100 Mg, 3 Times Daily	Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16900157	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019AMR164312			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Infection; Malaise; Pneumonia; Product Dose Omission	Salbutamol Sulphate			S	Intravenous (not otherwise specified)	Unk Unk, Prn		Glaxosmithkline	
	Nucala			S		100 Mg, Z (1 Months)		Glaxosmithkline	
	Advair			S		Unk		Glaxosmithkline	
	Azithromycin			S		Unk 250		Glaxosmithkline	
	Spiriva			S		Unk		Not Reported	
	Prednisone			S		10 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16918400	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2019-06612		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	Unk		Lupin	
	Vancomycin			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Piperacilin/Tazobactam			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16918404	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2019-06610		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown	Unk		Lupin	
	Vancomycin			C	Unknown	Unk		Not Reported	
	Piperacilin/Tazobactam			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16930501	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC- 2019444759		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Granulomatosis With Polyangiitis; Vasculitis	Azithromycin			S		Unk		Pfizer	
	Amikacin			S		Unk		Not Reported	
	Imipenem			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16943563	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-067900		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ascites; Bronchitis; Drug Interaction; Drug-Induced Liver Injury; Hyperbilirubinaemia; Malaise; Pharyngitis; Pyrexia	Amoxicillin			S	Oral	500 Milligram		Aurobindo	
	Amoxicillin			S				Aurobindo	
	Harvoni			S	Oral	1 Dosage Form		Not Reported	
	Pms Azithromycin			S	Oral	250 Milligram		Not Reported	
	Pms Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16943859	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA- 1109051		56 DAY	Unknown	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Anaemia Neonatal; Foetal Exposure During Pregnancy; Maternal Exposure During Pregnancy	Acyclovir			S	Transplacental			Teva
	Azithromycin			S	Transplacental			Teva
	Bactrim			S	Transplacental			Not Reported
	Intelence			S	Transplacental			Not Reported
	Lamivudine			S	Transplacental			Not Reported
	Prezista			S	Transplacental			Not Reported
	Raltegravir Potassium			S	Transplacental			Not Reported
	Ritonavir			S	Transplacental			Not Reported
	Tenofovir			S	Transdermal			Not Reported
	Zidovudine			S	Unknown			Not Reported
	Isentress			S	Transplacental			Not Reported
	Abacavir			C	Transplacental			Not Reported
	Calcium D			C	Unknown			Not Reported
	Ergocalciferol			C	Unknown			Not Reported
	Folic Acid			C	Unknown			Not Reported
	Iron			C	Unknown			Not Reported
	Magnesium Gluconate			C	Unknown			Not Reported
	Nicotinamide			C	Unknown			Not Reported
	Pyridoxine Hydrochloride			C	Unknown			Not Reported
	Retinol Palmitate			C	Unknown			Not Reported
	Riboflavin			C	Unknown			Not Reported
	Thiamine Mononitrate			C	Unknown			Not Reported
	Vitamin B12			C	Unknown			Not Reported
	Vitamin C			C	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Ferrous Fumarate			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16943922	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124656		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Choking Sensation; Cough; Dyspnoea; Hot Flush; Hypersensitivity; Mouth Swelling; Pharyngeal Oedema; Rash; Swelling; Swelling Face; Throat Tightness	Azithromycin			S	Oral	2 Dosage Forms Daily;		Not Reported	
	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16943978	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124753		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Pneumonia	Amoxicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
	Stelara			S	Subcutaneous	Solution Subcutaneous		Not Reported	
	Stelara			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16943981	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124679		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported	
	Ipratropium Bromide And Salbutamol Sulphate Inhalation Solution			S	Unknown			Teva	
	Prednisone			S	Oral			Actavis	
	Salbutamol Sulfate			S	Unknown			Teva	
	Theophylline			S	Oral	450 Milligram Daily;		Barr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrovent	S	Unknown		Not Reported
Breo Ellipta	S	Unknown	1 Dosage Forms Daily;	Not Reported
Omalizumab	S	Intravenous (not otherwise specified)		Not Reported
Seebri Breezhaler	S	Unknown	1 Dosage Forms Daily;	Not Reported
Singulair	S	Oral	10 Milligram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16944464	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-224625		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urethral Stenosis	Azithromycin			S	Oral	250 Milligram, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16944608	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA- 1124595		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Pneumonia	Amoxicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
	Stelara			S	Subcutaneous			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16944689	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA- 1124743		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate	Azithromycin			S	Oral	1 Dosage Forms Daily;		Not Reported	
	Fluoxetine			S	Unknown			Barr	
	Omalizumab			S	Unknown			Not Reported	
	Avamys			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia; Rash Pustular; Staphylococcal Infection; Syncope	Prozac	C	Unknown	Not Reported
	Quetiapine	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16944766	EXPEDITED (15-DAY)		LT, OT	PT-ACCORD-158128		73 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Pneumonia; Toxic Epidermal Necrolysis	Bisoprolol			S				Not Reported	
	Simvastatin			S				Not Reported	
	Pantoprazole			S				Not Reported	
	Amoxicillin/Clavulanic Acid			S				Not Reported	
	Azithromycin			S				Not Reported	
	Acetylsalicylic Acid (Cardio)			S				Not Reported	
	Losartan			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16945267	EXPEDITED (15-DAY)		HO, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-19-495		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Granulomatosis With Polyangiitis	Imipenem			S	Unknown			Not Reported	
	Amikacin			S	Unknown			Westward	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16946084	NON-EXPEDITED			US-PFIZER INC-2019450030		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea; Drug Ineffective	Zithromax	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Zithromax	S	250 Mg, Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16946771	NON-EXPEDITED			US-PFIZER INC-2019455608		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin Phosphate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16946871	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124686		79 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Pruritus	Acetylsalicylic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Cefazolin			S	Unknown			Not Reported	
	Amlodipine			C				Not Reported	
	Bisoprolol			C				Not Reported	
	Docusate			C				Not Reported	
	Eprex			C				Not Reported	
	Ergocalciferol			C				Not Reported	
	Fluticasone			C				Not Reported	
	Megestrol			C				Not Reported	
	Nepafenac			C				Not Reported	
	One Alpha			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Salbutamol			C				Not Reported	
	Sevelamer			C				Not Reported	
	Sodium Polystyrene Sulfonate			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16946947	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124675		41 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthropathy;	Azithromycin			S	Unknown			Not Reported
Blister; Burning Sensation;	Azithromycin			S				Not Reported
Chest Pain; Cough;	Azithromycin			S				Not Reported
Cystitis; Dizziness; Drug	Azithromycin			S				Not Reported
Ineffective; Fall; Feeling	Azithromycin			S				Not Reported
Abnormal; Gait	Xolair			S	Subcutaneous			Not Reported
Disturbance; Headache;	Xolair			S	Unknown			Not Reported
Heart Rate Increased;	Xolair			S	Subcutaneous			Not Reported
Hypertension; Incorrect	Xolair			S	Subcutaneous			Not Reported
Dose Administered;	Xolair			S	Subcutaneous			Not Reported
Influenza Like Illness;	Xolair			S	Subcutaneous			Not Reported
Injection Site Rash;	Xolair			S	Subcutaneous			Not Reported
Insomnia; Lip Swelling;	Xolair			S	Subcutaneous			Not Reported
Mobility Decreased;	Cetirizine			C				Not Reported
Muscular Weakness;	Demulen			C				Not Reported
Nasopharyngitis; Pain;	Fucidin			C				Not Reported
Pain In Extremity; Painful	Hydroxyzine			C				Not Reported
Respiration; Peripheral	Metronidazole			C				Not Reported
Swelling; Product Storage	Nystatin			C				Not Reported
Error; Pruritus; Rash;	Pantoprazole			C				Not Reported
Respiratory Tract	Pepcid			C				Not Reported
Congestion; Sensation Of	Prednisone			C				Not Reported
Foreign Body; Stress;	Reactine [Cetirizine			C				Not Reported
Swelling; Tooth Fracture;	Hydrochloride]							
Urticaria	Sertraline			C				Not Reported
	Singulair			C				Not Reported
	Ventolin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16947514	EXPEDITED (15-DAY)		DS	CA-TEVA-2019-CA-1124651		4 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Paraesthesia;	Azithromycin			S	Unknown	200 Milligram Daily;		Not Reported
Stress; Tinnitus	Azithromycin			S	Unknown	90 Milligram Daily;		Not Reported
	Azithromycin			S	Unknown	180 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16947521	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1124584		90 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Haemorrhage; Haematemesis	Azithromycin			S	Unknown			Not Reported	
	Eliquis			S	Oral	5 Milliequivalents Daily;		Not Reported	
	Acetaminophen			C				Not Reported	
	Calcium			C				Not Reported	
	Ergocalciferol			C				Not Reported	
	Finasteride			C				Not Reported	
	Metoprolol			C				Not Reported	
	Pregabalin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16947591	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124709		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Haematochezia; Product Use In Unapproved Indication	Amoxicillin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
	Xeljanz			S	Oral	20 Milligram Daily;		Not Reported	
	Eliquis Film Coated			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Oct-2019	16947722	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124739			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Diarrhoea; Dyspnoea; Nausea	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16913973	EXPEDITED (15-DAY)		HO, LT, OT	PT-PFIZER INC-2019433306		73 YR	Female	PRT

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Toxic Epidermal Necrolysis	Azithromycin			S		Unk		Pfizer
	Amoxicillin Trihydrate/Clavulanate Potassium Pantoprazole			S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid			C	Unknown	Unk		Not Reported
	Losartan Potassium			C	Unknown	Unk		Not Reported
	Bisoprolol			C	Unknown	Unk		Not Reported
	Simvastatin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16948871	NON-EXPEDITED			PHHY2019US226819		8 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Diarrhoea; Hair Colour Changes; Skin Discolouration	Lamprene			S	Oral	50 Mg, Unk		Novartis
	Linezolid			S	Oral	300 Mg, Bid		Not Reported
	Amikacin			S	Respiratory (inhalation)	250 Mg/ML, Bid		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Bactrim			S	Oral	1.5 Df (400/80), Bid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16949471	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-4549			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Hepatic Enzyme Increased; Rheumatoid Arthritis; Therapeutic Product Effect	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Celebrex			S	Unknown			Not Reported
	Zithromax			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased	Humira	S	Subcutaneous	Not Reported
	Simponi	S	Subcutaneous	Not Reported
	Plaquenil	C	Unknown	Not Reported
	Tylenol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16949739	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124648			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Azithromycin			S	Unknown	250 Milligram Daily;		Not Reported	
	Levofloxacin			S	Unknown			Teva	
	Methotrexate			S	Unknown			Barr	
	Arava			S	Unknown			Not Reported	
	Benadryl			S	Unknown			Not Reported	
	Celebrex			S	Unknown			Not Reported	
	Cimzia Single-Use Prefilled Syringe			S	Unknown			Not Reported	
	Demerol			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Imuran			S	Unknown			Not Reported	
	Plaquenil			S	Unknown			Not Reported	
	Procytos			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
	Ezetrol			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16949744	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1124719		48 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterovirus Infection; Transplant Rejection	Azithromycin			S	Unknown			Not Reported	
	Mycophenolic Acid			S	Unknown	2 Gram Daily;		Teva	
	Prednisone			S	Unknown	15 Milligram Daily;		Actavis	
	Valganciclovir			S	Unknown			Actavis	
	Abacavir			S	Unknown			Not Reported	
	Sulfamethoxazole			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Tivicay			S	Unknown			Not Reported	
	Trimethoprim			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16950125	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-062887			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Dose Omission	Azithromycin 250 Mg Tablets Usp			S	Unknown	500 Milligram (2 Tablets First Day)		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16950929	NON-EXPEDITED			US-TEVA-2019-US-1124733		85 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Abdominal Pain Upper; Cough; Gait Inability; Muscular Weakness; Nasopharyngitis; Pyrexia; Tinnitus	Azithromycin Tablets			S	Unknown	Dose Strength: 250		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16953267	NON-EXPEDITED			US-PFIZER INC-2019456547			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Biaxin			S		Unk		Not Reported	
	Darvocet			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16953786	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2075981			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral			Wockhardt	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Oct-2019	16954341	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2019-CA-1124663		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchospasm;	Azithromycin			S	Unknown			Not Reported	
Candida Infection;	Potassium Acetate			S	Unknown			Not Reported	
Cerebrovascular Accident;	Xolair			S	Subcutaneous			Not Reported	
Dyspnoea; Heart Rate	Xolair			S	Subcutaneous			Not Reported	
Increased; Hemiplegia;	Levaquin			C				Not Reported	
Inappropriate Schedule Of	Prednisone			C				Not Reported	
Product Administration;	Singulair			C				Not Reported	
Oxygen Saturation	Spiriva			C				Not Reported	
Decreased; Peritonsillar	Ventolin			C				Not Reported	
Abscess; Pharyngeal	Zenhale			C				Not Reported	
Inflammation; Pilonidal									
Cyst; Postoperative									
Wound Complication;									
Productive Cough;									
Pulmonary Pain;									
Respiratory Rate									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Increased; Rhonchi;
Therapy Partial
Responder; Wheezing

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2019	16912301	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-223546		55 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Face	Azithromycin			S	Oral	500 Milligram, Tablet, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2019	16942713	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019447170		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress Syndrome; Cough; Distributive Shock; Dyspnoea; Pneumonia; Pyrexia	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Isavuconazonium Sulfate			C		Unk		Not Reported	
	Azathioprine			C		Unk		Not Reported	
	Azathioprine			C				Not Reported	
	Prednisone			C		Unk		Not Reported	
	Prednisone			C				Not Reported	
	Voriconazole			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2019	16955670	NON-EXPEDITED			US-PFIZER INC- 2019107223			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Doxycycline Monohydrate			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ambien	S	Unk	Not Reported
Cephalexin Monohydrate	S	Unk	Not Reported
Keflex [Cefalexin Monohydrate]	S	Unk	Not Reported
Levaquin	S	Unk	Not Reported
Lexapro	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Oct-2019	16955875	EXPEDITED (15-DAY)		HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-224830		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Granulomatosis With Polyangiitis	Azithromycin			S	Unknown	Unk		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2019	15507178	EXPEDITED (15-DAY)		HO	FR-PFIZER INC- 2018413824		55 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophil Count Increased; Hepatocellular Injury; Pyrexia; Rash Pruritic	Tazocilline			S	Intravenous drip	16 G, 1x/Day		Pfizer	
	Vancomycine Mylan [Vancomycin Hydrochloride]			S	Intravenous drip	1.5 G, 1x/Day		Not Reported	
	Ordipha			S	Oral	1 Df, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2019	16886894	EXPEDITED (15-DAY)		HO, OT	GB-VERTEX PHARMACEUTICALS- 2019-009348		13 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Hypoglycaemia;	Orkambi			S	Oral	2 Dosage Form (200/125 Mg Each), Bid		Vertex	
	Minocycline			S	Oral	100 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypothermia	Azithromycin	S	Oral	375 Mg, Qd	Not Reported
	Prednisone	C		5 Milligram, Qd	Not Reported
	Prednisone	C		20 Mg,Qd	Not Reported
	Moxifloxacin	C	Oral	400 Mg, Qd	Not Reported
	Amikacin	C		500 Mg, Bid, Neb	Not Reported
	Creon	C	Respiratory (inhalation)	1-4 With Meals And Snacks	Not Reported
	Cetirizine	C		10 Mg, Qd	Not Reported
	Symbicort	C		Unk, Bid	Not Reported
	Deoxyribonuclease Human	C		2.5 Mg, Qd, Neb	Not Reported
	Omeprazole	C	Respiratory (inhalation)	20 Mg, Qd	Not Reported
	Vitamin E [Tocopherol]	C		75 Mg, Qd	Not Reported
	Vitamin A + D	C		2 Dosage Form, Qd	Not Reported
	Menadiol	C		10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2019	16947556	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1125538		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Toxicity; Neurotoxicity	Azithromycin			S	Unknown			Not Reported
	Amikacin			S	Respiratory (inhalation)			Teva
	Clofazimine			S	Unknown			Not Reported
	Tigecycline			S	Unknown			Not Reported
	Mycophenolate Mofetil			C	Unknown			Not Reported
	Tacrolimus			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Trimethoprim / Sulfamethoxazole			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Posaconazole	C	Unknown	Not Reported
Valganciclovir	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Oct-2019	16964286	DIRECT		OT			196 DAY	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Zithromax			S				Not Reported
Abdominal Pain;	Cozarr			C				Not Reported
Haematochezia; Vaginal Haemorrhage	Metformin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2019	16205710	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-019697		76 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Ineffective; Dyspnoea; Malaise; Pneumonia; Throat Irritation	Amlodipine			S	Unknown	10 Milligram, Daily		Aurobindo
	Amlodipine			S	Unknown	1 Dosage Form, Once A Day		Aurobindo
	Valsartan			S	Unknown	160 Milligram, Once A Day		Aurobindo
	Apo-Amlodipine			S	Unknown	10 Milligram, Once A Day		Not Reported
	Xolair			S	Subcutaneous	375.0 Milligram, 1 Every Two Week		Not Reported
	Azithro			S	Unknown	25 Milligram		Not Reported
	Budesonide			C	Unknown	4.0 Dosage Form, Daily		Not Reported
	Claritin			C	Unknown	1.0 Dosage Form, Daily		Not Reported
	Spiriva			C	Unknown	1.0 Dosage Form, Daily		Not Reported
	Alvesco			C	Unknown	2 Dosage Form, Two Times A Day		Not Reported
	Symbicort			C	Unknown	4 Dosage Form, Two Times A Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2019	16964867	EXPEDITED (15-DAY)		DE, HO, OT	US-AUROBINDO-AUR-APL-2019-068626		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Amoxicillin			S	Unknown	Unk		Aurobindo	
	Lamotrigine			S	Unknown	Unk		Aurobindo	
	Clozapine			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2019	16966890	NON-EXPEDITED			US-SA-2019SA296682		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Influenza; Urticaria	Praluent			S	Subcutaneous	75 Mg, Qow		Sanofi	
	Azithromycin			S		Unk		Not Reported	
	Repatha			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Oct-2019	16967823	NON-EXPEDITED			US-PFIZER INC-2019465095			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16658445	EXPEDITED (15-DAY)		OT	PHHY2019BR053163		34 YR	Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Extra Dose Administered;	Cosentyx			S	Subcutaneous	300 Mg, Qw		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inappropriate Schedule Of Product Administration; Injection Site Bruising; Injection Site Pain; Pneumonia; Pruritus	Cosentyx	S	Subcutaneous	300 Mg, Qw	Novartis
	Cosentyx	S	Subcutaneous	300 Mg, Qw	Novartis
	Cosentyx	S	Subcutaneous	300 Mg, Qw	Novartis
	Cosentyx	S	Subcutaneous	300 Mg, Qw	Novartis
	Cosentyx	S	Unknown	Unk (Every 15 Days)	Novartis
	Cosentyx	S	Unknown	Unk (Every 15 Days)	Novartis
	Cosentyx	S	Unknown	Unk (Every 15 Days)	Novartis
	Cosentyx	S	Subcutaneous	Unk Unk, Qw	Novartis
	Azithromycin Dihydrate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16968698	NON-EXPEDITED			US-JNJFOC-20191012451			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Fluconazole			S	Unknown			Not Reported
	Ibuprofen			S	Unknown			Not Reported
	Amlodipine Besilate			S	Unknown	Unk		Not Reported
	Dilantin /00017401/			S	Unknown	Unk		Not Reported
	Cerebyx			S	Unknown	Unk		Not Reported
	Fosphenytoin Sodium			S	Unknown	Unk		Not Reported
	Phenobarbital			S	Unknown	Unk		Not Reported
	Tetracycline Hcl			S	Unknown	Unk		Not Reported
	Acyclovir /00587301/			S	Unknown	Unk		Not Reported
	Allopurinol			S	Unknown	Unk		Not Reported
	Carbatrol			S	Unknown	Unk		Not Reported
	Cilostazol			S	Unknown	Unk		Not Reported
	Lunesta			S	Unknown	Unk		Not Reported
	Isovue			S	Unknown	Unk		Not Reported
	Phenytek			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Propafenone	S	Unknown	Unk		Not Reported
	Rifadin	S	Unknown	Unk		Not Reported
	Azithromycin	S	Unknown			Not Reported
	Phenytoin	S	Unknown			Not Reported
	Carbamazepine	S	Unknown			Not Reported
	Tegretol	S	Unknown			Not Reported
	Rifampin	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16968728	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1128786		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Granulomatosis With Polyangiitis; Renal Tubular Necrosis	Amikacin			S	Unknown			Teva	
	Azithromycin			S	Unknown			Teva	
	Imipenem			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16969007	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-069187		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematuria; Mouth Ulceration; Purpura; Thrombocytopenia	Azithromycin			S	Oral	1 Dosage Form		Aurobindo	
	Nabucox			S	Oral	2 Dosage Form, Daily		Not Reported	
	Ezetrol			C	Oral	1 Dosage Form, Daily		Not Reported	
	Flectortissugelep			C	Cutaneous	3 Dosage Form, Daily		Not Reported	
	Ropinirole Hydrochloride			C	Oral	0.5 Milligram, Daily		Not Reported	
	Bronchodual			C	Respiratory (inhalation)	2 Dosage Form, Daily		Not Reported	
	Spasfon			C	Oral	6 Dosage Form, Daily		Not Reported	
	Loxen			C	Oral	2 Dosage Form, Daily		Not Reported	
	Aspirine Protect			C	Oral	1 Dosage Form, Daily		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Nebivolol			C	Oral	1 Dosage Form, Daily			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16969581	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019462908			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Interaction; Maternal Exposure During Pregnancy	Azithromycin			S		Unk		Pfizer	
	Isotretinoin			S		Unk		Not Reported	
	Mirena			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16969681	EXPEDITED (15-DAY)		OT	HR-MYLANLABS-2019M1101639		76 YR	Male	HRV
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Infectious Pleural Effusion	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Piperacillin+Tazobactam			S		Unk		Mylan	
	Piperacillin+Tazobactam			S	Parenteral	Unk		Mylan	
	Nebivolol			C	Unknown	Unk		Mylan	
	Amoxicillin			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16970077	EXPEDITED (15-DAY)		HO	PHHO2017SG005902		77 YR	Female	SGP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Myocardial Infarction; Dehydration; Diarrhoea; Escherichia Urinary Tract Infection; Fluid Overload; Hyperkalaemia; Hypernatraemia; Iron Deficiency Anaemia;	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Novartis	
	Sacubitril,Valsartan			S	Oral	200 Mg, Bid		Not Reported	
	Placebo			S	Oral	Unk		Not Reported	
	Benzylpenicillin			S	Intravenous (not otherwise specified)	3 Million Unit		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nausea; Pneumonia; Rectal Haemorrhage; Septic Shock; Thrombocytopenia; Transaminases Increased; Vitamin B12 Deficiency	Ceftazidime Bisoprolol Acetaminophen Furosemide	S C C C	Unknown Unknown Unknown Unknown	250 Mg, Bid Unk Unk Unk	Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Oct-2019	16975127	DIRECT		DS, OT			71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness	Azithromycin			S	Oral	Quantity:1 Tablet(S);Other 2 DAY Frequency:Z-Pak;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2019	16776266	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC- 2019383531		32 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Ovarian Hyperstimulation Syndrome; Product Use In Unapproved Indication	Zithromax Orgalutran Lutinus Ovitrelle Puregon [Follitropin Beta]			S S S S S		Unk Unk Unk Unk Unk		Pfizer Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2019	16972673	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR- APL-2019-069621		60 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Haematochezia; Vomiting	Azithromycin Anastrozole Hydrochlorothiazide;Losartan Potassium			S C C	Oral Unknown Unknown	1 Dosage Form, Once A Day Unk Unk		Aurobindo Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2019	16975620	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- SLTR-AE-19-109		9 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Fatigue; Nausea; Transaminases Increased; Vena Cava Thrombosis; Vomiting	Imipenem/Cilastatin			C	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses		Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Not Reported	
	Clofazimine			C	Oral	If Weight Is Greater Than 40kg, Then 100 Mg Once Daily		Not Reported	
	Imipenem/Cilastatin			C	Topical	5/5 Mg/MI Three Drops Three Times Daily		Not Reported	
	Tigecycline			S	Topical	5 Mg/MI Three Drops Three Times Daily		Not Reported	
	Metoclopramide 70436-019-82 Azithromycin For Injection Dry Vial Usd 500 Mg			C S	Oral			Not Reported Hainan Poly Pharmaceuticals	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2019	16975876	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2019466706		60 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Haematochezia; Vomiting	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Losartan			C		Unk		Not Reported	
	Potassium/Hydrochlorothiazide Anastrozole			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Oct-2019	16976234	EXPEDITED (15-DAY)		OT	NL-APOTEX- 2019AP024038		6 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deafness Neurosensory	Azithromycin	S	Unknown	250 Mg, Qd	Apotex
	Fantomalt /00023548/	C	Unknown	50 G, Qd	Not Reported
	Aprepitant	C	Unknown	80 Mg, Qd	Not Reported
	Mometason	C	Unknown	1 Df, Qd	Not Reported
	Imipenem Cilastatine	C	Unknown	1 Df, Bid	Not Reported
	Salbutamol	C	Unknown	100 Mg, Unk	Not Reported
	Nutrini	C	Unknown	1 Df, Tid	Not Reported
	Fresubin /07459901/	C	Unknown	1 Df, Qd	Not Reported
	Tigecycline	C	Unknown	26 Mg, Bid	Not Reported
	Omeprazol /00661201/	C	Unknown	20 Mg, Qd	Not Reported
	Granisetron	C	Unknown	1 Mg, Bid	Not Reported
	Clofazimine	C	Unknown	50 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16842668	EXPEDITED (15-DAY)		OT	BR-009507513-1909BRA008408		75 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased; Drug Interaction; Incorrect Dose Administered; Pleural Effusion; Pneumonia	Januvia			S	Oral	50 Milligram, 1 Tablet Qd		Merck
	Januvia			S	Oral	50 Milligram, 1 Tablet Qd		Merck
	Januvia			S	Oral	Two Tablets Of Januvia 50mg, One In The Morning And One Before Bed Time,		Merck
	Januvia			S	Oral	1 Tablet, Qd		Merck
	Levoxin			S	Oral	1 Tablet Per Day		Not Reported
	Azithromycin			S	Oral	1 Tablet Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16847140	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2019-US-1112153		27 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective	Fluconazole	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Miltifosine	S	Unknown	Not Reported
	Flucytosine	S	Unknown	Not Reported
	Pentaminidine	S	Unknown	Not Reported
	Sulfdiazine	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16890916	NON-EXPEDITED			US-PFIZER INC-2019429807		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Gastrointestinal Disorder	Azithromycin			S		250 Mg, 2x/Day (2 The First Day)		Pfizer
	Azithromycin			S		250 Mg, 1x/Day (1 For 5 Days)		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16918931	NON-EXPEDITED			US-PFIZER INC-2019441867			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16933340	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-066918		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Granulomatosis With Polyangiitis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amikacin			S	Unknown	Unk		Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16978085	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1130015		60 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Haematochezia; Vomiting	Azithromycin			S	Oral	1 Dosage Forms		Not Reported	
	Losartan			C				Not Reported	
	Potassico/Ildroclorotiazide								
	Anastrozole			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16978167	EXPEDITED (15-DAY)		OT	US-ZYDUS-042669		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Deafness; Ear Disorder; Granulomatosis With Polyangiitis; Haemoptysis; Viral Infection	Azithromycin			S				Zydus Pharm	
	Amikacin/Amikacin Sulfate			S				Not Reported	
	Imipenem			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16978263	EXPEDITED (15-DAY)		OT	US-ZYDUS-042671		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Toxicity; Neurotoxicity	Azithromycin			S		Inhalation		Zydus Pharm	
	Amikacin			S				Not Reported	
	Clofazimine			S				Not Reported	
	Tigecycline			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16979098	NON-EXPEDITED			US-PFIZER INC-2019469984			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2019	16979367	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019466850		78 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Intracranial Mass; Ischaemic Stroke	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Lercan			C				Not Reported	
	Cacit Vitamine D3			C				Not Reported	
	Diffu K			C				Not Reported	
	Temeritduo			C				Not Reported	
	Uvedose			C				Not Reported	
	Speciafoldine			C				Not Reported	
	Oxycodone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2019	16826199	EXPEDITED (15-DAY)		OT	PHEH2019US038570		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Colour Blindness; Dyschromatopsia; Pulmonary Hypertension; Vision Blurred	Azithromycin			S	Oral	50 Mg, Qd		Novartis	
	Rifampin			S	Oral	600 Mg, Qd		Not Reported	
	Ethambutol			S	Oral	15 Mg/Kg, Unknown		Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)	5 Mg/Kg (Monday, Wednesday And Friday)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2019	16982240	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1130183		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematuria; Mouth Ulceration; Purpura; Thrombocytopenia	Azithromycine Dihydraté			S	Oral	1 Df		Not Reported	
	Nabucox 500 Mg, Comprimé			S	Oral	2 Df		Not Reported	
	Pelliculé								
	Ezetrol 10 Mg, Comprimé			C	Oral	1 Df		Not Reported	
	Flector Tissugel 1 %, Emplâtre Médicamenteux			C	Cutaneous	3 Df; 1 %		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ropinirole (Chlorhydrate De)	C	Oral	0.5 Mg	Not Reported
Bronchodual	C	Respiratory (inhalation)	2 Df	Not Reported
Spasfon	C	Oral	6 Df	Not Reported
Loxen L P 50 Mg, Gélule À Libération Prolongée	C	Oral	2 Df	Not Reported
Aspirine Protect 100 Mg, Comprimé Gastro-Résistant	C	Oral	1 Df	Not Reported
Nebivolol	C	Oral	1 Df	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2019	16983159	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2019M1103486		66 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia; Visual Impairment	Azithromycin			S	Oral	2250 Milligram, Qw		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Nov-2019	16983282	EXPEDITED (15-DAY)		OT	NL-009507513-1910NLD017145		7 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatotoxicity; Hypertriglyceridaemia	Imipenem (+) Cilastatin Sodium			S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses		Merck	
	Imipenem (+) Cilastatin Sodium			S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses		Merck	
	Imipenem (+) Cilastatin Sodium			S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses		Merck	
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Not Reported	
	Azithromycin			S	Oral	10 Mg/Kg Once Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	10 Mg/Kg Once Daily	Not Reported
Clofazimine	S	Oral	50mg Once Daily; If Weight Greater Than 40kg, Then 100mg Once Daily	Not Reported
Clofazimine	S	Oral	50mg Once Daily; If Weight Greater Than 40kg, Then 100mg Once Daily	Not Reported
Clofazimine	S	Oral	50mg Once Daily; If Weight Greater Than 40kg, Then 100mg Once Daily	Not Reported
Cilastatin Sodium (+) Imipenem	S	Topical	5/5 Mg/ML; Three Drops Three Times Daily	Not Reported
Cilastatin Sodium (+) Imipenem	S			Not Reported
Tigecycline	S	Topical	5 Mg/ML; Three Drops Three Times Daily	Not Reported
Tigecycline	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2019	16136923	EXPEDITED (15-DAY)		OT	AU-ACCORD-115916		9 YR	Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated;	Mycophenolic Acid			S				Accord
Dyspnoea Exertional;	Montelukast			S				Not Reported
Oxygen Saturation	Methylprednisolone			S				Not Reported
Decreased; Pulmonary	Azithromycin			S				Not Reported
Function Test Decreased	Sirolimus			S		Frequency : 2 Times A Day		Not Reported
	Ciclosporin			C		At Weaning Dose		Not Reported
	Prednisolone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2019	16987686	NON-EXPEDITED			NVSC2019US012125			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Rash; Swelling; Vomiting	Penicillin G Sodium	S	Unknown	Novartis
	Sulphazine	S	Unknown	Not Reported
	Zithromax	S	Unknown	Not Reported
	Keflex	S	Unknown	Not Reported
	Aspirin	S	Unknown	Not Reported
	Lyrica	S	Oral	Not Reported
				150 Mg, Bid(One Capsule Twice A Day 90 Days)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2019	16123761	EXPEDITED (15-DAY)		OT	AU-MYLANLABS- 2019M1027245			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; No Adverse Event	Azithromycin			S		250 Milligram, 3xw		Not Reported
	Methylprednisolone			S		10 Mg/Kg/Qd, 4 Days Q2- 3 Wk		Not Reported
	Montelukast			S		10 Milligram, Qd		Mylan
	Sirolimus			S		1 Milligram, Bid		Mylan
	Sirolimus			S				Mylan
	Prednisolone			S		2 Mg/Kg		Mylan
	Mycophenolate			S		Unk		Mylan
	Mycophenolate			S				Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2019	16989122	NON-EXPEDITED			US-PFIZER INC- 2019473266		48 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Azithromycin			S		Unk [5 Day Course]		Pfizer
	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2019	16989440	EXPEDITED (15-DAY)		LT, OT	CN-PFIZER INC- 2019472349		182 DAY	Male	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cyanosis; Loss Of Consciousness; Off Label Use; Product Use Issue; Shock	Zithromax			S	Intravenous drip	0.125 G, 1x/Day		Pfizer
	Hemocoagulase			C	Intravenous bolus	0.5 Kiu, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2019	16989453	NON-EXPEDITED			US-PFIZER INC-2019472779		82 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Clindamycin			S		Unk		Pfizer
	Doxycycline Calcium			S		Unk		Pfizer
	Lidocaine Hcl			S		Unk		Unknown
	Atorvastatin Calcium			S				Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Propanolol Hcl			S		Unk		Unknown
	Actonel			S		Unk		Not Reported
	Cefdinir			S		Unk		Not Reported
	Diprivan			S		Unk		Not Reported
	Flonase			S		Unk		Not Reported
	Kenalog			S		Unk		Not Reported
	Macrodantin			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Penicillin [Penicillin Nos]			S				Not Reported
	Sulfa [Sulfanilamide]			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Nov-2019	16991395	NON-EXPEDITED			US-PFIZER INC-2019475207			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	15699315	EXPEDITED (15-DAY)		HO, OT	TH-ACTELION-A-CH2018-181023		70 YR	Female	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Back Pain; Chest Pain; Diarrhoea; Dyspnoea; Hepatitis; Hypoxia; Infection; Nausea; Oxygen Saturation Decreased; Pleuritic Pain; Pneumonia; Productive Cough; Pulmonary Tuberculosis; Pyrexia; Sputum Abnormal	Macitentan			S	Oral	10 Mg, Qd		Actelion	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Amoxicilline/Acide Clavulanique			S	Oral			Not Reported	
	Paracetamol			S	Oral	1000 Mg, Unk		Not Reported	
	Paracetamol			S	Oral	1500 Mg, Qd		Not Reported	
	Pyrazinamide			S	Oral	1500 Mg, Unk		Not Reported	
	Lodoz			C		Unk		Not Reported	
	Meloxicam			C		Unk		Not Reported	
	Dorner			C		Unk		Not Reported	
	Warfarin			C		Unk		Not Reported	
	Celecoxib			C		Unk		Not Reported	
	Omeprazole			C		Unk		Not Reported	
	Pregabalin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16760314	NON-EXPEDITED			US-PFIZER INC-2019372731			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Diclofenac Sodium			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16766771	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1081268		64 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Inflammation; Ischaemia;	Azithromycin			S	Unknown	Unk		Not Reported	
Pleural Effusion; Pyrexia;	Ceftriaxone			S	Unknown	Unk		Mylan	
Spinal Cord Compression;	Ceftriaxone			S	Unknown	Unk		Mylan	
Spinal Cord Injury									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16993484	EXPEDITED (15-DAY)		OT	NL-ACCORD-159654		9 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Fatigue;	Tigecycline			S	Intravenous (not otherwise specified)	(2.4 Mg/Kg/Day In 2 Doses)		Not Reported	
Hepatotoxicity; Nausea;	Clofazimine			S	Oral			Not Reported	
Venous Thrombosis;	Azithromycin			S	Oral			Not Reported	
Vomiting	Cilastatin/Imipenem			S	Intravenous (not otherwise specified)	(60/60 Mg/Kg/Day In 2-4 Doses)		Not Reported	
	Sodium Chloride			C		Strength: 0.9 %		Not Reported	
	Clofazimine			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Tigecycline			S	Topical	Strength: 5 Mg/ML		Not Reported	
	Cilastatin/Imipenem			S	Topical	Strength: 5 Mg/ML / 5 Mg/ML		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16994054	EXPEDITED (15-DAY)		OT	NL-ACCORD-159684		7 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Cholesterol Increased; Decreased	Tigecycline			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Appetite; Hepatotoxicity; Hypertriglyceridaemia; Nausea; Poor Feeding Infant; Vomiting	Cilastatin/Imipenem	S	otherwise specified)		
	Azithromycin	S	Topical	Strength 5/5 Mg/ML	Not Reported
	Cilastatin/Imipenem	S	Oral		Not Reported
		S	Intravenous (not otherwise specified)		Not Reported
	Clofazimine	S	Oral		Not Reported
	Sodium Chloride	C		Strength 0.9%	Not Reported
	Granisetron	C			Not Reported
	Cilastatin/Imipenem	S	Intravenous (not otherwise specified)		Not Reported
	Clofazimine	S	Oral		Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)	Reduced Dose	Not Reported
	Tigecycline	S	Topical	Strength 5 Mg/ML	Not Reported
	Cilastatin/Imipenem	S	Topical		Not Reported
	Azithromycin	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16994599	EXPEDITED (15-DAY)		DE, HO, OT	CA-SA-2019SA303113		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptococcosis; Drug Ineffective; Drug Intolerance; Drug Resistance; Enterocolitis; Multiple Organ Dysfunction Syndrome; Mycobacterium Avium Complex Infection; Nosocomial Infection	Rifampicin			S	Intravenous (not otherwise specified)			Sanofi
	Amikacin			S	Parenteral	Unk Unk, Unk		Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)	Unk Unk, Unk, Powder For Solution		Not Reported
	Clarithromycin			S	Oral	Unk Unk, Unk		Not Reported
	Ethambutol			S	Oral	Unk Unk, Unk		Not Reported
	Fluconazole			S	Oral	Unk Unk, Unk		Not Reported
	Moxifloxacin Hydrochloride			S		Unk Unk, Unk		Not Reported
	Prednisone			S		Unk Unk, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mycophenolate Sodium	S	Unknown	Unk Unk, Unk	Not Reported
Tacrolimus	S			Not Reported
Rifabutin	S	Oral	Unk Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16994937	EXPEDITED (15-DAY)		HO, OT	NVSC2019US022669		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Dyspnoea; Hypoxia; Interstitial Lung Disease; Pneumonia	Paclitaxel			S	Unknown	Unk Unk, Cyclic (11 Cycles)		Not Reported
Pneumococcal; Product Use In Unapproved Indication; Productive Cough; Tachycardia; Tachypnoea	Ceftriaxone			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk Unk, Cyclic (11 Cycles)		Not Reported
	Adriamycin			S	Unknown	Unk Unk, Cyclic (11 Cycles)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Nov-2019	16994940	NON-EXPEDITED			US-PFIZER INC-2019472265		68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	9943337	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-PFIZER INC-2014058013		54 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bladder Cancer; Decreased Appetite; Dyspnoea; Headache; Hypoaesthesia; Insomnia; Ischaemic Stroke; Loss Of Personal Independence In	Azithromycin Teva			S	Oral	Unk		Not Reported
	Azithromycin Teva			S				Not Reported
	Azithromycin Teva			S				Not Reported
	Diazepam			C		10 Mg, Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Daily Activities; Memory
Impairment; Suffocation
Feeling; Swollen Tongue

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	14271555	EXPEDITED (15-DAY)		DE, OT	US-MYLANLABS-2017M1076609		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Vancomycin			S	Unknown	Unk		Not Reported	
Ecchymosis;	Ceftriaxone			S	Unknown	Unk		Not Reported	
Haemoptysis;	Azithromycin			S	Unknown	Unk		Not Reported	
Thrombocytopenia	Piperacillin/Tazobactam			S	Unknown	Unk		Not Reported	
	Coumadin			C	Unknown	Unk		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	16712596	EXPEDITED (15-DAY)		HO, OT	PHHY2019BR138647			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Bacterial	Cosentyx			S	Unknown	1 Df, Q4w		Novartis	
Infection; Breast Mass;	Amoxicillin			S	Unknown			Not Reported	
Daydreaming; Gait	Amoxicillin			S				Not Reported	
Inability; Inflammation;	Azithromycin			S	Unknown			Not Reported	
Localised Infection;	Azithromycin			S				Not Reported	
Malaise; Nasopharyngitis;									
Oropharyngeal Pain; Pain									
In Extremity; Pharyngitis;									
Secretion Discharge;									
Sinusitis; Spondylitis;									
Wound									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	16799193	NON-EXPEDITED			US-PFIZER INC-2019393084		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Ketorolac Tromethamine	S	Unk	Pfizer
	Plaquenil	S	Unk	Not Reported
	Toradol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	16997459	EXPEDITED (15-DAY)		DE, OT	CA-SA-2019SA303106		76 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Rifampicin			S	Intravenous (not otherwise specified)			Sanofi
	Rifampicin			S				Sanofi
	Imipenem/Cilastatin			S				Not Reported
	Imipenem/Cilastatin			S				Not Reported
	Azithromycin Monohydrate			S	Vials			Not Reported
	Azithromycin Monohydrate			S				Not Reported
	Tigecycline			S				Not Reported
	Tigecycline			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	16998173	EXPEDITED (15-DAY)		HO, OT	US-GLAND PHARMA LIMITED-2076496		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Granulomatosis With Polyangiitis	Azithromycin Monohydrate			S				Gland Pharma
	Rituximab			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	16998949	EXPEDITED (15-DAY)		OT	NL-ACCORD-159656		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Nausea; Transaminases Increased; Vomiting	Tigecycline			S	Intravenous (not otherwise specified)	In 2 Doses, Dilution Of Powder Formulations		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clofazimine	S	Oral		Not Reported
Cilastatin/Imipenem	S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses, Dilution Of Powder Formulations	Not Reported
Azithromycin	S	Oral		Not Reported
Sodium Chloride	C		Strength: 0.9%	Not Reported
Clofazimine	S	Oral		Not Reported
Cilastatin/Imipenem	S	Intravenous (not otherwise specified)	Strength: 5 Mg/ML / 5 Mg/ML, Three Drops Three Times Daily	Not Reported
Azithromycin	S	Oral		Not Reported
Tigecycline	S	Topical	Strength: 5 Mg/ML	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	17002123	EXPEDITED (15-DAY)			US-ROCHE-2248503		11 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infection	Pulmozyme			S	Unknown	Ongoing: Yes		Not Reported
	Aztreonam Lysine			S	Respiratory (inhalation)	Ongoing: Yes, 28 Days On And 28 Days Off		Not Reported
	Rifampicin			S	Unknown	Ongoing		Not Reported
	Ethambutol			S	Unknown	Ongoing: Unknown		Not Reported
	Azithromycin			S	Unknown	Ongoing: Unknown		Not Reported
	Tobramycin			S	Unknown	Ongoing: Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	17002192	EXPEDITED (15-DAY)			US-ROCHE-2379983			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Chest Discomfort; Dyspnoea	Pulmozyme			S	Respiratory (inhalation)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Aztreonam Lysine	S	Respiratory (inhalation)					Not Reported
	Orkambi	S	Unknown					Not Reported
	Ventolin [Salbutamol]	S	Respiratory (inhalation)					Not Reported
	Ventolin [Salbutamol]	S						Not Reported
	Omeprazole	S	Oral					Not Reported
	Ascorbic Acid;Betacarotene;Biotin;Colecal ciferol;Cyanocobalamin;Folic [Minerals\Vitamins]	S	Oral					Not Reported
	Loratadine	S	Oral					Not Reported
	Symdeko	S	Oral			1 Yellow Tab Qam And 1 Blue Tab Qpm		Not Reported
	Tobramycin	S	Respiratory (inhalation)			5 MI Every 12 Hours For 28 Days On And 28 Days Off		Not Reported
	Creon	S	Oral			5 Caps With Meals And 2 Caps With Snacks		Not Reported
	Azithromycin	S	Oral					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Nov-2019	17005842	DIRECT		HO, LT			54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis	Azithromycin 250 Mg Tablet (6-Count, 5-Day Supply)			S	Oral	Quantity:6 Tablet(S);	4 DAY	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2019	16951488	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2019458645			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Injury; Cerebrovascular Accident	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2019	17002970	EXPEDITED (15-DAY)		HO, OT	LB-LUPIN PHARMACEUTICALS INC.-2019-07135		81 YR	Male	LBN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Oral	Unk		Lupin	
	Azithromycin			S				Lupin	
	Azithromycin			S				Lupin	
	Esomeprazole			C	Oral	40 Milligram, Qd		Not Reported	
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Qd		Not Reported	
	Candesartan Cilexetil			C	Oral	16 Milligram, Qd		Not Reported	
	Bisoprolol			C	Oral	2.5 Milligram, Bid		Not Reported	
	Atorvastatin			C	Oral	10 Milligram, Qd		Not Reported	
	Clopidogrel			C	Oral	75 Milligram, Qd		Not Reported	
	Iron Polymaltose			C	Oral	100 Milligram		Not Reported	
	Folic Acid			C	Unknown	0.35 Milligram, Qd		Not Reported	
	Acetaminophen			C	Intravenous (not otherwise specified)	1 Gram, Qid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2019	17003159	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR- APL-2019-070249		9 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Fatigue; Hepatotoxicity; Nausea; Venous Thrombosis; Vomiting	Azithromycin			S	Oral	10 Milligram/Kilogram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Tigecycline			S	Intravenous (not otherwise specified)	Tigecycline (2.4 Mg/Kg/Day In 2 Doses)		Not Reported	
	Cilastatin Sodium;Imipenem			S	Intravenous (not otherwise specified)	Intravenous Imipenem/Cilastatin (60/60 Mg/Kg/Day In 2-4 Doses)		Not Reported	
	Cilastatin Sodium;Imipenem			S	Topical	3 Gtt Drops		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Clofazimine	S	Oral	Unk			Not Reported	
		Tigecycline	S	Topical	3 Gtt Drops, 3 Times A Day			Not Reported	
		Sodium Chloride	C	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2019	17003458	NON-EXPEDITED		OT	US-APOTEX-2019AP024460		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Syncope; Urticaria	Azithromycin			S	Oral	250 Mg, Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2019	17004321	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019478472		1 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Peripheral Swelling	Zithromax			S	Oral	0.1 G, 1x/Day		Pfizer	
	Rocephin			S	Intravenous drip	0.8 G, 1x/Day		Not Reported	
	Mucosolvan			C	Intravenous drip	10 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Nov-2019	17006936	NON-EXPEDITED			US-TEVA-2019-US-1133136		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Blister; Oral Mucosal Blistering; Oral Pain; Tongue Blistering	Azithromycin			S	Oral	250		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	15591930	EXPEDITED (15-DAY)		OT	CA-009507513-1811CAN000832		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Mental Status Changes	Primaxin I.V.	S	Unknown	Unk	Merck
	Primaxin I.V.	S			Merck
	Tigecycline	S	Unknown	Unk	Not Reported
	Tigecycline	S			Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Azithromycin	S			Not Reported
	Rifampin	S	Unknown	Unk	Not Reported
	Rifampin	S			Not Reported
	Minocycline	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	16995747	NON-EXPEDITED			US-PFIZER INC-2019474088			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Urticaria	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	17007870	NON-EXPEDITED			US-TEVA-2019-US-1132910		10 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea	Azithromycin Tablets Usp			S	Unknown	500 Mg On The1st Day On 25-Oct-2019 And 250 Mg The Following Two Days On 29-Oct-2019 And 30-Oct-2019		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	17008032	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-226742		69 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematuria; Mouth Ulceration; Purpura;	Azithromycin			S	Oral	1 Dosage Form, Unk		Sun

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Thrombocytopenia	Nabucox 500 Mg, Comprime Pellicule	S	Oral	2 Dosage Form, Daily	Not Reported
	Ezetrol 10 Mg, Comprime	C	Oral	1 Dosage Form, Daily	Not Reported
	Flector Tissugel 1 %, Emplatre Medicamenteux	C	Cutaneous	3 Dosage Form, Daily	Not Reported
	Ropinirole (Chlorhydrate De)	C	Oral	0.5 Milligram, Daily	Not Reported
	Bronchodual	C	Respiratory (inhalation)	2 Dosage Form, Daily	Not Reported
	Spasfon	C	Oral	6 Dosage Form, Daily	Not Reported
	Loxen L P 50 Mg, Gelule A Liberation Prolongee	C	Oral	2 Dosage Form, Daily	Not Reported
	Aspirine Protect 100 Mg, Comprime Gastro-Resistant	C	Oral	1 Dosage Form, Daily	Not Reported
	Nebivolol	C	Oral	1 Dosage Form, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	17010381	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1106450		54 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ageusia; Hypoaesthesia	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Diffu K			S	Oral	2 Dosage Form		Mylan
	Diamox /00016901/			S	Oral	3 Dosage Form, Qd		Mylan
	Cosopt			S	Ophthalmic	2 Gtt Drops		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	17010991	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1106589		33 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Gastrointestinal Pain	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	17011864	NON-EXPEDITED			US-PFIZER INC-2019481734			Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Zithromax			S		Unk		Pfizer	
	Repatha			S		Unk		Not Reported	
	Repatha			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2019	17109464	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Packaging Quantity Issue	Z-Pak Azithromycinz-Pak			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	13386820	NON-EXPEDITED			US-PFIZER INC- 2017138222			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	15288239	NON-EXPEDITED			US-PFIZER INC- 2018331465		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	16365197	EXPEDITED (15-DAY)		HO	CA- GLAXOSMITHKLINE- CA2019GSK056336			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Blood Lactic Acid Increased; Blood Potassium Decreased; Breath Sounds Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Cough; Dyspnoea; Ear Pruritus; Eosinophilia; Eye Pruritus; Lacrimation Increased; Loss Of Personal Independence In Daily Activities; Nasal Congestion; Nasal Polyps; Platelet Count Increased; Pulmonary Function Test Abnormal; Rhinitis Allergic; Rhinorrhoea; Sneezing; Upper-Airway Cough Syndrome; Urticaria; Vasculitis; Wheezing	Nucala	S	100 Mg, Z (Monthly)	Glaxosmithkline
	Salbutamol	S	Unk	Glaxosmithkline
	Ceftriaxone	S	Unk	Glaxosmithkline
	Azithromycin	S	Unk	Glaxosmithkline
	Symbicort	S	2 Mg, Unk	Not Reported
	Xolair	S	150 Mg, Unk	Not Reported
	Rupall	S		Not Reported
	Singulair	S	10 Mg, Unk	Glaxosmithkline
	Tamiflu	S		Not Reported
	Prednisone	S	Unk	Not Reported
	Rupatadine	S	10 Mg, Unk	Not Reported
	Pulmicort	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	16862986	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1089942		73 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cachexia; Chills; Condition Aggravated; Disseminated Bacillus Calmette-Guerin Infection; Hepatitis Cholestatic; Infection; Inflammation; Kidney Infection; Medication Error; Normochromic Anaemia; Normocytic Anaemia; Pyrexia; Respiratory Rate Increased	Azithromycin			S	Unknown	Unk		Not Reported	
	Cefixime			S	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	16866465	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2019GSK038997		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Dyspnoea; Increased Upper Airway Secretion; Loss Of Personal Independence In Daily Activities; Polymyositis; Sleep Apnoea Syndrome; Sleep Disorder Due To A General Medical Condition; Therapeutic Product Effect Incomplete; Thyroid Disorder; Wheezing	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z Monthly		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z, Monthly		Glaxosmithkline	
	Alvesco			S		2 Puff(S), Qd		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Zenhale			S		2 Puff(S), Bid		Not Reported	
	Spiriva Respimat			S		2 Puff(S), Qd		Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	16969807	EXPEDITED (15-DAY)		HO	PL-TEVA-2019-PL-1128016		9 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Ineffective; Sinusitis; Vomiting	Sumamed Forte			S	Oral	8 MI Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	17015419	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1135258			Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholecystitis; Condition Aggravated; Hepatomegaly	Sumamed			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	17015451	EXPEDITED (15-DAY)		OT	CA-009507513-1911CAN001744			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Invanz			S	Unknown			Merck
	Diprolene			S	Unknown	Unk		Merck
	Acetaminophen			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Amoxicillin			S	Unknown	Unk		Not Reported
	Apo Hydroxyzine			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Avamys			S	Unknown	Unk, Dosage Form: Spray, Metered Dose		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Bactroban (Mupirocin)			S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
	Betaderm (Povidone-Iodine)			S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
	Biaxin XI			S	Unknown	Unk		Not Reported
	Bisacodyl			S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
	Calcium Carbonate (+) Magnesium (Unspecified) (+) Vitamin D (Unspecifi			S	Unknown	Unk		Not Reported
	Calcium Carbonate (+) Cholecalciferol			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Clotrimazole			S	Unknown	Unk		Not Reported
	Desonide			S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
	Dilaudid			S	Unknown	Unk, Dosage Form: Not		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			Specified	
Diphenhydramine	S	Unknown	Unk	Not Reported
Entocort	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Glycerin	S	Unknown	Unk	Not Reported
Gramicidin (+) Neomycin Sulfate (+) Polymyxin B Sulfate	S	Unknown	Unk	Not Reported
Habitrol	S	Unknown	Unk, Dosage Form: Patch	Not Reported
Humira	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	Not Reported
Kenalog	S	Unknown	Unk, Dosage Form: Suspension Intra-Articular	Not Reported
Lomotil (Atropine Sulfate (+) Diphenoxylate Hydrochloride)	S	Oral	Unk Unk, Qid	Not Reported
Polyethylene Glycol 3350 (+) Potassium Chloride (+) Sodium Bicarbonate	S	Unknown	Unk	Not Reported
Metronidazole	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Msir	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Mupirocin	S	Unknown	Unk, Dosage Form: Ointment Topical	Not Reported
Nadolol	S	Unknown	Unk	Not Reported
Nicoderm	S	Unknown	Unk, Dosage Form: Patch	Not Reported
Nicotine Polacrilex	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Pentasa	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Prednisone	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pulmicort	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Refresh Tears	S	Unknown	Unk, Dosage Form: Drops Ophthalmic	Not Reported
Salinex [Sodium Chloride]	S	Unknown	Unk, Dosage Form: Solution Nasal	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Sulfamethoxazole (+) Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole (+) Trimethoprim	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
Cholecalciferol	S	Unknown	Unk	Not Reported
Calcium Carbonate (+) Cholecalciferol	C	Unknown		Not Reported
Valsartan	C	Unknown	Unk, Dosage Form: Not Specified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Nov-2019	17015690	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019480861		2 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Dysphoria; Irritability	Zithromax			S	Intravenous drip	0.12 G, 1x/Day		Pfizer	
	Zithromax			S				Pfizer	
	Solu-Medrol			S	Intravenous drip	20 Mg, 1x/Day		Pfizer	
	Singulair			S	Oral	4 Mg, 1x/Day		Not Reported	
	Bricanyl			C	Respiratory (inhalation)	2.5 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	16909579	NON-EXPEDITED			US-PFIZER INC-2019439184		46 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Zithromax	S	Unk	Pfizer
	Klonopin	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	16943676	EXPEDITED (15-DAY)	CA		US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-100536		< 1 DAY	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Brain Stem Auditory Evoked Response Abnormal; Foetal Exposure During Pregnancy; Low Birth Weight Baby	Atazanavir Sulfate			S	Transplacental	1 Dosage Form, Qd		Bristol Myers Squibb
	Norvir			S	Transplacental	1 Dosage Form, Qd		Not Reported
	Triumeq			S	Transplacental	1 Dosage Form, Qd		Not Reported
	Emtricitabine; Rilpivirine; Tenofovir Disoproxil Fumarate			S	Transplacental	1 Dosage Form, Qd		Not Reported
	Trimethoprim Sulfamethoxazole			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Clotrimazole			S	Transplacental	Unk		Not Reported
	Enoxaparin			S	Transplacental	Unk		Not Reported
	Codeine			S	Transplacental	Unk		Not Reported
	Prenatal Vitamins [Ascorbic Acid; Betacarotene; Calcium Sulfate; Colecalciferol; Ferrous Sulfate]			C	Transplacental	Unk		Not Reported
				C	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17008736	EXPEDITED (15-DAY)	OT		NL-ACS-001548		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Hepatotoxicity; Hypertriglyceridaemia; Nausea; Off Label Use; Vomiting	Cilastatin, Imipenem			S	Intravenous (not otherwise specified)			Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Clofazimine		S	Oral				Not Reported
		Granisetron		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17008737	EXPEDITED (15-DAY)		OT	NL-ACS-001549		9 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthropathy; Fatigue; Hepatotoxicity; Nausea; Off Label Use; Vomiting	Cilastatin, Imipenem			S	Intravenous (not otherwise specified)			Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Clofazimine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17018851	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2019-071249		66 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia; Visual Impairment	Azithromycin Film-Coated Tablets			S	Oral	2250 Milligram, Every Week		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17019568	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-071929		64 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Oseltamivir			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17019641	NON-EXPEDITED		HO, OT	US-APOTEX- 2019AP024753		2 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sjs-Ten Overlap	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17020610	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019482113		22 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema; Sensation Of Foreign Body	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17021167	EXPEDITED (15-DAY)		HO	CZ-MYLANLABS-2019M1106805		50 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Erythema; Erythema Nodosum; Inflammation; Oedema Peripheral; Rheumatoid Arthritis; Urinary Tract Infection; Viral Infection	Klacid			S	Unknown	Unk		Mylan	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Biweekly		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Nov-2019	17022946	NON-EXPEDITED			US-PFIZER INC-2019485860		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	15593813	NON-EXPEDITED			US-PFIZER INC-2018449898		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Demerol			S		Unk		Pfizer
	Enbrel			S		Unk		Pfizer
	Fentanyl Citrate			S		Unk		Unknown
	Ibuprofen			S		Unk		Pfizer
	Percodan			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Hydrocodone			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Aleve			S		Unk		Not Reported
	Tramadol Hcl			S		Unk		Not Reported
	Penicillin V Potassium			S		Unk		Not Reported
	Oxycontin			S		Unk		Not Reported
	Acetaminophen			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	16763278	EXPEDITED (15-DAY)		OT	IT-TEVA-2019-IT-1100300		24 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abdominal Pain; Dysentery; Nausea	Azithromycin			S	Oral	500 Mg Per Day		Not Reported
	Coumadin 5 Mg Compresse			S	Oral	5 Mg, As Required		Not Reported
	Paracetamol			C	Oral	1 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17020975	EXPEDITED (15-DAY)		HO	PT-PFIZER INC-2019477383		77 YR	Female	PRT

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17025078	NON-EXPEDITED			US-MYLANLABS-2019M1106860		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Muscle Spasms	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17025693	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019482962		23 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17026236	EXPEDITED (15-DAY)		LT	CN-PFIZER INC-2019489439		43 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Discomfort; Cold Sweat; Dizziness; Hypoaesthesia	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17026525	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019486115		66 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia; Off Label Use; Product Use Issue; Visual	Azithromycin			S	Oral	2250 Mg, Weekly (3 Of 250 Mg On		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Impairment

Monday/Wednesday/Friday)

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026535	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019484027		42 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Malaise; Tremor	Zitromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026560	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019485255			Female	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Chills; Dyspnoea; Face Oedema; Hypersensitivity; Off Label Use; Product Use Issue; Pyrexia; Rash; Temperature Intolerance	Zithromax			S	Oral	0.5 Ug, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17026823	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2019483744		34 YR	Male	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Alanine Aminotransferase Increased; Cholestasis; Condition Aggravated; Off Label Use; Product Use In Unapproved Indication; Product Use Issue	Zithromax Prograf			S C	Oral	500 Mg, Daily Unk		Pfizer Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Nov-2019	17027044	EXPEDITED (15-DAY)		OT	CA-SA-2019SA305810			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Macular Degeneration	Triamcinolone Acetonide	S	Unknown	Unk	Sanofi
	Paracetamol	S	Unknown	Unk	Not Reported
	Alprazolam	S	Unknown	Unk	Not Reported
	Amoxicillin Trihydrate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Atorvastatin	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Mupirocin	S	Unknown	Unk	Not Reported
	Betamethasone Dipropionate	S	Unknown	Unk	Not Reported
	Clarithromycin	S	Unknown	Unk	Not Reported
	Bisacodyl	S	Unknown	Unk	Sanofi
	Cetirizine Hydrochloride	S	Unknown	Unk	Not Reported
	Clarithromycin	S	Unknown	Unk	Not Reported
	Clotrimazole	S	Unknown	Unk	Not Reported
	Desonide	S	Unknown	Unk	Not Reported
	Hydromorphone Hydrochloride	S	Unknown	Unk	Not Reported
	Diphenhydramine	S	Unknown	Unk	Sanofi
	Budesonide	S	Unknown	Unk	Not Reported
	Glycerine	S	Unknown	Unk	Not Reported
	Nicotine	S	Unknown	Unk	Sanofi
	Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;So	S	Unknown	Unk	Not Reported
	Metronidazole	S	Unknown	Unk	Sanofi
	Morphine Sulfate	S	Unknown	Unk	Not Reported
	Mupirocin	S	Unknown	Unk	Not Reported
	Nadolol	S	Unknown	Unk	Not Reported
	Nicoderm	S	Unknown	Unk	Sanofi
	Nicotine Polacrilex	S	Unknown	Unk	Not Reported
	Pantoprazole	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mesalazine	S	Unknown	Unk	Sanofi
Prednisone	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Budesonide	S	Unknown	Unk	Not Reported
Sodium Chloride	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Unk	Not Reported
Colecalciferol	S	Unknown	Unk	Not Reported
Avamys	S	Unknown	Unk	Not Reported
Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Refresh Tears	S	Unknown	Unk	Not Reported
Sinus Rinse	S	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17027574	NON-EXPEDITED			US-PFIZER INC-2019488147		60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17027695	EXPEDITED (15-DAY)		OT	JP-JNJFOC-20190525279		37 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Chlamydial	Prezistanaive			S	Oral			Not Reported	
Cervicitis; Exposure	Prezistanaive			S	Oral			Not Reported	
During Pregnancy	Utemerin			S	Oral			Not Reported	
	Ferrogradumet			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromac	S	Oral	Not Reported
Truvada	C	Oral	Not Reported
Truvada	C	Oral	Not Reported
Norvir	C	Oral	Not Reported
Norvir	C	Oral	Not Reported
Xyzal	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17028320	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2019-061339			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Metronidazole			S	Unknown			Not Reported
	Budesonide			S	Unknown			Santarus
	Sodium Chloride		Y	S	Unknown			Bausch And Lomb
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Mesalazine			S	Unknown			Valeant
	Paracetamol			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Amoxicillin Trihydrate			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Betamethasone Dipropionate			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Bisacodyl			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Clotrimazole			S	Unknown			Not Reported
	Desonide			S	Unknown			Not Reported
	Hydromorphone Hydrochloride			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diphenhydramine	S	Unknown	Not Reported
Nicotine	S	Unknown	Not Reported
Morphine Sulfate	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Nicotine Polacrilex	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Not Reported
Colecalciferol	S	Unknown	Not Reported
Colecalciferol	S	Unknown	Not Reported
Avamys	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Refresh Tears	S	Unknown	Not Reported
Sinus Rinse	S	Unknown	Not Reported
Glycerine	S	Unknown	Not Reported
Biaxin XI	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Betaderm	S	Unknown	Not Reported
Kenalog	S	Unknown	Not Reported
Lomotil	S	Unknown	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Not Reported
Calcium Carbonate/Magnesium Sulfate/Vitamin D3	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
Mupirocin	S	Unknown	Not Reported
Bactroban	S	Unknown	Not Reported

Extended Release Tablet

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate Anhydrous	S	Unknown	Not Reported
	Valsartan	C		Not Reported
	Calcium Carbonate/Vitamin D3	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Nov-2019	17116818	DIRECT	Y	HO			57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Spinal Fusion Surgery; Therapy Interrupted	Humira 40mg/0.4ml			S	Subcutaneous			Abbvie
	Cyclobenzapr			C				Not Reported
	Stool Softnr			C				Not Reported
	Losartan Pot			C				Not Reported
	Jinteli			C				Not Reported
	Hydroco/Apap			C				Not Reported
	Cyclobenzapr			C				Not Reported
	Proair Hfa Aer			C				Not Reported
	Tirosint			C				Not Reported
	Symbicort			C				Not Reported
	Prednisone			C				Not Reported
	Diazepam			C				Not Reported
	Prometh/Cod			C				Not Reported
	Azithromycin			S				Not Reported
	Duloxetine			C				Not Reported
	Amox/K Clav			C				Not Reported
	Atorvastatin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	14762789	NON-EXPEDITED			US-PFIZER INC-2018154283		31 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	16979915	EXPEDITED (15-DAY)		OT	NVSC2019NL016822		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Dermatitis; Dysphagia; Hepatotoxicity; Hypertriglyceridaemia; Leukopenia; Product Use In Unapproved Indication; Rash; Thrombocytopenia; Transaminases Increased; Urticaria	Azithromycin			S	Oral	10 Mg/Kg, Qd		Novartis
	Clofazimine			S	Oral	50 Mg/Kg, Qd		Not Reported
	Imipenem/Cilastatin			S	Intravenous (not otherwise specified)	60 Mg/Kg, Qd (In 2-4 Doses)		Not Reported
	Imipenem/Cilastatin			S	Topical	5 Mg/ML, Tid (Three Drops)		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg, Qd (In 2 Doses)		Not Reported
	Tigecycline			S	Topical	5 Mg/ML, Qid (Three Drops)		Not Reported
	Sodium Chloride Solution			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Dexamethasone			C				Not Reported
	Granisetron			C	Unknown	Unk		Not Reported
	Granisetron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17029106	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-072434		72 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatosis; Erythema; Malaise; Pharyngeal Enanthema; Pruritus; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17030695	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2019486857			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Alprazolam			S		Unk		Pfizer
	Atorvastatin Calcium			S		Unk		Pfizer
	Calcium Carbonate			S		Unk		Pfizer
	Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cholecalciferol/Vitamin D			S		Unk		Unknown
	Magnesium Sulfate			S		Unk		Unknown
	Metronidazole			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Pregabalin			S		Unk		Pfizer
	Acetaminophene			S		Unk		Not Reported
	Amoxicillin			S		Unk		Not Reported
	Apo Hydro			S	Endocervical	Unk		Not Reported
	Atropine Sulfate/Diphenoxylate Hydrochloride			S	Oral	Unk		Not Reported
	Avamys			S		Unk		Not Reported
	Azithromycin Dihydrate			S		Unk		Not Reported
	Betamethasone			S		Unk		Not Reported
	Betamethasone Dipropionate			S		Unk		Not Reported
	Biaxin XL			S		Unk		Not Reported
	Bisacodyl			S		Unk		Not Reported
	Cetirizine			S		Unk		Not Reported
	Clarithromycin			S		Unk		Not Reported
	Clotrimazole			S		Unk		Not Reported
	Cupric Oxide			S		Unk		Not Reported
	Desonide			S		Unk		Not Reported
	Dilaudid			S		Unk		Not Reported
	Diphenhydramine			S		Unk		Not Reported
	DL-Alpha Tocopheryl Acetate			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Entocort	S	Unk	Not Reported
Ertapenem Sodium	S	Unk	Not Reported
Flovent	S	Unk	Not Reported
Glycerine	S	Oral	Unk
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unk	Not Reported
Humira	S	Subcutaneous	Unk
Kenalog [Triamcinolone Acetonide]	S	Intra-articular	Unk
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;So	S	Unk	Not Reported
Ms Ir	S	Unk	Not Reported
Mupirocin	S	Unk	Not Reported
Nadolol	S	Unk	Not Reported
Nicoderm	S	Unk	Not Reported
Nicotine	S	Unk	Not Reported
Nicotine Polacrilex	S	Unk	Not Reported
Pantoprazole	S	Unk	Not Reported
Pentasa	S	Unk	Not Reported
Prednisone	S	Unk	Not Reported
Pulmicort	S	Unk	Not Reported
Refresh Tears	S	Ophthalmic	Unk
Sinus Rinse	S	Nasal	Unk
Sulfamethoxazole And Trimethoprim	S	Unk	Not Reported
Vitamin D3	S	Unk	Not Reported
Xantofyl Palmitate	S	Unk	Not Reported
Zeaxanthin	S	Unk	Not Reported
Zinc Oxide	S	Unk	Not Reported
Valsartan	C	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17031016	EXPEDITED (15-DAY)		OT	FR-ZYDUS-042914		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematuria; Mouth Ulceration; Purpura; Thrombocytopenia	Nabumetone			S	Oral			Not Reported	
	Azithromycin			S	Oral			Zydus Pharm	
	Ezetimibe			C	Oral			Not Reported	
	Diclofenac			C	Cutaneous			Not Reported	
	Ropinirole/Ropinirole Hydrochloride			C	Oral			Not Reported	
	Fenoterol Hydrobromide/Ipratropium Bromide			C	Respiratory (inhalation)			Not Reported	
	Phloroglucinol			C	Oral			Not Reported	
	Nicardipine			C	Oral			Not Reported	
	Acetylsalicylic Acid			C	Oral			Not Reported	
	Nebivolol/Nebivolol Hydrochloride			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17031287	EXPEDITED (15-DAY)		OT	JP-PFIZER INC- 2019485934			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Helicobacter Infection	Zithromac 250mg			S	Oral	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17031743	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2019487264		78 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic	Zithromax			S	Oral	0.25 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17032554	NON-EXPEDITED			NVSC2019US035340			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Unknown	Unk		Novartis	
	Bactrim			S	Unknown	Unk		Not Reported	
	Lactulose			C	Unknown	Unk		Not Reported	
	Percocet			C	Unknown	Unk		Not Reported	
	Sertraline Hcl			C	Unknown	Unk		Not Reported	
	Colace			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17032701	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2076856		63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral			Wockhardt	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2019	17033118	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2076860		92 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Oral			Wockhardt	
	Losartan			C				Not Reported	
	Hytrin			C				Not Reported	
	Amlodipine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	16071476	NON-EXPEDITED			US-PFIZER INC-2019110830		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Celebrex	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	16206003	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-020285		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Sputum Discoloured	Amlodipine			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Amlodipine			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Azithromycin			S	Oral	3 Dosage Form		Aurobindo
	Omalizumab			S	Subcutaneous	225 Milligram		Not Reported
	Omalizumab			S	Subcutaneous	225 Milligram		Not Reported
	Advair			C	Unknown	1 Dosage Form		Not Reported
	Asa			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Brilinta			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Hydrochlorothiazide			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Pantoprazole Sodium			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Singulair			C	Oral	1 Dosage Form, Once A Day		Not Reported
	Spiriva			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Ventolin			C	Unknown	2 Dosage Form		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	16577373	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019302857		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Blood	Pantoprazole	S	Oral	Unk, Qd	Pfizer
Cholesterol Increased;	Azithromycin	S	Unknown	Unk	Pfizer
Blood Immunoglobulin E	Cholecalciferol	S	Oral	Unk	Not Reported
Increased; Blood Urine	Xolair	S	Subcutaneous	Unk	Not Reported
Present; Bronchitis; Chest	Xolair	S	Subcutaneous	300 Milligram, Q2weeks	Not Reported
Discomfort; Chest Pain;	Calcium	C	Unknown	Unk	Not Reported
Cough; Drug Ineffective;	Desoximetason	C	Unknown	Unk	Not Reported
Dyspnoea; Fatigue;	Ergocalciferol	C	Unknown	Unk	Not Reported
Malaise; Nasopharyngitis;	Estroge	C	Unknown	Unk	Not Reported
Nausea; Productive	Spiriva	C	Unknown	Unk	Not Reported
Cough; Upper Respiratory	Symbicort Tu	C	Unknown	Unk	Not Reported
Tract Infection; Vomiting;	Synthroid	C	Unknown	Unk	Not Reported
Wheezing	Ventolin [Salbutamol]	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	16961069	EXPEDITED (15-DAY)		OT	US-UCBSA-2019044269		56 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Mouth; Nasopharyngitis; Urticaria	Cimzia			S	Subcutaneous	400 Milligram, Ev 4 Weeks		Ucb
	Cimzia			S				Ucb
	Cimzia			S				Ucb
	Zithromax			S				Not Reported
	Meloxicam			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Benadryl [Diphenhydramine Hydrochloride]			C				Not Reported
	Leflunomide			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	17034335	EXPEDITED (15-DAY)		OT	CA-009507513-1911CAN004388		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anaemia Neonatal; Foetal Exposure During Pregnancy	Isentress	S	Transplacental	400 Milligram	Merck
	Isentress	S	Transplacental	Unk	Merck
	Acyclovir	S	Transplacental		Not Reported
	Azithromycin	S	Transplacental		Not Reported
	Bactrim	S	Transplacental		Not Reported
	Lamivudine	S	Transplacental	150 Milligram	Not Reported
	Prezista	S	Transplacental	600 Milligram	Not Reported
	Ritonavir	S	Transplacental	100 Milligram	Not Reported
	Tenofovir	S	Transplacental	300 Milligram	Not Reported
	Intelence	S	Transplacental	200 Milligram	Not Reported
	Zidovudine	S	Transplacental	300 Milligram	Not Reported
	Abacavir	C	Transplacental	300 Milligram	Not Reported
	Calcium Carbonate	C	Unknown		Not Reported
	Calcium D (Calcium Carbonate (+) Calcium Citrate (+) Cholecalciferol)	C	Unknown		Not Reported
	Ergocalciferol	C	Unknown		Not Reported
	Folic Acid	C	Unknown		Not Reported
	Iron (Unspecified)	C	Unknown		Not Reported
	Magnesium Gluconate	C	Unknown		Not Reported
	Pyridoxine Hydrochloride	C	Unknown		Not Reported
	Vitamin A Palmitate	C	Unknown		Not Reported
	Riboflavin	C	Unknown		Not Reported
	Thiamine Mononitrate	C	Unknown		Not Reported
	Cyanocobalamin	C	Unknown		Not Reported
	Ascorbic Acid	C	Unknown		Not Reported
	Niacinamide	C	Unknown		Not Reported
	Ferrous Fumarate	C	Unknown		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	17034661	EXPEDITED (15-DAY)		OT	CA-009507513-1911CAN004389		19 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Isentress			S	Oral	400 Milligram, Bid		Merck
	Abacavir			S		300 Milligram, Bid		Not Reported
	Acyclovir			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	2 Dosage Form, Qd		Not Reported
	Bactrim			S	Unknown	400 Milligram, Bid		Not Reported
	Intelence			S	Unknown	200 Milligram, Bid		Not Reported
	Lamivudine			S	Unknown	150 Milligram, Bid		Not Reported
	Prezista			S	Oral	600 Milligram, Bid		Not Reported
	Ritonavir			S	Unknown	100 Milligram, Bid		Not Reported
	Tenofovir			S	Unknown	300 Milligram, Qd		Not Reported
	Zidovudine			S	Unknown	300 Milligram, Bid		Not Reported
	Folic Acid			C	Unknown			Not Reported
	Iron (Unspecified)			C	Unknown	Unk		Not Reported
	Magnesium Gluconate			C	Unknown			Not Reported
	Vitamins (Unspecified)			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	17037759	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019487436		71 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemorrhage; Hypersensitivity; Pruritus	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer
	12 Vitamins For Injection			S	Intravenous drip	1 Df, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	17038634	NON-EXPEDITED			US-PFIZER INC-2019494415			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Ampicillin Sodium			S		Unk		Unknown
	Azithromycin			S		Unk		Pfizer
	Bupropion			S		Unk		Not Reported
	Keflex [Cefalexin]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Nov-2019	17038849	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1109509		68 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cheilitis; Dermatitis Exfoliative Generalised; Mouth Ulceration	Levofloxacin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pantoprazole			S	Oral	20 Milligram, Qd		Not Reported
	Lasilix /00032601/			S	Respiratory (inhalation)	40 Milligram, Qd		Mylan
	Rocephine			S	Intravenous (not otherwise specified)	Unk		Mylan
	Zithromax			S	Oral	Unk		Mylan
	Flagyl /00012501/			S	Intravenous (not otherwise specified)	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2019	15207327	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2018297278		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthropathy; Blister; Burning Sensation; Chest Pain; Cough; Dizziness; Drug Ineffective; Fall; Feeling Abnormal; Gait Disturbance; Headache; Heart Rate Increased;	Pantoprazole			S		40 Mg, Qd		Pfizer
	Pantoprazole			S		Unk, Qd		Pfizer
	Azithromycin			S		250 Milligram		Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hypertension; Incorrect Dose Administered;	Xolair	S	Subcutaneous	150 Mg, 2x/Week	Not Reported
Influenza Like Illness;	Xolair	S	Subcutaneous	300 Milligram, 4/Week	Not Reported
Injection Site Rash;	Xolair	S	Subcutaneous	Unk	Not Reported
Insomnia; Lip Swelling;	Xolair	S	Subcutaneous	Unk	Not Reported
Muscular Weakness;	Xolair	S	Subcutaneous	Unk	Not Reported
Nasopharyngitis; Painful Respiration; Peripheral Swelling; Product Storage Error; Pruritus; Rash;	Xolair	S	Subcutaneous	200 Mg, 2x/Week	Not Reported
Respiratory Tract Congestion; Stress;	Xolair	S	Subcutaneous	Unk	Not Reported
Swelling; Tooth Fracture;	Xolair	S	Subcutaneous	Unk	Not Reported
Urticaria; Urticaria	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	Unk	Not Reported
	Xolair	S	Subcutaneous	300 Mg, Unk	Not Reported
	Cetirizine	C	Unknown	Unk	Not Reported
	Demulen /00040701/	C	Unknown	Unk	Not Reported
	Fusidate Sodium	C	Unknown	Unk	Not Reported
	Hydroxyzine	C	Unknown	Unk	Not Reported
	Metronidazole	C	Unknown	Unk	Not Reported
	Nystatin	C	Unknown	Unk	Not Reported
	Pepcid	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	Unk, Qd	Not Reported
	Reactine	C	Unknown	Unk, Qd	Not Reported
	Singulair	C	Unknown	Unk	Not Reported
	Ventolin	C	Unknown	Unk	Not Reported
	Sertraline [Sertraline Hydrochloride]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2019	15589184	NON-EXPEDITED			US-AMGEN-USASP2018154852		79 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Enbrel	S	Unknown	Unk	Amgen
	Azithromycin	S	Unknown	Unk	Not Reported
	Demerol	S	Unknown	Unk	Not Reported
	Fentanyl Citrate	S	Unknown	Unk	Not Reported
	Ibuprofen	S	Unknown	Unk	Not Reported
	Percodan [Acetylsalicylic Acid; Oxycodone Hydrochloride]	S	Unknown	Unk	Not Reported
	Codeine	S	Unknown	Unk	Not Reported
	Hydrocodone	S	Unknown	Unk	Not Reported
	Iodine	S	Unknown	Unk	Not Reported
	Aleve	S	Unknown	Unk	Not Reported
	Tramadol Hcl	S	Unknown	Unk	Not Reported
	Penicillin V Potassium	S	Unknown	Unk	Not Reported
	Oxycontin	S	Unknown	Unk	Not Reported
	Acetaminophen	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2019	17041489	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1137196		66 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myalgia; Visual Impairment	Azithromycin			S	Oral	2250 Milligram Per Week			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2019	17041763	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1137889		64 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain Upper; Asthenia; Diarrhoea	Azithromycin			S	Oral	750 Mg, Monday, Wednesday, Friday			Not Reported
	Zapain			C					Not Reported
	Ventolin			C					Not Reported
	Montelukast Sodium			C					Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Omeprazole	C	Not Reported
	Symbicort	C	Not Reported
	Flomax Mr	C	Not Reported
	Prednisolone	C	Not Reported
	Calcichew	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2019	17043840	EXPEDITED (15-DAY)		LT	FR-PFIZER INC-2019492999		71 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered; Pancytopenia; Thrombocytopenic Purpura	Novatrex			S	Oral	4 Df, 1x/Day		Pfizer
	Imeth [Methotrexate Sodium]			S	Subcutaneous	1 Df, Weekly		Not Reported
	Efient			S	Oral	1 Df, 1x/Day		Not Reported
	Leflunomide			S	Oral	20 Mg, 1x/Day		Not Reported
	Kardegic			S	Oral	1 Df, 1x/Day		Not Reported
	Liptruzet			C		Unk		Not Reported
	Ventoline [Salbutamol Sulfate]			C		Unk		Not Reported
	Ultibro Breezhaler			C		Unk		Not Reported
	Bisoprolol Hemifumarate			C		Unk		Not Reported
	Speciafoldine			C		Unk		Not Reported
	Ramipril			C		Unk		Not Reported
	Lercanidipine Hcl			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Nov-2019	17043842	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019496337		66 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Electrocardiogram Qt Prolonged; Palpitations	Zithromax			S	Intravenous drip	500 Mg, 1x/Day		Pfizer
	Zithromax			S	Intravenous drip	500 Mg, 1x/Day		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17048144	NON-EXPEDITED			US-PFIZER INC-2019494007			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aura; Off Label Use; Product Use In Unapproved Indication; Visual Impairment	Zithromax			S	Intravenous (not otherwise specified)	250 ML, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17048414	NON-EXPEDITED		OT	US-PFIZER INC-2019499241		40 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17048725	EXPEDITED (15-DAY)		OT	CA-SA-2019SA316028			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Increased; Drug Hypersensitivity; Suicidal Ideation	Arava			S	Unknown	Unk		Sanofi	
	Azithromycin			S	Unknown	Unk, Unk		Not Reported	
	Methotrexate			C	Unknown	Unk Unk, Unk		Not Reported	
	Folic Acid			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17048780	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2019M1109728		61 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Paracetamol			S	Oral	4 Gram, Qd		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17048794	NON-EXPEDITED			NVSC2019US040147			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain	Azithromycin			S	Unknown	Unk, Unknown		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17048837	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1109763		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burn Oesophageal; Cough	Doxycycline			S	Oral	200 Milligram, Qd		Not Reported	
	Zithromax			S	Oral	250 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17049308	EXPEDITED (15-DAY)		OT	JP-MYLANLABS-2019M1109610		72 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Tinnitus	Piperacillin/Tazobactam			S	Intravenous drip	4.5 Gram, Bid		Not Reported	
	Zithromac			S	Oral	2 Gram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17050312	EXPEDITED (15-DAY)		DE	US-TEVA-2019-US-1138941		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown			Not Reported	
	Piperacillin/Tazobactam			S	Unknown			Not Reported	
	Vancomycin			C	Unknown			Not Reported	
	Coumadin			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Nov-2019	17050583	EXPEDITED (15-DAY)		OT	CN-BAXTER-2019BAX023007		2 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Heart Rate Decreased; Pallor; Seizure	0.9% Sodium Chloride Injection			S	Intravenous drip			Baxter	
	Azithromycin			S	Intravenous drip			Not Reported	
	Cefuroxime			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	16062797	EXPEDITED (15-DAY)		DE	US-BAYER-2019-048573			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Drug Hypersensitivity; Drug Hypersensitivity	Avelox			S		Unk		Bayer	
	Spiriva			S	Respiratory (inhalation)	Unk		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Fish Oil			S				Not Reported	
	Plavix			S				Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Paracetamol			S		Unk		Not Reported	
	Aspirin (Pain And Fever)			S				Bayer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	17051621	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-073673		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Cough; Lung Hyperinflation; Lung Neoplasm Malignant; Middle Insomnia; Obstructive Airways	Moxifloxacin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	500 Milligram, 3 Times A Day		Aurobindo	
	Clavulin			S	Unknown	Unk		Not Reported	
	Levaquin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Productive Cough; Wheezing	Prednisone	S	Unknown	20 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	30 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	40 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	50 Milligram, Once A Day	Not Reported
	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
	Symbicort Turbuhaler	S	Unknown	3 Dosage Form, 3 Times A Day	Not Reported
	Symbicort Turbuhaler	S	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Tiotropium	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	17053134	EXPEDITED (15-DAY)		OT	CA-009507513-1911CAN004527			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Exposure During Pregnancy; Maternal Exposure During Pregnancy	Isentress			S	Transplacental	400 Milligram		Merck
	Abacavir			S	Transplacental	300 Milligram, 1 Every 1 Day(S) (Qd)		Not Reported
	Acyclovir			S	Transplacental	Unk		Not Reported
	Azithromycin			S	Transplacental	Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Milligram, 1 Every 1 Day(S) (Qd)		Not Reported
	Lamivudine			S	Transplacental	150 Milligram		Not Reported
	Prezista			S	Transplacental	600 Milligram, 1 Every 1 Day(S) (Qd)		Not Reported
	Ritonavir			S	Transplacental	100 Milligram		Not Reported
	Viread			S	Transdermal	300 Milligram, 1 Every 1 Day(S) (Qd)		Not Reported
	Zidovudine			S	Transplacental	300 Milligram		Not Reported
	Abacavir			C	Transplacental	300 Milligram		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Folic Acid	C	Unknown	Unk		Not Reported
	Iron (Unspecified)	C	Unknown	Unk		Not Reported
	Magnesium Gluconate	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	17053499	NON-EXPEDITED			US-PFIZER INC-2019498725			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance	Amlodipine Besilate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Benzympenicillin Potassium			S		Unk		Pfizer	
	Diflucan			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	
	Metronidazole			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
	Cephalexin [Cefalexin]			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Losartan			S		Unk		Not Reported	
	Pravastatin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	17053783	EXPEDITED (15-DAY)		LT	IT-MYLANLABS-2019M1110484		20 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Abuse; Hypoglycaemia; Respiratory Failure	Paroxetine			S	Oral	20 Milligram, Total		Not Reported	
	Quetiapine			S	Oral	1 Gram, Total		Not Reported	
	Amisulpride			S	Oral	600 Milligram, Total		Not Reported	
	Azithromycin			S	Oral	1500 Milligram, Total		Not Reported	
	En			S	Oral	20 Milligram, Total		Mylan	
	Novorapid			S	Subcutaneous	2 Dosage Form, Total		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tegretol		S	Oral	8 Gram, Total		Mylan			
Lobivon		S	Oral	140 Milligram, Total		Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	17055953	EXPEDITED (15-DAY)		DE, OT	CA-AUROBINDO-AUR-APL-2019-073940		69 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Cardiac Failure; Cardio-Respiratory Arrest	Azithromycin			S	Intravenous drip	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Nov-2019	17055957	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-073972		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abscess; Anaemia; Anal Abscess; Arthralgia; Bipolar li Disorder; Cholecystectomy; Diarrhoea; Fistula; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Hypothyroidism; Post-Traumatic Stress Disorder; Therapeutic Product Effect Decreased; Tonsillectomy; Uterine Dilation And Curettage	Azithromycin			S	Unknown	Unk		Aurobindo	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Azathioprine			C	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17056812	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-074208		57 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection Susceptibility Increased; Lower Respiratory Tract Infection	Azithromycin	S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17056832	EXPEDITED (15-DAY)		OT	CZ-AUROBINDO-AUR-APL-2019-074255		66 YR	Male	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Burning Sensation; Penile Ulceration; Pyrexia	Azithromycin			S	Unknown	1 Gram		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17056934	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-033536		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Blood Cholesterol Increased; Blood Immunoglobulin E Increased; Blood Urine Present; Bronchitis; Chest Discomfort; Chest Pain; Cough; Drug Ineffective; Dyspnoea; Fatigue; Malaise; Nasopharyngitis; Nausea; Productive Cough; Upper Respiratory Tract Infection; Vomiting; Wheezing	Pantoprazole			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Xolair			S	Subcutaneous	Unk		Not Reported
	Xolair			S	Subcutaneous	300 Milligram, 1 Every 2 Weeks		Not Reported
	Cholecalciferol			S	Oral	1 Dosage Form		Not Reported
	Calcium			C	Unknown	Unk		Not Reported
	Desoximetasone			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Unknown	Unk		Not Reported
	Estrogel			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Symbicort			C	Unknown	Unk		Not Reported
	Synthroid			C	Unknown	Unk		Not Reported
Ventolin			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17056953	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-073971		11 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Madarosis	Azithromycin Oral Suspension			S	Oral	200 Milligram, Once A Day		Aurobindo	
	Azithromycin Oral Suspension			S				Aurobindo	
	Azithromycin			S	Oral	400 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Fluoxetine			C	Unknown	Unk		Not Reported	
	Gabapentin			C	Unknown	Unk		Not Reported	
	Guanfacine Hydrochloride			C	Unknown	Unk		Not Reported	
	Montelukast			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17057054	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2019-07081		83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Syncope; Urticaria	Azithromycin			S	Oral	250 Milligram		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17058648	NON-EXPEDITED			US-NEOPHARMA INC-000213			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Amoxil			S				Neopharma	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Nov-2019	17061384	EXPEDITED (15-DAY)		OT	US-TEVA-2019-US-1137141			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abulia; Dysgraphia; Mental Impairment		Azithromycin		S	Unknown		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	16682885	EXPEDITED (15-DAY)		DE, HO, LT, OT	PHHY2019DE182449			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Brain Abscess; Iris Adhesions; Multiple Allergies; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Levetiracetam			S	Unknown	1000 Df, Qd (1000 Absent, Qd)		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Nivolumab			S	Intravenous (not otherwise specified)	1 Mg/Kg, Q3cycles		Not Reported	
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Mg/Kg (Q3cycles)		Not Reported	
	Novalgine (Metamizole Sodium)			S	Unknown	Unk		Not Reported	
	Ranitidine			C	Unknown	300 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	16933190	NON-EXPEDITED			US-ASTRAZENECA- 2019SF46102		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Interaction	Nexium 24hr			S	Oral			Astrazeneca	
	Azithromycin			S	Unknown	Unk (Take Two Tablets First Day And Then Take 5 One Day)		Not Reported	
	Amlodipine			C	Unknown	10 Mg,Unknown		Not Reported	
	Lisinopril			C	Unknown	20 Mg,Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17062627	EXPEDITED (15-DAY)		HO	BA-TEVA-2019-BA- 1139262		51 YR	Female	BIH
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Immune Thrombocytopenia; Purpura; Thrombocytopenia	Sumamed Letrox 50 Mg Aspirin Tbl Corvitol Tbl	S C C C	Oral	500 Milligram Daily;	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17063420	EXPEDITED (15-DAY)		OT	NVSC2019US041855		3 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Pathogen Resistance	Azithromycin			S	Unknown	Unk		Novartis
	Vancomycin			S	Unknown	Unk		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064194	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2019M1113159			Female	NLD

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Treatment Failure	Azithromycin			S	Unknown	1 Gram		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064351	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019499586		90 YR	Female	JPN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Eruption	Zithromac Sr 2g			S		1 Df, Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Nov-2019	17064556	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1113203		32 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Device Related Infection; Incorrect Product Administration Duration; Mycobacterial Infection;	Metronidazole			S	Oral			Not Reported
	Clindamycin			S	Intravenous (not otherwise specified)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pathogen Resistance	Ciprofloxacin	S	Unknown	Administered Every Other Day	Not Reported
	Azithromycin	S	Unknown		Not Reported
	Sulphamethoxazole/Trimethoprim	S	Unknown		Not Reported
	Vancomycin	S	Unknown		Not Reported
	Rifabutin	S	Oral		Mylan
	Meropenem	S	Intravenous (not otherwise specified)	Unk	Mylan
	Meropenem	S	Unknown	Administered Every Other Day Along With Ciprofloxacin	Mylan
	Tigecycline	S	Intravenous (not otherwise specified)		Mylan
	Pyrimethamine	C	Oral		Mylan
	Leucovorin /00566701/	C	Oral		Mylan
	Ivermectin	C	Oral		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17064726	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2019M1114028		3 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pathogen Resistance	Azithromycin			S	Unknown	10 Milligram/Kilogram, Qd		Not Reported
	Azithromycin			S	Unknown	Restarted During Re-Admission [Dosage Not Stated].		Not Reported
	Cefepime			C	Unknown	Unk		Mylan
	Fluconazole			C	Unknown	Unk		Mylan
	Doxorubicin			C	Unknown	Unk		Mylan
	Vincristine			C	Unknown	Unk		Mylan
	Vancomycin			C	Unknown	Unk		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17065313	NON-EXPEDITED			US- GLAXOSMITHKLINE- US2019AMR207645			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Hypersensitivity; Rash; Urticaria	Flonase Otc Unspecified			S	Unknown	Unk		Glaxosmithkline	
	Ingredient Nasal Spray			S	Unknown	Unk		Glaxosmithkline	
	Azithromycin			S	Unknown	Unk		Glaxosmithkline	
	Ceftin			S	Unknown	Unk		Glaxosmithkline	
	Keflex			S	Unknown	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17067265	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2019501768		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Dyspnoea	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
	Ibrance			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17067340	NON-EXPEDITED			NVSC2019US044520			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Drug Ineffective; Malaise	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17067613	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2019501157		152 DAY	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Faeces	Zithromax			S	Oral	0.08 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Discoloured; Urine Output
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2019	17067860	NON-EXPEDITED		OT	US-TEVA-2019-US-1139224			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Drug Ineffective; Product Label Issue	Azithromycin Tablet			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2019	17012364	EXPEDITED (15-DAY)		OT	CN-009507513-1911CHN001906		2 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aggression; Cough; Dysphoria; Irritability; Poor Quality Sleep; Product Use In Unapproved Indication	Singulair (Local Dist)			S	Oral	4 Mg/Day		Merck	
	Zithromax			S	Intravenous drip	0.12 G, Qd		Not Reported	
	Solu-Medrol			S	Intravenous drip	20 Mg, Qd		Not Reported	
	Bricanyl			C		2.5 Mg, Qd		Not Reported	
	Glucose Injection			C	Intravenous drip	200 MI, Qd		Not Reported	
	Glucose Injection			C	Intravenous drip	50 MI, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2019	17163280	DIRECT	Y				72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	13004983	NON-EXPEDITED			US-PFIZER INC-2016556887		72 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Heart Rate Increased; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer	
	Naprosyn [Naproxen Sodium]			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	16845179	NON-EXPEDITED			US-PFIZER INC- 2019410979		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	17055205	NON-EXPEDITED			US-PFIZER INC- 2019503637		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	17071044	EXPEDITED (15-DAY)		HO	PT-PFIZER INC- 2019504469		78 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Vulvovaginal Candidiasis	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Ceftriaxone			S		Unk		Not Reported	
	Ceftriaxone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	17071466	NON-EXPEDITED			US-PFIZER INC- 2019503916			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	17072359	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1112928		84 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Diabetic Neuropathy; Fatigue; Oedema Peripheral; Orthopnoea; Palpitations	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Amlodipine			S	Unknown	10 Milligram, Qd		Not Reported	
	Omeprazole			S	Unknown	20 Milligram, Qd		Not Reported	
	Metformin W/Vildagliptin			S	Unknown	2 Dosage Form, Qd, 1 Df, Bid		Mylan	
	Levothyroxine			C	Unknown	0.1 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	17072692	NON-EXPEDITED			US-PFIZER INC-2019505886			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Distension; Anxiety; Insomnia; Muscle Spasms	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Nov-2019	17072781	EXPEDITED (15-DAY)		DE	KE-PFIZER INC-2019505367		2 YR	Female	KEN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Seizure	Blinded Azithromycin			S		4.0 MI, Stat		Pfizer	
	Blinded Azithromycin			S		4.0 MI, Stat		Pfizer	
	Blinded Placebo			S		4.0 MI, Stat		Pfizer	
	Blinded Placebo			S		4.0 MI, Stat		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2019	9571535	NON-EXPEDITED			US-PFIZER INC-2013278834		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Norvasc			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2019	16946655	NON-EXPEDITED			US-PFIZER INC-2019451221		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertension; Limb Injury; Muscular Weakness; Rotator Cuff Syndrome; Tendon Discomfort; Tendon Rupture; Urinary Tract Infection	Azithromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Prednisone			S		3 Rounds Of Prednisone		Not Reported	
	Cortisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2019	17048408	EXPEDITED (15-DAY)		HO, OT	PT-PFIZER INC-2019493039		64 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin			S		Unk		Pfizer	
	Oseltamivir			S		Unk		Not Reported	
	Amoxicillin And Clavulanate Potassium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2019	17073464	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2019-07554		89 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin Tablets Usp, 500 Mg			S	Oral	2 Dosage Form, Qd		Lupin	
	Azithromycin Tablets Usp, 500 Mg			S	Oral	1 Dosage Form, Qd		Lupin	
	Lisinopril			C	Unknown	Unk		Not Reported	
	Metformin			C	Unknown	Unk		Not Reported	
	Glimepiride			C	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Pravastatin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Nov-2019	17077419	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019506844		3 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dairy Intolerance; Diarrhoea Haemorrhagic	Zitromax			S	Oral	3 MI, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	12932555	EXPEDITED (15-DAY)		CA, HO, OT	IL-TEVA-711328ISR		2 DAY	Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Escherichia Infection; Foetal Exposure During Pregnancy; Pyloric Stenosis; Respiratory Distress	Azithromycin			S	Transplacental	500 Milligram Daily; For 3 Days		Pliva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17070988	NON-EXPEDITED			US-PFIZER INC-2019507551			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vomiting	Azithromycin			S	Oral	600 Mg, Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17075100	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019508931		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Ramipril			S	Oral	Unk		Pfizer
	Retacrit			S	Oral	1 Unk, Qw		Unknown
	Zithromax			S	Oral	Unk		Pfizer
	Inipomp			S	Oral	Unk		Pfizer
	Racecadotril			S	Oral	100 Mg, Unk		Not Reported
	Imodium			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	3 Df, Qw		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Oflozet [Ofloxacin]			S	Oral	Unk		Not Reported
	Valaciclovir			S	Oral	1 Unk, Qd		Not Reported
	Tiorfanor			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17078644	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-074594		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Valaciclovir			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Ramipril			S	Oral	Unk		Aurobindo
	Imodium			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	3 Dosage Form, Every Week		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Inipomp			S	Oral	Unk		Not Reported
	Tiorfan			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax	S	Oral	Unk	Not Reported
Oflocet	S	Oral	Unk	Not Reported
Retacrit	S	Unknown	1 Dosage Form, Every Week	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17079409	EXPEDITED (15-DAY)		OT	LV-TEVA-2019-LV-1143309		64 YR	Female	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mouth Ulceration; Mouth Ulceration; Oesophageal Ulcer	Sumamed			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17079796	EXPEDITED (15-DAY)		OT	GB-TEVA-2019-GB-1141610		1 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Allergic; Vomiting	Azithromycin			S	Oral			Not Reported
	Amoxicillin			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17084459	EXPEDITED (15-DAY)		OT	FR-GLAXOSMITHKLINE-FR2019210079		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Valaciclovir			S	Oral	Unk Unk, Qd		Glaxosmithkline
	Oflocet			S	Oral	Unk		Glaxosmithkline
	Tiorfan			S	Oral	Unk		Glaxosmithkline
	Ramipril			S	Oral	Unk		Glaxosmithkline
	Imodium			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	Unk Unk, We		Not Reported
	Kardegic			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inipomp	S	Oral	Unk	Not Reported
Zithromax	S	Oral	Unk	Not Reported
Retacrit (Epoetine Zeta)	S	Unknown	Unk, We	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Nov-2019	17085973	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Z-Pak			S				Not Reported	
	Sudafed			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	13721805	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2017-US-008511			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autonomic Nervous System Imbalance;	Xyrem			S	Oral	2.25 G, Bid		Jazz	
Cardiomyopathy; Crohn'S Disease; Drug Ineffective;	Xyrem			S	Oral	Dose Adjustment		Jazz	
Fatigue; Fungal Skin Infection; Hospitalisation; Sleep Apnoea Syndrome; Weight Decreased	Xyrem			S	Oral	4.5 G, Bid		Jazz	
	Azithromycin			S				Not Reported	
	Ciprofloxacin			S				Not Reported	
	Levaquin			S				Not Reported	
	Avelox			S				Not Reported	
	Lipoderm			S				Not Reported	
	Allegra Allergy			C				Not Reported	
	Atacand Hct			C				Not Reported	
	Coreg Cr			C				Not Reported	
	Dexilant			C				Not Reported	
	Entocort			C				Not Reported	
	Fentanyl			C				Not Reported	
	Forteo			C				Not Reported	
	Hydrochlorothiazide			C				Not Reported	
	Midodrine Hcl			C				Not Reported	
	Oxycodone Hcl			C				Not Reported	
	Premarin			C				Not Reported	
	Ergocalciferol			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Wellbutrin		C		Unk		Not Reported		
	Ativan		C		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17085369	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-075269		52 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Synovial Sarcoma	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ceftriaxone			S	Unknown	Unk		Aurobindo	
	Meropenem			S	Unknown	Unk		Aurobindo	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17086569	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-075271		44 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eosinophilic Pneumonia	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Rupatadine			C	Unknown	Unk		Not Reported	
	Bromazepam			C	Unknown	Unk		Not Reported	
	Venlafaxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17087192	EXPEDITED (15-DAY)		HO	NL-AUROBINDO-AUR- APL-2019-075479		20 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hypersensitivity; Pharyngeal Swelling; Swollen Tongue	Azithromycin Film Coated Tablet 250mg			S	Oral	1 Dosage Form, Once A Day		Aurobindo	
	Microgynon			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Methylphenidate

C

Unknown

1 Dosage Form, Two
Times A Day

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17087390	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2019AP025301		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Maternal Exposure During Pregnancy	Lamivudine			S	Transplacental	150 Mg, Unk		Apotex
	Azithromycin			S	Transplacental	Unk		Apotex
	Tenofovir			S	Transplacental	300 Mg, Unk		Apotex
	Zidovudine			S	Transplacental	300 Mg, Unk		Not Reported
	Acyclovir			S	Transplacental	Unk		Apotex
	Abacavir			S	Transplacental	300 Mg, Unk		Not Reported
	Bactrim			S	Transplacental	Unk		Not Reported
	Intelence			S	Transplacental	200 Mg, Unk		Not Reported
	Prezista			S	Transplacental	600 Mg, Unk		Not Reported
	Raltegravir Potassium			S	Transplacental	400 Mg, Unk		Not Reported
	Ritonavir			S	Transplacental	100 Mg, Unk		Not Reported
	Magnesium Gluconate			C	Unknown	Unk		Not Reported
	Iron			C	Unknown	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Abacavir			C	Transplacental	300 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17088188	EXPEDITED (15-DAY)		OT	CN-PFIZER INC- 2019509901		6 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Cyanosis; Dizziness; Hyperhidrosis; Off Label Use; Product Use Issue	Zithromax			S	Intravenous drip	0.29 G, 1x/Day		Pfizer
	Zithromax			S				Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17088614	EXPEDITED (15-DAY)		HO	UA-TEVA-2019-UA-1144683		16 YR	Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Ear Swelling	Sumamed			S		Took Half Of Tablet On 22-Nov-2019 And 23-Nov-2019		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2019	17089264	EXPEDITED (15-DAY)		OT	NVSC2019DE049417		3 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Decreased Appetite; Diarrhoea; Fatigue; Flatulence; Hot Flush; Malaise; Palpitations; Pyrexia; Tongue Discolouration; Urinary Retention; Visual Impairment	Azithromycin Hexal 200 Mg/5 Ml Pulver Zur Herstellung Einer Suspension			S	Unknown	Unk, Qd		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2019	17091661	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2019R1-228620		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacteraemia; Device Related Infection; Medication Error; Septic Embolus	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Sun	
	Ciprofloxacin			S	Intravenous (not otherwise specified)	Unk		Sun	
	Clindamycin			S	Intravenous (not otherwise specified)	Unk		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cotrimoxazole	S	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2019	17091662	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019R1-228723			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance	Azithromycin			S	Unknown	Unk		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2019	17092201	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2019511565		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematuria; Mouth Ulceration; Purpura; Thrombocytopenia	Azithromycin			S	Oral	1 Df, Unk		Pfizer	
	Nabucox			S	Oral	2 Df, 1x/Day		Not Reported	
	Ezetrol			C	Oral	1 Df, 1x/Day		Not Reported	
	Spasfon [Phloroglucinol; Trimethylphloroglucinol]			C	Oral	6 Df, 1x/Day		Not Reported	
	Bronchodual			C	Respiratory (inhalation)	2 Df, 1x/Day		Not Reported	
	Bronchodual			C		Unk		Not Reported	
	Loxen L P			C	Oral	2 Df, 1x/Day		Not Reported	
	Nebivolol			C	Oral	1 Df, 1x/Day		Not Reported	
	Ropinirole Hydrochloride			C	Oral	0.5 Mg, 1x/Day		Not Reported	
	Aspirine Protect			C	Oral	1 Df, 1x/Day		Not Reported	
	Flectortissugelep			C	Cutaneous	3 Df, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2019	17094156	EXPEDITED (15-DAY)		OT	NVSC2019FR047746		68 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported	
	Lamprene			S	Oral	1 Df, Qd		Novartis	
	Cefoxitine			S	Intravenous (not otherwise specified)	12 G, Qd		Not Reported	
	Tigecycline			S	Intravenous (not otherwise specified)	100 Mg, Qd		Not Reported	
	Amiklin			C	Intravenous (not otherwise specified)	Unk (Inconnue)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2019	16938573	NON-EXPEDITED		OT	NVSC2019US008520		60 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Intolerance; Drug Resistance; Mycobacterium Avium Complex Infection	Azithromycin			S	Oral	250 Mg, Unknown		Novartis	
	Azithromycin			S				Novartis	
	Rifampin			S	Unknown	Unk		Not Reported	
	Moxifloxacin			S	Oral	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Nov-2019	17095205	NON-EXPEDITED			NVSC2019US048320			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fistula; Hypoacusis;	Azithromycin			S	Oral	Unk		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nausea; Rash; Vomiting	Linezolid	S	Oral	Unk	Not Reported
	Cefoxitin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Imipenem	S	Unknown	Unk	Not Reported
	Amikacin	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Tygacil	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Levaquin	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	12318429	NON-EXPEDITED			US-PFIZER INC-2016222095			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Vytorin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	15560684	NON-EXPEDITED			US-PFIZER INC-2018439976			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
	Tylenol			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16212354	NON-EXPEDITED			US-PFIZER INC-2019162653		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Nausea; Vomiting	Oxycodone	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16715418	NON-EXPEDITED			US-PFIZER INC-2019349618		89 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Levofloxacin			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Darvon [Betahistine Mesilate]			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Losartan Potassium			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Nembutal			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16880162	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2019M1091243		27 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Encephalopathy	Alprazolam Mylan 0,25 Mg			S	Oral	2 Dosage Form, Qd		Mylan
	Sandimmun			S	Intravenous (not otherwise specified)	Unk		Mylan
	Zarzio			S	Intravenous (not otherwise specified)	Unk		Mylan
	Difclir			S	Oral	2 Dosage Form, Qd		Mylan
	Smecta /07327601/			S	Oral	Unk		Mylan
	Cellcept /01275104/			S	Oral	Unk		Mylan
	Vfend			S	Oral	2 Dosage Form, Qd		Mylan
	Ondansetron Accord			S	Intravenous (not otherwise specified)	Unk		Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azyter	S	Ophthalmic	Unk	Mylan
Magne B6 /01431101/	S	Oral	Unk	Mylan
Tranxene	S	Oral	2 Dosage Form, Qd	Mylan
Pantoprazole Arrow	S	Intravenous (not otherwise specified)	40 Milligram, Qd	Mylan
Hydroxyzine Arrow	S	Oral	1 Dosage Form, Qd	Mylan
Celluvisc /00007002/	S	Ophthalmic	Unk	Mylan
Valaciclovir Arrow	S	Oral	1 Dosage Form, Qd	Mylan
Zerbaxa	S	Intravenous (not otherwise specified)	Unk	Mylan
Vancomycine Sandoz	S	Intravenous (not otherwise specified)	2 Gram, Qd	Mylan
Oxynorm	S	Intravenous (not otherwise specified)	Unk	Mylan
Furosemide Renaudin	S	Intravenous (not otherwise specified)	20 Milligram, Bid	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16898246	EXPEDITED (15-DAY)		HO, LT, OT	PT-AUROBINDO-AUR-APL-2019-064997		73 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Pneumonia; Toxic Epidermal Necrolysis	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Losartan			S	Unknown	Unk		Aurobindo
	Bisoprolol			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Simvastatin			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16914326	NON-EXPEDITED			US-PFIZER INC-2019440892		72 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Inhibitory Drug Interaction	Nexium 24hr			S		Unk		Unknown	
	Nexium 24hr			S		Unk		Unknown	
	Azithromycin			S		Unk (Take Two Tablets First Day And Then Take 5 One Day)		Pfizer	
	Amlodipine			C		10 Mg, Unk		Not Reported	
	Lisinopril			C		20 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16918929	NON-EXPEDITED			US-PFIZER INC- 2019442646			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Gastrointestinal Disorder; Ulcer	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	16965920	NON-EXPEDITED			US-PFIZER INC- 2019459213		53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Urticaria	Azithromycin			S		500 Mg, Daily		Pfizer	
	Azithromycin			S		500 Mg, Daily		Pfizer	
	Azithromycin			S	Oral	400 Mg, 1x/Day		Pfizer	
	Mycobutin			S		150 Mg, Unk (Twice A Day Five Days A Week)		Pfizer	
	Mycobutin			S		150 Mg, (Once A Day Three Times A Week; Monday, Wednesday, Friday)		Pfizer	
	Mycobutin			S	Oral	400 Mg, 1x/Day		Pfizer	
	Rifabutin			S		150 Mg, Unk (150mg		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					Twice A Day Five Days A Week)	
Rifabutin	S	Oral	400 Mg, 1x/Day	Pfizer		
Ethambutol	S		400 Mg, 1x/Day	Not Reported		
Ethambutol	S		400 Mg, 1x/Day	Not Reported		
Ethambutol	S	Oral	400 Mg, 1x/Day	Not Reported		

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	17097789	EXPEDITED (15-DAY)		DE, HO	NVSC2019ES053398		77 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Clostridium Difficile Colitis	Azithromycin			S	Oral	500 Mg, Qd		Novartis
	Levofloxacin			S	Intravenous (not otherwise specified)	500 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	17097955	EXPEDITED (15-DAY)		OT	NVSC2019GB053585		16 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Disease Progression;	Hydroxychloroquine			S	Unknown	Unk		Novartis
Product Use In	Prednisolone			S	Unknown	Unk		Not Reported
Unapproved Indication;	Azithromycin			S	Unknown	250 Mg (Three Times Weekly)		Not Reported
Pulmonary Alveolar Haemorrhage								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	17099012	NON-EXPEDITED			US-PFIZER INC-2019514911			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neurological Symptom	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	17100572	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-BRISTOL-MYERS SQUIBB COMPANY- BMS-2019-114889			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Brain Abscess; Cardiogenic Shock; Iris Adhesions; Multiple Allergies; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Nivolumab			S	Intravenous (not otherwise specified)	1 Milligram Per Kilogram, Q3cycles		Bristol Myers Squibb	
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram (Q3cycles)		Bristol Myers Squibb	
	Levetiracetam			S	Unknown	1000 Dosage Form, Qd		Not Reported	
	Novalgine [Caffeine;Paracetamol;Propyph nazole]			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ranitidine			C	Unknown	300 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	17101836	EXPEDITED (15-DAY)		OT	BE-MYLANLABS- 2019M1116982			Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Hepatotoxicity; Nausea; Vomiting	Linezolid			S	Unknown	Unk		Not Reported	
	Linezolid			S				Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Amikacin Sulfate			S	Unknown	Unk		Mylan	
	Amikacin Sulfate			S				Mylan	
	Clofazimine			S	Oral	Unk		Mylan	
	Clofazimine			S				Mylan	
	Bedaquiline			S	Unknown	Unk		Mylan	
	Bedaquiline			S				Mylan	
	Imipenem			S	Unknown	Unk		Mylan	
	Imipenem Tigecycline			S	Intravenous (not	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tigecycline		S		otherwise specified)		Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2019	17195364	DIRECT	Y	OT				Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Heart Rate Increased; Pharyngeal Swelling; Swollen Tongue	Azithromycin			S	Intravenous (not otherwise specified)			Fresenius Medical Care	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	14590352	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2018087628		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Glucose Increased;	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer	
Body Height Decreased;	Xeljanz Xr			S	Oral	11 Mg, 1x/Day		Pfizer	
Cerebrovascular Accident;	Zithromax			S	Oral	250 Mg, 2x/Day		Pfizer	
Cystitis; Immune System	Zithromax			S				Pfizer	
Disorder; Infection;	Tamiflu			S	Oral	75 Mg, 2x/Day		Not Reported	
Influenza; Malaise;	Tamiflu			S				Not Reported	
Memory Impairment;	Pyridium			S	Oral	200 Mg, As Needed (Q 8 Hrs, Prn)		Not Reported	
Nausea; Pain; Transient	Pyridium			S				Not Reported	
Ischaemic Attack; Urinary	Pyridium			S	Oral	100 Mg, 1x/Day (For 7 Days)		Not Reported	
Tract Infection; Vomiting;	Macrobid			S				Not Reported	
White Blood Cell Count	Macrobid			S				Not Reported	
Decreased	Tylenol			C		1000 Mg, As Needed (2q 6 Hrs.)		Not Reported	
	Tylenol			C		Unk, As Needed (Every 6 Hours As Needed)		Not Reported	
	Pomegranate			C		Unk Unk, Daily (2 Oz)		Not Reported	
	Prednisone			C		5 Mg, 1x/Day, (Early A.M.)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	C	5 Mg, Daily	Not Reported
Prednisone	C		Not Reported
Hydroxychloroquine	C	200 Mg, 1x/Day [At Hs]/ (At Bed Time)	Not Reported
Hydroxychloroquine	C		Not Reported
Lipitor	C	40 Mg, 1x/Day, (Each Evening)	Not Reported
Levothyroxine	C	75 Ug, Daily	Not Reported
Plavix	C	1 Df, 1x/Day	Not Reported
Plavix	C	0.5 Df, Unk (Half A Tablet)	Not Reported
Lisinopril	C	2.5 Mg, Daily	Not Reported
Keflex	C	2000 Mg, Unk, (Take 4 Tab. 1 Hour Before Any Dental Or Surgical Procedure)	Not Reported
Keflex	C		Not Reported
Cranberry	C	Unk Unk, Daily (Juice 4-6 Oz Daily)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17103299	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-229487		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Ramipril			S	Oral	()		Ranbaxy
	Valacyclovir			S	Oral	(1), Daily		Sun
	Imodium			S	Oral	()		Not Reported
	Bactrim			S	Oral	(3)		Not Reported
	Kardegic			S	Oral	()		Not Reported
	Inipomp			S	Oral	()		Not Reported
	Tiorfan			S	Oral	()		Not Reported
	Zithromax			S	Oral	()		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Oflozet (Ofloxacin)		S	Oral	()			Not Reported	
	Retacrit		S	Unknown	Unk Unk, Weekly			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17103540	EXPEDITED (15-DAY)		OT	CA-ROCHE-2480026			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cognitive Disorder; Depression; Dizziness; Drug Intolerance; Fatigue; Feeling Hot; Impaired Gastric Emptying; Pain In Extremity	Ocrevus			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17104033	EXPEDITED (15-DAY)		LT	NVSC2019IT053862		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister; Conjunctivitis; Epidermolysis; Mucosal Inflammation; Oropharyngeal Pain; Pyrexia	Azithromycin			S	Unknown	Unk		Novartis	
	Allopurinol			S	Unknown	150 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17105410	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US- 1146528		32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterial Infection; Pathogen Resistance	Metronidazole			S	Oral			Actavis	
	Clindamycin			S	Intravenous (not otherwise specified)			Teva	
	Ciprofloxacin			S	Unknown	Administered Every Other Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	Not Reported
Rifabutin	S	Oral	Not Reported
Meropenem	S	Intravenous (not otherwise specified)	Not Reported
Meropenem	S	Unknown	Administered Every Other Day Along With Ciprofloxacin
Tigecycline	S	Intravenous (not otherwise specified)	Not Reported
Pyrimethamine	C	Oral	Not Reported
Leucovorin	C	Oral	Not Reported
Ivermectin	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17105612	EXPEDITED (15-DAY)		OT	CA-APOTEX-2019AP025309		19 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin			S	Unknown	2 Df, Qd		Apotex
	Zidovudine			S	Unknown	300 Mg, Bid		Not Reported
	Acyclovir			S	Unknown	Unk		Apotex
	Tenofovir			S	Unknown	300 Mg, Qd		Apotex
	Lamivudine			S	Unknown	150 Mg, Bid		Apotex
	Abacavir			S	Unknown	300 Mg, Bid		Not Reported
	Bactrim			S	Unknown	400 Mg, Bid		Not Reported
	Intelence			S	Unknown	200 Mg, Bid		Not Reported
	Isentress			S	Oral	400 Mg, Bid		Not Reported
	Prezista			S	Oral	600 Mg, Bid		Not Reported
	Ritonavir			S	Unknown	100 Mg, Bid		Not Reported
	Magnesium Gluconate			C	Oral	Unk		Not Reported
	Folic Acid			C	Unknown	Unk		Not Reported
	Iron			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17106515	NON-EXPEDITED			US-PFIZER INC-2019519970			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Dronedarone			S		Unk		Not Reported	
	Hydrocodone			S		Unk		Not Reported	
	Phentermine			S		Unk		Not Reported	
	Sotalol			S		Unk		Not Reported	
	Serotonin (5ht3) Antagonists			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17107048	EXPEDITED (15-DAY)		OT	ES-MYLANLABS-2019M1116524		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Laryngospasm; Paraesthesia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17108669	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1116945		32 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Cytomegalovirus Infection; Epstein-Barr Virus Infection; Flushing; Hepatocellular Injury; Hepatosplenomegaly; Inflammation; Pleurisy; Portal Vein Thrombosis; Pyrexia; Therapy Non-Responder	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Desogestrel			S	Oral	Unk		Not Reported	
	Levothyroxine			C	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Dec-2019	17111838	DIRECT	Y	OT			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin Ointment 0.5%			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2019	16831691	EXPEDITED (15-DAY)		OT	JP-UCBSA-2019039584		35 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Irritability; Sudden Hearing Loss; Vertigo	E Keppra			S	Oral	500 Milligram, 2x/Day (Bid)			Not Reported
	E Keppra			S					Not Reported
	Azithromycin Dihydrate			S	Oral	500 Milligram Dially			Not Reported
	Carbocisteine			C	Oral	1500 Milligram Daily			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2019	17108824	NON-EXPEDITED			NVSC2019US050379		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Intolerance	Azithromycin			S	Unknown	Unk			Novartis
	Amikacin			S	Unknown	Unk			Not Reported
	Imipenem			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2019	17111685	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2077455		25 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gastrointestinal Disorder	Azithromycin			S	Oral				Wockhardt

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Dec-2019	17111728	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2077456		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Palpitations	Azithromycin			S	Oral			Wockhardt	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	16159590	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK052972			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Appetite Disorder; Asthma; Chest Discomfort; Chest Pain; Cough; Depressed Mood; Depressive Symptom; Dyspnoea; Dyspnoea Exertional; Fall; Heart Sounds; Influenza; Injury; Insomnia; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Productive Cough; Prolonged Expiration; Pyrexia; Rales; Respiration Abnormal; Rhinorrhoea; Sleep Disorder Due To A General Medical Condition; Stress; Upper Respiratory Tract Infection; Weight Decreased; Wheezing	Mepolizumab			S	Subcutaneous	100 Mg, Z, Monthly		Glaxosmithkline	
	Ventolin			S		Unk Unk, Prn		Glaxosmithkline	
	Advair			S	Respiratory (inhalation)	2 Puff(S), Bid		Glaxosmithkline	
	Singulair			S		Unk		Glaxosmithkline	
	Betaderm			S		Unk, Once Twice Daily		Glaxosmithkline	
	Advair Diskus			S		1 Puff(S), Bid		Glaxosmithkline	
	Vitamin B12			S	Intravenous (not otherwise specified)	1 Ml, Z, Monthly		Glaxosmithkline	
	Spiriva Respimat			S	Respiratory (inhalation)	2 Puff(S), Qd		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Uniphyl			S		Unk		Not Reported	
	Combivent			S		Unk		Not Reported	
	Atrovent			S		Unk		Not Reported	
	Theophylline			S		Unk		Not Reported	
	Teva-Doxycycline			S		1 Df, Bid		Not Reported	
	Metformin Sandoz			S		1 Df, Bid		Not Reported	
	Teva-Diltiazem Hcl Er			S		1 Df, Bid		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo-Atorvastatin	S		1 Df, Qd	Not Reported
Apo-Furosemide	S		Unk	Not Reported
Novorapid Flextouch	S	Intravenous (not otherwise specified)	3 Df, Qd, 100units/MI	Not Reported
Apo-Prednisone	S		4 Df, Qd	Not Reported
Apo-Prednisone	S		3 Df, Qd	Not Reported
Apo-Prednisone	S		2 Df, Qd	Not Reported
Apo-Prednisone	S		1 Df, Qd	Not Reported
Ozempic	S	Intravenous (not otherwise specified)	1.25 Mg, We	Not Reported
Seebri Breezhaler	S		1 Df, Qd	Not Reported
Apo-Dimenhydrinate	S			Not Reported
Azithromycin	S		3 Df, 3 Days	Not Reported
Proctosone	S		1 Df, Bid	Not Reported
Rho-Nitro	S		1 Df, Prn	Not Reported
Lactaid Extra Strength	S		1 Df, Tid	Not Reported
Flovent Hfa	S	Respiratory (inhalation)	2 Puff(S), Bid	Not Reported
Pms-Nitrofurantoin	S		1 Df, Bid	Not Reported
Loperamide	S		1 Df, Bid	Not Reported
Mometasone	S		2 Df, Bid	Not Reported
Apo-Acetaminophen	S		2 Df, Qid	Not Reported
Pms Cyclobenzaprine	S		1 Df, Qd	Not Reported
Apo-Amitriptyline	S		4 Df, Qd	Not Reported
Teva-Montelukast	S		1 Df, Qd	Not Reported
Sandoz Levofloxacin Tablets	S		1 Df, Qd	Not Reported
Fluoxetine	S		2 Df, Bid	Not Reported
Dicetel	S		Unk	Not Reported
Tresiba Flexpen	S	Subcutaneous	50 Iu, Qd	Not Reported
Accupril	S		1 Df, Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ratio Lactulose			S		1.5 MI, Bid			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	16712800	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-AUROBINDO-AUR-APL-2019-053340			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Brain Abscess; Iris Adhesions; Multiple Allergies; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Levetiracetam			S	Unknown	1000 Dosage Form, Once A Day		Aurobindo	
	Nivolumab			S	Intravenous (not otherwise specified)	1 Milligram/Kilogram, Cyclical (Q3cycles)		Not Reported	
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclical (Q3cycles)		Not Reported	
	Novalglin (Metamizole Sodium)			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ranitidine			C	Unknown	300 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	16716658	EXPEDITED (15-DAY)		OT	PHHY2019IT192170		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain; Anaesthesia; Dysentery; Nausea	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Coumadin			S	Oral	5 Mg, Prn (As Necessary)		Not Reported	
	Paracetamol			C	Oral	1 G, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	16790983	EXPEDITED (15-DAY)		DS, OT	US-PFIZER INC-2019382969		54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agraphia; Brain Injury; Cerebral Disorder; Cerebrovascular Accident; Condition Aggravated;	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Memory Impairment

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17114386	EXPEDITED (15-DAY)		HO	US-ZYDUS-044195		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Fatigue; Leukocytosis; Mycobacterial Infection; Pathogen Resistance; Pyrexia	Azithromycin			S				Zydus Pharm
	Clindamycin			S	Intravenous (not otherwise specified)			Zydus Pharm
	Metronidazole			S	Oral			Cadila
	Rifabutin			S	Oral			Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)			Not Reported
	Meropenem			S				Not Reported
	Meropenem			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Intravenous (not otherwise specified)			Zydus Pharm
	Azithromycin			S	Oral			Zydus Pharm
	Ciprofloxacin/Ciprofloxacin Hydrochloride/Ciprofloxacin Lactate			S	Intravenous (not otherwise specified)			Not Reported
	Ciprofloxacin/Ciprofloxacin Hydrochloride/Ciprofloxacin Lactate			S	Intravenous (not otherwise specified)			Not Reported
	Ciprofloxacin/Ciprofloxacin Hydrochloride/Ciprofloxacin Lactate			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17115359	EXPEDITED (15-DAY)		HO	NL-PFIZER INC- 2019519730		20 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea;	Azithromycin	S	Oral	2 Df, 1x/Day	Pfizer
Hypersensitivity;	Azithromycin	S	Oral	1 Df, 1x/Day	Pfizer
Pharyngeal Swelling;	Microgynon 50	C			Not Reported
Swollen Tongue	Methylphenidate Hydrochloride	C		1 Df, 2x/Day (Morning 1, Afternoon Half A Tablet)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17115970	NON-EXPEDITED			US-PFIZER INC-2019524293		30 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17116257	EXPEDITED (15-DAY)		HO	GR-MYLANLABS-2019M1118666		50 YR	Male	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated;	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported	
Fatigue; Hepatomegaly;	Azithromycin			S	Unknown			Not Reported	
Hypergammaglobulinaemi a; Inflammatory Marker Increased; Pancytopenia; Product Use In Unapproved Indication; Pyrexia; Sepsis; Splenomegaly; Visceral Leishmaniasis									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17116949	NON-EXPEDITED			US-NEOPHARMA INC-000160			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Augmentin			S				Not Reported	
Urticaria	Aspirin			S				Not Reported	
	Aspartame			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Avelox	S	Not Reported
Cipro	S	Not Reported
Iodine	S	Not Reported
Keppra	S	Not Reported
Ketoconazole	S	Not Reported
Levaquin	S	Not Reported
Lipitor	S	Not Reported
Lovenox	S	Not Reported
Mirapex	S	Not Reported
Motrin	S	Not Reported
Naprosyn	S	Not Reported
Neosporin	S	Not Reported
Neurontin	S	Not Reported
Prozac	S	Not Reported
Requip	S	Not Reported
Septra	S	Not Reported
Sinemet	S	Not Reported
Tetracycline	S	Not Reported
Toradol	S	Not Reported
Voltaren	S	Not Reported
Zithromax Z-Pak	S	Not Reported
Zoloft	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17117030	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2077503			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Tinnitus	Azithromycin			S	Oral			Wockhardt

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17117034	NON-EXPEDITED			US-PFIZER INC- 2019525989			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17117040	NON-EXPEDITED			US-PFIZER INC-2019525163		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ceftin			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17117053	NON-EXPEDITED			US-PFIZER INC-2019526486			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Quinapril Hcl			S		Unk		Pfizer	
	Verapamil Hcl			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	
	Carvedilol			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Diovan			S		Unk		Not Reported	
	Felodipine			S		Unk		Not Reported	
	Hydrocodone/Acetaminophen			S		Unk		Not Reported	
	Lexapro			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	
	Losartan			S		Unk		Not Reported	
	Suprep Bowel Prep Kit			S		Unk		Not Reported	
	Topamax			S		Unk		Not Reported	
	Tricor [Fenofibrate]			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17117512	EXPEDITED (15-DAY)		HO, OT	NVSC2019GB053847		66 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Alanine Aminotransferase Increased; Drug-Induced Liver Injury; Serum Ferritin Increased	Azithromycin			S	Unknown			Novartis	
	Flixotide			C	Unknown	Unk		Not Reported	
	Omeprazole			C	Unknown	Unk		Not Reported	
	Losartan			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17118528	EXPEDITED (15-DAY)		HO	DE-AUROBINDO-AUR- APL-2019-092846			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
B-Lymphocyte Count Decreased	Fluconazole			S	Unknown	Unk		Aurobindo	
	Eremfat			S	Oral	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Cefotaxim			S	Unknown	Unk		Not Reported	
	Duloxetine			C	Unknown	Unk		Not Reported	
	Zopiclone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2019	17206598	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circumstance Or Information Capable Of Leading To Medication Error; Product Appearance Confusion	Azithromycin			S	Intravenous (not otherwise specified)			Auromedics	
	Pantoprazole Sodium			S				Auromedics	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	15658569	NON-EXPEDITED			US-PFIZER INC-2018483530			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	16984587	NON-EXPEDITED			US-PFIZER INC-2019470440			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17083449	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2019PT048905		73 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Distress; Syndrome; Pneumonia; Toxic Epidermal Necrolysis	Losartan			S	Unknown	Unk Unk, Unknown Freq.		Novartis	
	Bisoprolol			S	Unknown	Unk		Not Reported	
	Pantoprazole			S	Unknown	Unk		Not Reported	
	Simvastatin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Amoxicillin Trihydrate,Potassium Clavulanate			S	Unknown	Unk		Not Reported	
	Acetylsalicylic Acid (Cardio)			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17118640	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2019-076013		3 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pathogen Resistance	Azithromycin			S	Unknown	10 Milligram/Kilogram (High-Dose)		Aurobindo
	Doxorubicin			C	Unknown	Unk		Not Reported
	Vincristine			C	Unknown	Unk		Not Reported
	Cefepime			C	Unknown	Unk		Not Reported
	Fluconazole			C	Unknown	Unk		Not Reported
	Vancomycin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17119211	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-UCBSA-2019050956			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Brain Abscess; Iris Adhesions; Multiple Allergies; Off Label Use; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Levetiracetam			S		1000 Df, Qd (1000 Absent, Qd)		Not Reported
	Levetiracetam			S				Not Reported
	Nivolumab			S	Intravenous (not otherwise specified)	1 Mg/Kg, Q3cycles		Not Reported
	Novalgine [Metamizole Sodium]			S		Unk		Not Reported
	Azithromycin			S		Unk		Ucb
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Mg/Kg (Q3cycles)		Not Reported
	Ranitidine			C	Unknown	300 Mg, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17120559	EXPEDITED (15-DAY)		OT	FR-TEVA-2019-FR-1147503		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Ramipril			S	Oral			Actavis
	Imodium			S	Oral			Not Reported
	Bactrim			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Kardegic	S	Oral			Not Reported
	Inipomp	S	Oral			Not Reported
	Tiorfan	S	Oral			Not Reported
	Zithromax	S	Oral			Not Reported
	Oflocet 200 Mg, Comprimé Pelliculé Sécable	S	Oral	200 Milligram		Not Reported
	Retacrit	S	Unknown			Not Reported
	Valaciclovir	S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17121743	NON-EXPEDITED		DE	NVSC2019US058272		56 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterial Infection; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	Unk		Novartis	
	Ethambutol			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17121749	EXPEDITED (15-DAY)		DE, OT	NVSC2019US058276		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mycobacterial Infection; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Novartis	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Amikacin			S	Unknown	Unk		Not Reported	
	Rifabutin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17121942	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019521756		10 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alopecia; Off Label Use		Azithromycin		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17122456	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019523284		90 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; International Normalised Ratio Increased	Zitromax			S	Oral	1 Df, 1x/Day		Pfizer	
	Coumadin			S	Oral	1 Df, As Needed		Not Reported	
	Levoxacin			S	Oral	1 Df, 1x/Day		Not Reported	
	Kanrenol			C	Oral	Unk		Not Reported	
	Bisoprolol Fumarate			C	Oral	2.5 Mg, Unk		Not Reported	
	Furosemide			C	Oral	25 Mg, Unk		Not Reported	
	Glimepiride			C	Oral	Unk		Not Reported	
	Quetiapine			C	Oral	25 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17123831	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2019520440		2 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Macule; Rash	Zithromax			S	Oral	0.1 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17124512	NON-EXPEDITED			US-NEOPHARMA INC-000271		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Augmentin			S				Neopharma	
	Lyrice			S	Oral	Take 1 Capsules 3 Times A Day By Oral Route For 90 Days.		Not Reported	
	Avelox			S				Not Reported	
	Betadine			S				Not Reported	
	Caffeine			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cipro	S	Not Reported
Dilaudid	S	Not Reported
Fluticasone	S	Not Reported
Gabapentin	S	Not Reported
Hydroxyzine	S	Not Reported
Iodine	S	Not Reported
Ipratropium	S	Not Reported
Levaquin	S	Not Reported
Meloxicam	S	Not Reported
Menthol	S	Not Reported
Morphine	S	Not Reported
Naprosyn	S	Not Reported
Prednisone	S	Not Reported
Reglan	S	Not Reported
Skelaxin	S	Not Reported
Triple Antibiotic (Bacitracin Zinc\Neomycin Sulfate\Polymyxin B Sulfate)	S	Not Reported
Xanax	S	Not Reported
Zithromax	S	Not Reported
Eucrisa	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17124513	NON-EXPEDITED			US-NEOPHARMA INC-000272			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Augmentin Zithromax			S S				Neopharma Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17124596	NON-EXPEDITED			US-PFIZER INC-2019529553		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Ineffective	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17124780	EXPEDITED (15-DAY)		OT	AU-BAUSCH-BL-2019-063680			Unknown	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Hepatotoxicity	Dexamethasone			S	Unknown			Bausch And Lomb
	Metoclopramide			S	Unknown			Valeant
	Diclofenac Sodium			S	Unknown			Not Reported
	Heparin			S	Unknown			Not Reported
	Rifampicin			S	Unknown			Not Reported
	Pyridoxine Hydrochloride			S	Unknown			Not Reported
	Pyrazinamide			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Isoniazid			S	Unknown			Not Reported
	Ethambutol Hydrochloride			S	Unknown			Not Reported
	Cimetidine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17125237	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR-APL-2019-091924		32 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mycobacterial Infection	Metronidazole			S	Oral	Unk		Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Rifabutin			C	Oral	Unk		Not Reported
	Pyrimethamine			C	Oral	Unk		Not Reported
	Leucovorin			C	Oral	Unk		Not Reported
	Ivermectin			C	Oral	Unk		Not Reported
	Vancomycin			C	Unknown	Unk		Not Reported
	Piperacillin & Tazobactam			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2019	17215182	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Appearance Confusion	Etomidate			S	Intravenous (not otherwise specified)			Auromedics	
	Azithromycin			S	Intravenous (not otherwise specified)	Other Strength:500 Mg Per Vial;		Auromedics	
	Pantoprazole Sodium			S	Subcutaneous	Other Strength:40 Mg Per Vial;		Auromedics	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2019	15778708	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR- APL-2018-063860		35 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Live Birth; Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Systemic Inflammatory Response Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo	
	Cefixime			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Dec-2019	17128984	DIRECT		OT			27 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glossodynia; Mouth Ulceration; Oral Pain; Oral Pain	Azithromycin Tablets	Y		S	Oral	Quantity:6 Tablet(S);Other Frequency:2 Tabs Day 1, Then;		Not Reported	
	Propanolol Melatonin 3mg Prn			C C				Not Reported Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	15776587	NON-EXPEDITED			US-PFIZER INC-2018535249		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Diltiazem Hcl			S		Unk		Unknown
	Quinapril Hcl			S		Unk		Pfizer
	Verapamil Hcl			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Carvedilol			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Diovan			S		Unk		Not Reported
	Felodipine			S		Unk		Not Reported
	Hydrocodone Bitartrate And Acetaminophen			S		Unk		Not Reported
	Lexapro			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Losartan			S		Unk		Not Reported
	Suprep Bowel Prep			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Tricor [Fenofibrate]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17039569	NON-EXPEDITED		HO, OT	PHHY2019US143501		20 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Neurosensory; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Infective Pulmonary Exacerbation	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Of Cystic Fibrosis	Amikacin	S						Not Reported
	Azithromycin	S	Oral		Unk			Not Reported
	Azithromycin	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17100357	EXPEDITED (15-DAY)		HO, OT	IT-MYLANLABS-2019M1115705		16 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective;	Cefixime			S	Unknown	Unk		Not Reported
Endocarditis Bacterial;	Azithromycin			S	Unknown	Unk		Not Reported
Joint Swelling; Pharyngitis;								
Pyrexia								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17126167	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-AUROBINDO-AUR-APL-2019-103340			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis;	Levetiracetam			S	Unknown	1000 Dosage Form, Once A Day		Aurobindo
Brain Abscess; Iris								
Adhesions; Multiple	Azithromycin			S	Unknown	Unk		Not Reported
Allergies; Pancytopenia;	Ipilimumab			S	Intravenous (not otherwise specified)	3 Milligram/Kilogram, Cyclical (Q3cycles)		Not Reported
Pneumonia; Rash; Sepsis;								
Toxic Epidermal Necrolysis	Nivolumab			S	Intravenous (not otherwise specified)	1 Milligram/Kilogram, Cyclical (Q3cycles)		Not Reported
	Novalgine (Metamizole Sodium)			S	Unknown	Unk		Not Reported
	Ranitidine			C	Unknown	300 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17127499	EXPEDITED (15-DAY)		HO, OT	FR-GLAXOSMITHKLINE-FR2019221370		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Aciclovir			S	Intravenous (not	10 Mg/Kg, Tid		Glaxosmithkline
Hypotension								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Malocide [Pyrimethamine]	S	Unknown	50 Mg, Qd		Glaxosmithkline
Metformin Hydrochloride	S	Oral	3 Df, Qd		Not Reported
Zithromax	S	Oral	1 Df, Qd		Not Reported
Seretide	C	Unknown	Unk		Glaxosmithkline
Pantoprazole	C	Unknown	Unk		Glaxosmithkline
Nebivolol	C	Unknown	Unk		Glaxosmithkline
Galvus	C	Unknown	Unk		Glaxosmithkline
Furosemide	C	Unknown	Unk		Glaxosmithkline
Montelukast	C	Unknown	Unk		Glaxosmithkline
Novorapid	C	Unknown	Unk		Not Reported
Atorvastatin	C	Unknown	Unk		Not Reported
Moxonidine	C	Unknown	Unk		Not Reported
Lantus	C	Unknown	Unk		Not Reported
Tarka	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17128143	NON-EXPEDITED			US-UCBSA-2017002377			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity	Hydrocodone Polistirex			S				Not Reported
	Chlorpheniramine Polistirex							
	Prempro			S		0.3-1.5mg Once Daily		Not Reported
	Protonix			S				Not Reported
	Zithromax			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17128792	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1119553		24 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Haemolytic	Azithromycin Mylan			S		Unk		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Anaemia; Gastroenteritis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17128971	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019523643			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Pulmonary Mass; Squamous Cell Carcinoma Of Lung	Novatrex			S	Oral	Unk		Pfizer
	Arava			S	Oral	Unk		Not Reported
	Mabthera			S	Subcutaneous	Unk		Not Reported
	Cimzia			S	Oral	Unk		Not Reported
	Orencia			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Olumiant			S	Oral	Unk		Not Reported
	Roactemra			S	Subcutaneous	Unk		Not Reported
	Fixical			C		Unk		Not Reported
	Diffu K			C		Unk		Not Reported
	Flodil [Felodipine]			C		Unk		Not Reported
	Kardegic			C		Unk		Not Reported
	Esomeprazole			C		Unk		Not Reported
	Fenofibrate			C		Unk		Not Reported
	Cortancyl			C		Unk		Not Reported
	Nicorandil			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17129076	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019525853			Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Colitis; Diarrhoea; Gastric Disorder; Gastroenteritis; Haematochezia	Zithromac 250mg			S	Oral	Unk		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17129544	NON-EXPEDITED			US-PFIZER INC-2019530734		42 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17130122	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019529210		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Hypopnoea;	Zithromax			S		Unk		Pfizer	
Influenza; Off Label Use;	Firdapse			S	Oral	20 Mg, 3x/Day		Not Reported	
Product Administration	Firdapse			S				Not Reported	
Error; Product Use In	Mestinon			C		Unk		Not Reported	
Unapproved Indication;	Methotrexate			C		Unk		Not Reported	
Secretion Discharge									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2019	17130520	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2019M1119910		63 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For	Azithromycin			S		Unk		Not Reported	
Unapproved Indication;	Norfloxacin			S		Unk		Mylan	
Granulomatosis With	Prednisolon /00016201/			C		5 Milligram, Qd		Mylan	
Polyangiitis; Temporal									
Arteritis									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2019	7686793	EXPEDITED (15-DAY)		HO, OT	JP-JNJFOC-20101108379		28 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Prezista			S	Oral	300 Mg X 2 Tablets Per		Not Reported	
Anaemia; Atrioventricular									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Block Second Degree; Blood Triglycerides Increased; Bradycardia; Campylobacter Gastroenteritis; Dyslipidaemia; Gastrointestinal Haemorrhage; Haemoglobin Decreased; Haemorrhoids; Hepatic Function Abnormal; Herpes Zoster; Liver Function Test Abnormal; Liver Function Test Increased; Malaise; Oropharyngeal Discomfort; Tachycardia Paroxysmal	Prezista Prezista Norvir Truvada Epivir Epivir Epivir Epivir Isentress T-20 Raltegravir Zithromac Zithromac Tivicay Norvir Baktar Cross Eight M Cross Eight M Cross Eight M Cross Eight M Cross Eight M Cross Eight M Cross Eight M	S S S S S S S S S S S S S S S C C C C C C C	Oral Oral Oral Oral Oral Oral Oral Oral Oral Unknown Unknown Oral Oral Oral Oral Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified) Intravenous (not otherwise specified)	Day, Twice Daily. 300 Mg X 2 Tablets Per Day, Twice Daily. 2lu/Day Dose Given Once 1/3 Days 3000-2000ut 2000-1000ut Dose Given Once 1/3 Days	Not Reported Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Cross Eight M	C	Intravenous (not otherwise specified)	1000-2000ut	Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Cross Eight M	C	Intravenous (not otherwise specified)		Not Reported
Gascon	C	Oral		Not Reported
Biofermin R	C	Oral		Not Reported
Fero-Gradumet	C	Unknown		Not Reported
Maglax	C	Oral		Not Reported
Posterisan	C	Topical		Not Reported
Posterisan	C	Topical		Not Reported
Neriproct	C	Rectal	1-3 Times A Day	Not Reported
Neriproct	C	Rectal		Not Reported
Norvir	C	Oral		Not Reported
Neriproct	C	Topical		Not Reported
Neriproct	C	Topical		Not Reported
Borraza-G	C	Topical		Not Reported
Invirase	C	Oral		Not Reported
Hivid	C	Oral		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zerit	C	Oral	Not Reported
Zerit	C	Oral	Not Reported
Zerit	C	Oral	Not Reported
Viracept	C	Oral	Not Reported
Viracept	C	Oral	Not Reported
Viracept	C	Oral	Not Reported
Ziagen	C	Oral	Not Reported
Prozei	C	Oral	Not Reported
Prozei	C	Oral	Not Reported
Stocrin	C	Oral	Not Reported
Stocrin	C	Oral	Not Reported
Videx	C	Oral	Not Reported
Videx	C	Oral	Not Reported
Kaletra	C	Oral	Not Reported
Kaletra	C	Oral	Not Reported
Azithromycin	C	Oral	Not Reported
Combivir	C	Oral	Not Reported
Retrovir	C	Oral	Not Reported
Norvir	C	Oral	Not Reported
Cross Eight Mc	C		Not Reported
Biofermin	C	Oral	Not Reported
Maglax	C	Oral	Not Reported
Cobicistat W/Darunavir Ethanolate	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2019	15296153	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-SA-2018SA000739		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Furosemide			S	Oral	40 Mg,Qd		Sanofi	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	S	Oral	40 Mg, Qd	Sanofi
Amiodarone Hydrochloride	S	Unknown	Unk Unk,Unk	Not Reported
Amiodarone Hydrochloride	S	Unknown	Unk Unk, Unk	Not Reported
Enoxaparin Sodium	S	Subcutaneous	40 Mg, Qd	Sanofi
Enoxaparin Sodium	S	Subcutaneous	40 Mg, Qd	Sanofi
Enoxaparin Sodium	S	Subcutaneous	50 Mg, Q4h	Sanofi
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg,Qh,8 Mg, Once Every Hour	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Unk	Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)	1-2 Mg (Once In 10 Minutes, Prn)	Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	125 Mg,Q6h,125 Mg, 4x/Day (Every 6 Hours)	Not Reported
Methylprednisolone Sodium Succinate	S	Intravenous (not otherwise specified)	125 Mg, Qid (125 Mg, 4x/Day)	Not Reported
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 G, Qd, 1 G, 1x/Day	Not Reported
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 G, Q4h	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	0.25-0.5 Mg (Once In 4 To 6 Hrs Prn)	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Unk Unk, Unk	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg,Qow, 297 Mg, Q2weeks (Once Every 14 Days) (1 Every 2 Week(S))	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg,Qd	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd, 500 Mg, 1x/Day	Not Reported
Trastuzumab	S	Unknown	Unk Unk,Unk	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Mg,Qh, 10 Mg, (1 Every 1 Hour (S))	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	.25 Mg,Q4h,0.25 Mg (One Every Four Hours)	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg, Unk	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Mg, Unk	Not Reported
Diltiazem Hydrochloride	S	Oral	180 Mg,Unk	Sanofi
Diltiazem Hydrochloride	S	Oral	180 Mg, Unk	Sanofi
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg,Qow, 106 Mg, Q2weeks (Once Every 14 Days) (1 Every 2 Week(S))	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg, Unk	Not Reported
Metoprolol Salt Not Specified	S	Intravenous (not otherwise specified)	2.5 Mg, Q6h (4x/Day (Every 6 Hours))	Not Reported
Metoprolol Salt Not Specified	S	Intravenous (not otherwise specified)	5 Mg,Q6h (4x/Day (Every 6 Hours))	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg,Qow	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg,Qow	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg,Qow	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	125 Unk (4x/Day)	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qcy	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Unk	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Unk	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qd (1x/Day)	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q6h	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q6h (4x/Day (1 Every 6 Hour(S))	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Q4h	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, 4x/Day	Not Reported
Filgrastim	C	Subcutaneous	300 Ug, Qd	Not Reported
Filgrastim	C	Subcutaneous	Unk	Not Reported
Gabapentin	C	Unknown	100 Mg, Tid	Not Reported
Gabapentin	C	Unknown	Unk	Not Reported
Metoclopramide	C	Unknown	10 Mg, Q6h	Not Reported
Metoclopramide	C	Unknown	10 Mg, Unk	Not Reported
Ondansetron	C	Oral	8 G, Bid	Not Reported
Ondansetron	C	Oral	Unk	Not Reported
Dexamethasone	C	Unknown	20 Mg, Qd	Not Reported
Dexamethasone	C	Oral	Unk Unk, Unk	Not Reported
Aprepitant	C	Unknown	Unk, Unk	Not Reported
Acetaminophen;Caffeine;Dihydrocodeine	C	Unknown	Unk Unk, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2019	17132868	NON-EXPEDITED			US-TEVA-2019-US-1151028		68 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper	Azithromycin			S	Unknown	In 1970s		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2019	17134232	EXPEDITED (15-DAY)		HO	NL-TEVA-2019-NL-1148317		20 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hypersensitivity; Pharyngeal Swelling; Swollen Tongue	Azitromycine Tablet, 250 Mg (Milligram)			S		1st Day 2 At A Time, Then 1 Tablet Once A Day , 1 Dosage Forms 1 Days		Not Reported	
	Microgynon 50			C				Not Reported	
	Methylenidaat 10 Mg			C		Morning 1, Afternoon Half A Tablet , 1 Dosage Forms 12 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2019	17136025	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-US2019AMR219082		59 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Neurological Symptom	Panadol		Y	S	Unknown	Unk		Glaxosmithkline	
	Phenylephrine Hydrochloride			S	Unknown	Unk		Glaxosmithkline	
	Azithromycin			S	Unknown	Unk		Glaxosmithkline	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17135167	NON-EXPEDITED			US-PFIZER INC-2019531154		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Off Label Use; Product Use In Unapproved Indication	Zithromax			S		500 Mg, Daily (2 Tablets For 1 Day)		Pfizer	
	Zithromax			S		250 Mg, Daily (1 Tablet Daily For 4 Days)		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17139216	EXPEDITED (15-DAY)		OT	CA-CELLTRION INC.- 2019CA027151			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis Acute	Infliximab Pfizer (Unknown)			S	Intravenous (not otherwise specified)	5 Mg/Kg, Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Ethinylestradiol, Levonorgestrel			S		Unk		Not Reported
	5-Asa			S		Unk		Not Reported
	Asacol			S		Unk		Not Reported
	Azathioprine			S		Unk		Not Reported
	Mercaptopurine			S		Unk		Not Reported
	Mezavant			S		Unk		Not Reported
	Para-Aminosalicylic Acid			S		Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17140595	EXPEDITED (15-DAY)		OT	NVSC2019AT059580			Unknown	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S	Unknown			Novartis
	Azithromycin			S	Unknown	500 Mg, Qd (For 3 Days)		Novartis
	Rifaximin			S	Unknown			Not Reported
	Rifaximin			S	Unknown	600 Mg, Qd (200 Mg, 3x/Day (For 10days)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17141101	EXPEDITED (15-DAY)		HO	US-SLATE RUN PHARMACEUTICALS- SLTR-AE-19-116		89 YR	Female	ISR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acute Myocardial Infarction; Anxiety; Blood Immunoglobulin G Decreased; C-Reactive Protein Increased; Dyspnoea; Hyperhidrosis; Leukocytosis; Lymphadenopathy; Pneumonia; Sinus Tachycardia; Tumour Lysis Syndrome	Furosemide	C	Intravenous (not otherwise specified)	Not Reported
	Methylprednisolone	C	Intravenous (not otherwise specified)	Not Reported
	Ceftriaxone	C		Not Reported
	Prednisone	C	Oral	Not Reported
	Fluids With Bicarbonate	C	Intravenous (not otherwise specified)	Not Reported
	Febuxostat	C		Not Reported
	Sevelamer	C		Not Reported
	Aspirin	C		Not Reported
	Clopidogrel	C		Not Reported
	70436-019-82 Azithromycin For Injection Dry Vial Usp 500 Mg	S	Oral	Hainan Poly Pharmaceuticals

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17142683	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2019534614		69 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysentery	Zitromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17143711	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-104506		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Dyshidrotic Eczema; Hepatocellular Injury; Lymphocytosis	Paracetamol			S	Oral	1 Gram, Four Times/Day		Aurobindo	
	Zithromax			S	Oral	Unk		Not Reported	
	Cefotaxime Merck			S	Intramedullar (bone marrow)	1 Gram		Not Reported	
	Inflectra			C	Intravenous drip	5 Milligram/Kilogram, Every 2 Months		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Dec-2019	17144174	DIRECT	Y				65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S	Oral	Other Frequency:Once;		Teva	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17143586	NON-EXPEDITED			US-PFIZER INC-2019534217			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Dry Skin; Fatigue; Hypertension; Oral Discomfort; Pruritus; Rash	Zithromax			S	Oral	5 Df (05 Tabs)		Pfizer	
	Lenvima			S	Oral	24 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17143685	NON-EXPEDITED			US-PFIZER INC-2019536862		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cephalexin Hcl			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17146111	NON-EXPEDITED		HO, OT	US-APOTEX-2019AP025900		51 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Tubulointerstitial Nephritis	Amoxicillin /Clavulanate			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Lorazepam			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17146576	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2019M1122048		334 DAY	Male	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea;	Lamivudine			S		Unk		Not Reported
Hepatosplenomegaly; Hiv	Vancomycin			S		Unk		Not Reported
Viraemia; Hypertension;	Lopinavir/Ritonavir			S		Unk		Not Reported
Livedo Reticularis; Motor	Azithromycin			S		Unk		Not Reported
Developmental Delay;	Abacavir			S		Unk		Mylan
Oxygen Saturation	Meropenem			S		Unk		Mylan
Decreased; Pneumonia;	Dexamethasone			S		Unk		Mylan
Sepsis; Skin Candida;	Biseptol			S		Unk		Mylan
Tachycardia; Tachypnoea;	Co-Trimoxazole /00086101/			C		Unk		Mylan
Thyroid Hormones	Co-Trimoxazole /00086101/			C		Unk		Mylan
Decreased; Weight Gain	Furosemide			C		Unk		Mylan
Poor	Calcium Folate			C		Unk		Mylan
	Zidovudine			C		Unk		Mylan
	Dopamine			C		Unk		Mylan
	Levonor /00022701/			C		Unk		Mylan
	Prednisone			C		Unk		Mylan
	Iron			C		Unk		Mylan
	Etacrynic Acid			C		Unk		Mylan
	Amoxicillin Clavulanic Acid			C		Unk		Mylan
	Colecalciferol			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17146867	EXPEDITED (15-DAY)		DS, HO, OT	HU-MYLANLABS-2019M1122148		58 YR	Male	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Arthralgia; Asthenia;	Azithromycin	S	Oral	500 Mg, Unk	Not Reported
Conjunctivitis; Cough;	Doxycyclin /00055701/	S	Oral	100 Mg, Unk	Mylan
Dyspnoea Exertional;	Cetirizin	S	Oral	10 Mg, Unk	Mylan
Mastocytosis; Myalgia;	Zinnat /00454602/	S	Oral	500 Mg, Unk	Mylan
Nasopharyngitis; Pyrexia;					
Rash					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17147814	EXPEDITED (15-DAY)		OT	NVSC2019US000760		60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pulmonary Cavitation; Skin Hyperpigmentation; Tinnitus	Clofazimine			S	Intravenous (not otherwise specified)	Unk		Novartis
	Clofazimine			S	Unknown	Unk		Novartis
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amikacin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Amikacin			S	Respiratory (inhalation)	Unk		Not Reported
	Amikacin			S	Respiratory (inhalation)	Unk		Not Reported
	Cefoxitin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Tigecycline			S	Unknown	Unk		Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Dec-2019	17151736	DIRECT		DS			62 YR	Transgender	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Anxiety; Disturbance In Attention; Dyspnoea; Epicondylitis;	Azithromycin			S	Oral	Quantity:12 Tablet(S);		Teva
	Keppra			C				Not Reported
	Albuterol			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gait Disturbance;	Naprosyn	C	Not Reported
Insomnia; Irritability;	Cane	C	Not Reported
Ligament Pain;	Wheelchair	C	Not Reported
Somnolence; Tendon	Tens	C	Not Reported
Pain; Tendon Pain	Estradiol	C	Not Reported
	Estriol	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	12155336	EXPEDITED (15-DAY)		OT	US-UCBSA-2015038595			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction;	Cimzia			S		400 Mg, Ev 4 Weeks		Not Reported
Nasopharyngitis; Sinusitis	Z-Pak			S		Unk		Not Reported
	Mtx			C		6 Df, Weekly (Qw)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	15947667	NON-EXPEDITED			US-PFIZER INC-2019062564		74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Flagyl			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Cipro [Ciprofloxacin Hydrochloride]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	16852727	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-2019AMR171458			Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Condition	Salbutamol Sulphate			S		Unk		Glaxosmithkline
Aggravated; Cystic	Azithromycin			S		Unk		Glaxosmithkline
Fibrosis; Drug Ineffective;	Tobramycin			S		Unk		Glaxosmithkline
Dyspnoea; Eosinophil	Symbicort			S		Unk		Not Reported
Count Abnormal; Loss Of								
Personal Independence In								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Daily Activities; Lung Disorder; Sleep Disorder Due To A General Medical Condition; Wheezing	Symbicort	S	Unk	Not Reported
	Pulmicort	S	Unk	Not Reported
	Pulmicort	S	Unk	Not Reported
	Prednisone	S	20 Mg, Unk	Not Reported
	Prednisone	S	50 Mg, Qd	Not Reported
	Hypertonic Saline 7%	S	Unk	Not Reported
	Pulmozyme	S	Unk	Not Reported
	Peg 3350	S	Unk	Not Reported
	Cotazym E.C.S. 20	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	16964525	NON-EXPEDITED			PHHY2019US088990		48 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Clostridium Test Positive; Diarrhoea; Pyrexia; Tinnitus; Vision Blurred	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Azithromycin			S	Oral	500 Mg, Unk		Not Reported
	Amikacin			S	Intravenous (not otherwise specified)	400 Mg, Unk		Not Reported
	Tedizolid			S	Unknown	Unk		Not Reported
	Rifampin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	17016063	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC-2019484691		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Anaphylactic Reaction; Dyspnoea; Respiratory Arrest	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer
	Rocephin			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rocephin			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	17102388	EXPEDITED (15-DAY)		HO	US-TEVA-2019-US-1146563		3 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin			S	Unknown			Teva	
	Azithromycin			S	Unknown	Restarted During Re-Admission [Dosage Not Stated].		Teva	
	Cefepime			C	Unknown			Not Reported	
	Fluconazole			C	Unknown			Not Reported	
	Doxorubicin			C	Unknown			Not Reported	
	Vincristine			C	Unknown			Not Reported	
	Vancomycin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	17148684	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-2225297			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Blood Pressure Increased; Chest Pain; Chromaturia; Cough; Diarrhoea; Dysphonia; Dyspnoea; Fatigue; Intentional Product Use Issue; Intentional Product Use Issue; Mycobacterial Infection; Off Label Use; Pneumonia Staphylococcal; Rales; Rash; Rhinovirus Infection; Urinary Tract Infection; Vomiting	Valcyte			S	Oral			Not Reported	
	Cellcept [Mycophenolate Mofetil]			S	Oral	From Medication List Dated 23/10/2018		Not Reported	
	Cellcept [Mycophenolate Mofetil]			S	Oral			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Ferrous Sulfate			C	Oral			Not Reported	
	Coreg			C	Oral			Not Reported	
	Tylenol			C	Oral	As Needed		Not Reported	
	Xanax			C	Oral	As Needed		Not Reported	
	Florinef			C	Oral	Daily		Not Reported	
	Prograf			C	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prograf	C	Oral	Daily For 30 Days	Not Reported
Cozaar	C	Oral	1 Tablet Daily For 364 Days	Not Reported
Cozaar	C	Oral	1 Tablet Daily For 364 Days	Not Reported
Ecotrin	C	Oral	Daily	Not Reported
Vitamin D3	C	Oral		Not Reported
Protonix [Pantoprazole Sodium Sesquihydrate]	C	Oral	40mg Enteric Coated Tablet Every Morning	Not Reported
Dapsone	C	Oral	At Evening	Not Reported
Cartia Xt	C	Oral	Daily	Not Reported
Hypersal	C	Unknown	7 % Solution For Nebulization, Vial	Not Reported
Tums E-X	C	Oral	Chew 2 Tablets Nightly	Not Reported
Atrovent	C	Respiratory (inhalation)	0.02% As Needed	Not Reported
Mycostatin	C	Oral	100000 Unit/ML Suspension, Take 500000 Units	Not Reported
Miralax	C	Oral	Daily; As Needed	Not Reported
Ergocalciferol	C	Oral	50000 Unit	Not Reported
Zithromax	C	Oral		Not Reported
Oysco	C	Oral		Not Reported
Myfortic	C			Not Reported
Mucomyst [Acetylcysteine]	C			Not Reported
Pravachol	C	Oral		Not Reported
Lasix [Furosemide]	C	Oral		Not Reported
Prograf	C	Oral		Not Reported
Deltasone [Prednisone]	C	Oral		Not Reported
Mycobutin	C	Oral		Not Reported
Remeron	C			Not Reported
Zyrtec [Cetirizine Hydrochloride]	C			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149177	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1152492		40 YR	Female	UKR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hepatitis Toxic	Sumamed			S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17149303	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1149325		52 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Rash Maculo-Papular	Azithromycine Anhydre			S	Oral			Not Reported	
	Oxomemazine			S	Oral			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151324	NON-EXPEDITED			US-PFIZER INC-2019536897		62 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151534	NON-EXPEDITED		OT	US-PFIZER INC-2019536671		72 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Ear Congestion	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Dec-2019	17151541	NON-EXPEDITED			US-PFIZER INC-2019537825		63 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Malaise	Zithromax		S			Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2019	17158030	DIRECT	Y	HO			87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
International Normalised Ratio Increased	Warfarin			S					Not Reported
	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2019	17155124	EXPEDITED (15-DAY)			PT-MYLANLABS-2019M1119550		40 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use	Azithromycin			S		Unk			Not Reported
	Fidaxomicin			S		Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2019	17155143	NON-EXPEDITED			NVSC2019US001055		2 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Non-Responder	Azithromycin			S	Unknown	Unk			Novartis
	Cefotaxime			S	Unknown	Unk			Not Reported
	Vancomycin			S	Unknown	Unk			Not Reported
	Piperacillin Sodium,Tazobactam Sodium			S	Unknown	Unk			Not Reported
	Clindamycin			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Dec-2019	17155781	NON-EXPEDITED			NVSC2019US022485		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Maternal Exposure During Pregnancy	Azithromycin	S	Unknown	Unk	Novartis
	Chloramphenicol	S	Unknown	Unk	Not Reported
	Acyclovir	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	12267263	NON-EXPEDITED			US-PFIZER INC-2016209040		69 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Belladonna Alkaloids			S				Not Reported
	Q-Tuss			S		Unk		Not Reported
	Astelin			S		Unk		Not Reported
	Cephalexin			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Zyrtec			S		Unk		Not Reported
	Chlorpheniramine Maleate			S		Unk		Not Reported
	Tagamet			S		Unk		Not Reported
	Celexa			S		Unk		Not Reported
	Flexeril			S		Unk		Not Reported
	Diclofenac Potassium			S		Unk		Not Reported
	Vibramycin [Doxycycline]			S		Unk		Not Reported
	Allegra			S		Unk		Not Reported
	Flonase			S		Unk		Not Reported
	Foradil			S		Unk		Not Reported
	Mucinex			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Levaquin	S	Unk	Not Reported
Ofloxacin	S	Unk	Not Reported
Albuterol	S	Unk	Not Reported
Imitrex	S	Unk	Not Reported
Spiriva	S		Not Reported
Tramadol	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	12907862	NON-EXPEDITED			US-PFIZER INC-2016508282			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Demerol			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Oxycontin			S		Unk		Not Reported
	Keflex			S		Unk		Not Reported
	Avelox			S		Unk		Not Reported
	Fiorinal			S		Unk		Not Reported
	Macrochantin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	13124451	NON-EXPEDITED			US-PFIZER INC-2017013490		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer
	Ciprofloxacin Hcl			S		Unk		Unknown
	Cefuroxime			S		Unk		Unknown

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17149161	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191212694		25 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Reactine [Cetirizine Hydrochloride]	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Rifampin	S	Unknown	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17158466	NON-EXPEDITED			US-PFIZER INC- 2019537141		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
	Augmentin [Amoxicillin;Clavulanic Acid]			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17160298	EXPEDITED (15-DAY)		HO	CN-PFIZER INC- 2019539703		9 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Macule; Off Label Use; Product Use Issue; Pruritus; Rash	Zithromax			S	Intravenous drip	0.25 G, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17160550	NON-EXPEDITED			US-AMNEAL PHARMACEUTICALS- 2019-IPXL-00308			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Labelled Drug-Drug Interaction Medication	Colestipol Hydrochloride			S	Oral	1 Gram		Impax	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Error	Azithromycin			S	Oral	1 Dosage Form		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17160831	NON-EXPEDITED				NVSC2019US046560		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin				S	Oral	Unk			Novartis
	Dexamethasone				C	Unknown				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17161054	NON-EXPEDITED				NVSC2019US001084		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Delivery	Azithromycin				S	Unknown	Unk			Novartis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Dec-2019	17251534	DIRECT	Y						Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin				S	Intravenous (not otherwise specified)				Fresenius Medical Care
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	14406753	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT		CA-VALIDUS PHARMACEUTICALS LLC-CA-2018VAL000126			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Furosemide				S	Oral	40 Mg, Qd			Validus
	Furosemide				S	Oral	40 Mg, Qd			Validus

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amiodarone Hydrochloride	S	Unknown	Unk	Not Reported
Amiodarone Hydrochloride	S	Unknown	Unk	Not Reported
Enoxaparin Sodium	S	Subcutaneous	40 Mg, Qd	Not Reported
Enoxaparin Sodium	S	Subcutaneous	40 Mg, Qd	Not Reported
Enoxaparin Sodium	S	Subcutaneous	50 Mg, Q4h	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Qh, 8 Mg, Once Every Hour	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Unk	Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)	1-2 Mg (Once In 10 Minutes), Prn	Not Reported
Morphine Sulfate	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Q6h, 125 Mg, 4x/Day (Every 6 Hours)	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Qid (125 Mg, 4x/Day)	Not Reported
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 G, Qd	Not Reported
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 G, Qd, 1 G, 1x/Day	Not Reported
Ceftriaxone Sodium	S	Intravenous (not otherwise specified)	1 G, Q4h	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	0.25-0.5 Mg (Once In 4 To 6 Hrs Prn)	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Qow, 297 Mg, Q2weeks (Once Every 14 Days) (1 Every 2 Week(S))	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd, 500 Mg 1x/Day	Not Reported
Trastuzumab	S	Unknown	Unk	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Mg, Qh, 10 Mg, (1 Every 1 Hour (S))	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg, Q4h, 0.25 Mg (One Every Four Hours)	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg, Unk	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Mg, Unk	Not Reported
Diltiazem Hydrochloride	S	Oral	180 Mg, Unk	Not Reported
Diltiazem Hydrochloride	S	Oral	180 Mg, Unk	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg, Qow, 106 Mg Q2weeks (Once Every 14 Days) (1 Every 2 Week (S))	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg, Unk	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Mg, Q6h (4x/Day (Every 6 Hours))	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Mg, Q6h (4x/Day (Every 6 Hours))	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qow	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qow	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qow	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	125 Unk (4x/Day)	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qcy	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cyclophosphamide	S	otherwise specified)	1060 Unk, Unk	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Unk, Unk	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Qd (1x/Day)	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q6h	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q6h (4x/Day (1 Every 6 Hour (S))	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Q4h	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, 4x/Day	Not Reported
Filgrastim	C		Unk	Not Reported
Gabapentin	C		Unk	Not Reported
Metoclopramide /00041902/	C		Unk	Not Reported
Ondansetron	C		Unk	Not Reported
Dexamethasone	C		Unk	Not Reported
Aprepitant	C		Unk	Not Reported
Acetaminophen W/Caffeine/Dihydrocodeine	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	14683980	NON-EXPEDITED			US-TEVA-2018-US-874008			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exposure Via Breast Milk; Vomiting Projectile	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	14890221	NON-EXPEDITED			US-PFIZER INC-2018192307		67 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Norvasc			S		Unk		Pfizer
	Ampicillin Sodium			S		Unk		Unknown
	Zithromax			S		Unk		Pfizer
	Cefpodoxime Proxetil			S		Unk		Pfizer
	Ciprofloxacin			S		Unk		Unknown
	Chlorpropamide			S		Unk		Pfizer
	Ibuprofen			S		Unk		Pfizer
	Indomethacin			S		Unk		Unknown
	Flagyl			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Daypro			S		Unk		Pfizer
	Gabapentin			S				Pfizer
	Donnatal			S		Unk		Not Reported
	Cogentin			S		Unk		Not Reported
	Sinemet			S		Unk		Not Reported
	Ceftin [Cefatrizine Propyleneglycolate]			S		Unk		Not Reported
	Thorazine [Chlorpromazine Hydrochloride]			S		Unk		Not Reported
	Codeine			S		Unk		Not Reported
	Darvocet-N			S		Unk		Not Reported
	Vicodin			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Naprosyn [Naproxen]			S		Unk		Not Reported
	Bactrim			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	17129578	NON-EXPEDITED			US-PFIZER INC- 2019530619		67 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17161659	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR- APL-2019-105024			Female	NLD
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	1 Gram,Single Dose		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17162893	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2019-105902		35 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Dyspnoea	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17163774	EXPEDITED (15-DAY)		OT	NVSC2019IT066579		60 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Haematochezia; Vomiting	Azithromycin			S	Oral	1 Df, Qd		Novartis	
	Anastrozole			C	Unknown	Unk		Not Reported	
	Losartan Potasico Hydroclorotiazida			C	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17164909	EXPEDITED (15-DAY)		HO	CZ-MYLANLABS- 2019M1123204		41 YR	Female	CZE
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Gastrointestinal Inflammation; Intestinal Haemorrhage	Azithromycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	17165643	EXPEDITED (15-DAY)		OT	AU-PFIZER INC-2019537951			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Measles; Pruritus; Rash; Urticaria	Zithromax			S		6 Tablets		Pfizer	
	Fluimucil			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	17165669	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019537421		10 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sinoatrial Block	Solu-Medrol			S	Intravenous drip	80 Mg, 2x/Day		Pfizer	
	Solu-Medrol			S	Intravenous drip	40 Mg, 2x/Day		Pfizer	
	Solu-Medrol			S	Intravenous drip	20 Mg, 2x/Day		Pfizer	
	Zithromax			S	Intravenous drip	450 Mg, 1x/Day		Pfizer	
	Zithromax			S	Intravenous drip	450 Mg, 1x/Day		Pfizer	
	Sodium Chloride			S	Intravenous drip	450 MI, 1x/Day		Not Reported	
	Sodium Chloride			S	Intravenous drip	100 MI, 2x/Day		Not Reported	
	Sodium Chloride			S	Intravenous drip	450 MI, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	17166337	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2019M1125078		83 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2019	17166910	NON-EXPEDITED			NVSC2019US011974			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Rash	Azithromycin 250mg Tablets			S	Unknown	Unk		Novartis	
	Vitamin B12			C	Unknown	Unk		Not Reported	
	Vitamin B6			C	Unknown	Unk		Not Reported	
	Vitamin D3			C	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Dec-2019	17166911	NON-EXPEDITED			NVSC2019US007652			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burning Sensation; Rash	Azithromycin 250mg Tablets			S	Unknown	Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	15407632	EXPEDITED (15-DAY)		DE, OT	MY-PFIZER INC-2018379596		334 DAY	Male	MYS
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Death; Seizure	Zithromax			S	Intravenous (not otherwise specified)	45 Mg, Unk		Pfizer	
	Rocephin			S	Intravenous (not otherwise specified)	250 Mg, Unk		Not Reported	
	Paracetamol			C		Unk		Not Reported	
	Tamiflu			C		Unk		Not Reported	
	Hydrocortisone			C		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Dec-2019	16925253	EXPEDITED (15-DAY)			NVSC2019HU003400		9 YR	Male	HUN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Vomiting	Azithromycin			S	Oral			Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17167666	NON-EXPEDITED		OT	NVSC2019US070148		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Lamprene			S	Oral	100 Mg		Novartis	
	Azithromycin			S	Unknown	250 Mg, Bid		Not Reported	
	Sertraline			S	Unknown	100 Mg, Qd		Not Reported	
	Diphenoxylate/Atropine			S	Unknown	3 Df (2.5/0.25 Mg), Qd		Not Reported	
	Mirtazapine			S	Unknown	15 Mg, Qd		Not Reported	
	Omadacycline			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17167728	EXPEDITED (15-DAY)		OT	PT-AUROBINDO-AUR-APL-2019-105457		45 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Encephalomyelitis; Neuropathy Peripheral	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17169474	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1152493		50 YR	Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Toxic	Sumamed			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17169563	NON-EXPEDITED			US-MYLANLABS-2019M1120314		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vulvovaginal Mycotic Infection	Wixela™ Inhub			S		Twice A Day		Mylan	
	Prednisone			S		Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Albuterol W/Ipratropium	S	Unk	Mylan
	Azithromycin	S	Unk	Mylan
	Doxycycline	S	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17169801	NON-EXPEDITED			US-PFIZER INC-2019542126			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gait Disturbance; Inflammation; Movement Disorder; Pain	Azithromycin			S		250 Mg, Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17170355	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019540515		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coombs Negative Haemolytic Anaemia	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Tiorfan			S	Oral	3 G, 1x/Day		Not Reported	
	Rocephine			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported	
	Primperan			S	Intravenous (not otherwise specified)	30 Mg, 1x/Day		Not Reported	
	Riamet			S	Oral	3 Df, 1x/Day		Not Reported	
	Imovane			C	Oral	3.75 Mg, 1x/Day		Not Reported	
	Phosphoneuros			C	Oral	150 Gtt, 1x/Day		Not Reported	
	Doliprane			C	Oral	4 G, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17170905	EXPEDITED (15-DAY)		OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2019VAL000853			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cholestasis; Dyshidrotic Eczema; Hepatocellular Injury; Lymphocytosis	Cefotaxime Sodium	S	Other	1 G, Unk, Intraosseous Use	Validus
	Paracetamol	S	Oral	1 G, Q4h	Not Reported
	Azithromycin	S	Oral	Unk	Not Reported
	Inflectra /01445601/	C		100 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17171550	NON-EXPEDITED			US-PFIZER INC-2019545153			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Zithromax			S		Unk		Pfizer	
	Lisinopril			S		Unk		Not Reported	
	Vicodin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17171562	NON-EXPEDITED			US-PFIZER INC-2019542244			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Injury; Tinnitus	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Dec-2019	17172381	EXPEDITED (15-DAY)		HO	PT-PFIZER INC-2019541126		83 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Abdomen; Drug Ineffective; Incarcerated Hernia	Amoxicillin Trihydrate/Clavulanic Acid			S	Unknown	Unk		Pfizer	
	Azithromycin			S	Unknown	Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2019	17172872	NON-EXPEDITED			US-SA-2019SA352641		58 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eczema; Pruritus; Rash	Dupixent			S	Subcutaneous	300 Mg, Qow		Sanofi	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2019	17178616	EXPEDITED (15-DAY)		OT	IL-PFIZER INC-2019544852		83 YR	Male	ISR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination; Off Label Use; Product Administered To Patient Of Inappropriate Age	Azenil (Azithromycin)			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2019	17180192	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2019540585		37 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Dyshidrotic Eczema; Hepatocellular Injury; Lymphocytosis	Zithromax			S	Oral	Unk		Pfizer	
	Paracetamol			S	Oral	1 G, Every 4 Hrs		Not Reported	
	Cefotaxime Merck			S	Intramedullar (bone marrow)	1 G, (Bone Marrow)		Not Reported	
	Inflectra [Infliximab]			C	Intravenous drip	5 Mg/Kg, Every 2 Months		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2019	17266471	DIRECT	N				53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness	Azithromycin Tab 250mg*6-Pk			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	16873660	EXPEDITED (15-DAY)		DE, LT, OT	PL-MYLANLABS-2019M1091235		30 YR	Female	POL

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Neoplasm; Bronchopulmonary Aspergillosis; Device Related Infection; Disease Progression; Drug Ineffective; Graft Versus Host Disease In Gastrointestinal Tract; Graft Versus Host Disease In Lung; Product Use In Unapproved Indication; Stenotrophomonas Infection	Azithromycin			S		Unk		Not Reported
	Montelukast /01362602/			S	Oral	Unk		Mylan
	Montelukast /01362602/			S		Unk		Mylan
	Methylprednisolone			S	Unknown	2 Milligram/Kilogram		Mylan
	Voriconazole			C		Unk		Mylan
	Treosulfan			C		Unk		Mylan
	Busulfan			C		Unk		Mylan
	Cyclophosphamide			C		Unk		Mylan
	Mitoxantrone /00661302/			C		Unk		Mylan
	Fluconazole			C		Unk		Mylan
	Amphotericinum B			C		Unk		Mylan
	Cladribine			C		Unk		Mylan
	Posaconazole			C		Unk		Mylan
	Azacididine			C		Unk		Mylan
	Daunorubicin			C		Unk		Mylan
	Cytarabine			C		Unk		Mylan
	Tacrolimus			C		Unk		Mylan
	Fludarabine Phosphate			C		Unk		Mylan
	Fluticasone			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	16954396	EXPEDITED (15-DAY)		OT	CA-TEVA-2019-CA-1124577		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Biopsy Colon Abnormal; Blood Pressure Decreased; C- Reactive Protein Increased; Diarrhoea; Dysbiosis; Enteritis;	Azithromycin (Azithromycin Monohydrate)			S	Unknown			Not Reported
	Azithromycin (Azithromycin Monohydrate)			S				Not Reported
	Ciprofloxacin			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Frequent Bowel Movements;	Moxifloxacin	S	Unknown	Teva
Gastroenteritis	Cefixime	S	Unknown	Not Reported
Staphylococcal;	Pms-Azithromycin	S	Unknown	Not Reported
Gastrointestinal Mucosa	Pms-Azithromycin	S		Not Reported
Hyperaemia;				
Haematochezia; Heart Rate Increased; Nausea; Purulence; Staphylococcal Infection; Weight Decreased				

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17020981	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2019481719		57 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Infection Susceptibility Increased; Lower Respiratory Tract Infection	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17115890	NON-EXPEDITED			US-PFIZER INC-2019525153		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Pruritus	Zithromax			S	Oral	250 Mg, Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17179461	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-231506		37 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cholestasis; Dyshidrotic Eczema; Hepatocellular Injury; Lymphocytosis	Paracetamol		Y	S	Oral	1 Gram, 1dose/4hours		Ohm Lab
	Zithromax 250 Mg, Comprime Pellicule			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefotaxme Merck	S	Intramedullar (bone marrow)	1 Gram, Unk	Not Reported
Inflectra 100 Mg, Poudre Pour Solution A Diluer Pour Perfusion	C	Intravenous drip	5 Mg/Kg Tous Les 2 Mois ()	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17180692	EXPEDITED (15-DAY)		OT	US-ABBVIE-19K-163-3199073-00		2 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With Eosinophilia And Systemic Symptoms	Cefdinir			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17181825	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2019AP026102		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Complications Of Transplanted Lung; Enterovirus Infection; Graft Infection; Lung Transplant Rejection; Product Use In Unapproved Indication; Rhinovirus Infection; Transplant Rejection	Tacrolimus			S	Unknown	Unk		Not Reported
	Tacrolimus			S				Not Reported
	Tacrolimus			S				Not Reported
	Tacrolimus			S				Not Reported
	Prednisone			S	Unknown	15 Mg, Every One Day		Not Reported
	Prednisone			S	Unknown	10 Unk, Unk		Not Reported
	Prednisone			S	Unknown	5 Unk, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	60 Unk, Unk		Not Reported
	Mycophenolate Mofetil			S	Unknown	1 G, Unk		Apotex
	Mycophenolate Mofetil			S	Unknown	1 G, Bid		Apotex
	Mycophenolate Mofetil			S	Unknown	15 Mg, Qd		Apotex
	Mycophenolic Acid			S	Unknown	1 G, Bid		Apotex
	Azithromycin			S	Unknown	250 Mg, Unk		Apotex
	Sulfamethoxazole			S	Unknown	800 Mg, Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trimethoprim	S	Unknown	160 Mg, Unk	Not Reported
Valganciclovir	S	Unknown	900 Mg, Unk	Not Reported
Abacavir	S	Unknown	Unk	Not Reported
Tivicay	S	Unknown	Unk	Not Reported
Methylprednisolone	S	Unknown	500 Mg, Unk	Not Reported
Methylprednisolone	S	Unknown	125 Mg, Unk	Not Reported
Methylprednisolone	S			Not Reported
Basiliximab	S	Unknown	20 Mg, Unk	Not Reported
Basiliximab	S			Not Reported
Basiliximab	S			Not Reported
Abacavir	C	Unknown	Unk	Not Reported
Abacavir	C			Not Reported
Dolutegravir	C	Unknown	Unk	Not Reported
Dolutegravir	C			Not Reported
Lamivudine	C	Unknown	Unk	Not Reported
Lamivudine	C			Not Reported
Basiliximab	C	Unknown	20 Mg, Unk	Not Reported
Methylprednisolone	C	Unknown	500 Mg, Unk	Not Reported
Methylprednisolone	C	Unknown	125 Mg, Unk	Not Reported
Mycophenolate Mofetil	C	Unknown	1 G, Unk	Not Reported
Mycophenolate Mofetil	C	Unknown	1 G, Bid	Not Reported
Prednisone	C	Unknown	15 Mg, Qd	Not Reported
Prednisone	C	Unknown	10 Mg, Qd	Not Reported
Prednisone	C	Unknown	5 Mg, Qd	Not Reported
Azithromycin	C	Unknown	250 Mg, Qd	Not Reported
Azithromycin	C			Not Reported
Azithromycin	C			Not Reported
Valganciclovir	C	Unknown	900 Mg, Qd	Not Reported
Valganciclovir	C			Not Reported
Valganciclovir	C			Not Reported
Trimethoprim Sulfamethoxazole	C	Unknown	Unk, Qd	Not Reported
Trimethoprim Sulfamethoxazole	C	Unknown	800 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trimethoprim Sulfamethoxazole			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17183653	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019546382		1 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Cough; Erythema; Flushing; Off Label Use; Product Use Issue; Respiratory Disorder; Stridor	Azithromycin			S	Intravenous drip	0.1 G, 1x/Day		Pfizer	
	Glucose Injection			C	Intravenous drip	200 MI, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17183697	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2019545259		72 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dyspnoea; Fatigue; Malaise	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	
	Clopidogrel Cinfa			C		Unk		Not Reported	
	Pantoprazole			C		Unk		Not Reported	
	Carvedilol Cinfa			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17183938	EXPEDITED (15-DAY)		OT	UA-TEVA-2019-UA-1151914			Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Sumamed			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17184148	NON-EXPEDITED			US-RECKITT BENCKISER HEALTHCARE INT LIMITED-RB-807		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dysuria; Erythema; Penile Erythema; Penile Swelling; Peripheral Swelling; Pruritus; Rash Macular; Skin Exfoliation	Delsym Suspension Adult Grape	S	Unknown	10 Milliliter, Bid	Not Reported
	Azithromycin	S	Unknown	2 Tablet (Before Going To The Bed)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17184296	EXPEDITED (15-DAY)		HO	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001- 19-061		59 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Neurological Symptom	Phenylephrine			S	Unknown			Westward	
	Azithromycin			S	Unknown			Not Reported	
	Panadol			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17184746	EXPEDITED (15-DAY)		DE, HO, OT	NVSC2019CA074740		74 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Xolair			S	Subcutaneous	Unk		Not Reported	
Asthma; Blood Pressure Increased; Decreased	Xolair			S	Subcutaneous	150 Mg		Not Reported	
Appetite; Dyspnoea;	Xolair			S	Subcutaneous	150 Mg		Not Reported	
Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased;	Azithromycin			S	Oral	1 Df, Qd		Novartis	
Heart Rate Increased; Inappropriate Schedule Of Product Administration; Influenza; Malaise; Obstructive Airways Disorder; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Dec-2019	17186035	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019546188		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Frequent Bowel Movements; Nausea; Pneumonia; Vomiting	Azithromycin			S		Unk		Pfizer	
	Remicade			S	Intravenous (not otherwise specified)	500 Mg, 1 Every 8 Week(S)		Not Reported	
	Remicade			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	5 Mg/Kg, 1 Every 8 Week(S)		Not Reported	
	Remicade			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2019	16739045	EXPEDITED (15-DAY)		OT	IT-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-080524		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaesthesia; Dysentery; Nausea	Warfarin Sodium			S	Oral	5 Milligram, 1 As Necessary		Bristol Myers Squibb	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Paracetamol			C	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2019	17039780	NON-EXPEDITED			NVSC2019US036704			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema; Eye Irritation; Feeling Hot; Malaise; Product Physical Issue	Azithromycin			S	Unknown	1 Df, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Dec-2019	17187879	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2019-106275		82 YR	Male	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoacusis	Azithromycin Film-Coated Tablets			S	Unknown	1500 Milligram, Every Week		Aurobindo
	Ventolin			C	Respiratory (inhalation)	1 Dosage Form,As Necessary		Not Reported
	Metformin			C	Unknown	2 Dosage Form, Once A Day		Not Reported
	Braltus			C	Respiratory (inhalation)	1 Dosage Form, Once A Day,Using The Zonda Inhale...		Not Reported
	Clarithromycin			C	Unknown	1 Dosage Form, Two Times A Day		Not Reported
	Doxycycline			C	Unknown	Two Now Then One Daily (Alternative 1st Line)		Not Reported
	Prednisolone			C	Unknown	6 Dosage Form, Once A Day,Immediately Then Six Tablets E...		Not Reported
	Symbicort			C	Respiratory (inhalation)	2 Dosage Form, Once A Day,To Control Chest Sy...		Not Reported
	Cetraben			C	Unknown	Use Regularly On Dry Skin		Not Reported
	Atorvastatin			C	Unknown	1 Dosage Form, Once A Day		Not Reported
	Codeine Phosphate			C	Unknown	Take One Or Two Every 4 Hours		Not Reported
	Carbocisteine			C	Unknown	6 Dosage Form, Once A Day		Not Reported
	Thiamine			C	Unknown	2 Dosage Form, Once A Day,(If Still Drinking)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	16804570	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-060015		24 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Anaesthesia; Dysentery; Nausea	Azithromycin		S	Oral		500 Milligram, Once A Day			Aurobindo	
	Coumadin		S	Oral		5 Milligram, 1 As Necessary			Not Reported	
	Paracetamol		C	Oral		1 Gram			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17045855	EXPEDITED (15-DAY)		OT		FR-AUROBINDO-AUR- APL-2019-072196		10 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Alopecia; Off Label Use; Product Administered To Patient Of Inappropriate Age; Product Use In Unapproved Indication	Azithromycin				S	Unknown	Unk			Aurobindo
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17189979	EXPEDITED (15-DAY)		OT		GB-LUPIN PHARMACEUTICALS INC.-2019-08472		57 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; Lower Respiratory Tract Infection; Overdose	Azithromycin				S	Unknown	Unk			Lupin
	Cetirizine				S	Unknown	40 Milligram			Novel Labs
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>		<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17190598	EXPEDITED (15-DAY)		OT		CA-DRREDDYS- USA/CAN/19/0117447		15 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Atorvastatin				S	Oral				Not Reported
	Azithromycin				S	Oral				Not Reported
	Lansoprazole				S	Oral				Not Reported
	Mycophenolate Mofetil				S	Oral				Not Reported
	Pantoprazole				S	Oral				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Prednisone	S	Oral	Not Reported
	Sulfamethoxazole And Trimethoprim	S	Oral	Not Reported
	Tacrolimus	S	Oral	Not Reported
	Tacrolimus	S		Not Reported
	Voriconazole	S	Oral	Not Reported
	Voriconazole	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17191269	EXPEDITED (15-DAY)		OT	NVSC2019CA076415		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Stress	Azithromycin			S	Oral	250 Mg, 1 Every Three Weeks		Novartis
	Xolair			S	Subcutaneous	300 Mg, Unknown		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Prednisone			C	Unknown			Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17191272	EXPEDITED (15-DAY)		OT	NVSC2019CA074653		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Off Label Use; Stress	Xolair			S	Subcutaneous	300 Mg, Qw2		Not Reported
	Azithromycin			S	Oral	250 Mg, Qw3		Novartis
	Prednisone			C	Unknown			Not Reported
	Salbutamol			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17191301	EXPEDITED (15-DAY)		OT	NVSC2019CA075360		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthropathy;	Azithromycin			S	Unknown	250 Mg		Novartis
Blister; Burning Sensation;	Azithromycin			S				Novartis
Chest Pain; Cough;	Azithromycin			S				Novartis
Cystitis; Dizziness; Drug	Azithromycin			S				Novartis
Ineffective; Fall; Feeling	Azithromycin			S				Novartis
Abnormal; Gait	Xolair			S	Subcutaneous	225 Mg, Q2w		Not Reported
Disturbance; Headache;	Xolair			S	Subcutaneous	300 Mg, Q2w		Not Reported
Heart Rate Increased;	Xolair			S	Unknown	150 Mg, Q2w		Not Reported
Hypertension; Incorrect	Xolair			S	Subcutaneous	200 Mg, Q2w		Not Reported
Dose Administered;	Xolair			S	Subcutaneous	300 Mg		Not Reported
Influenza Like Illness;	Xolair			S	Subcutaneous	Unk		Not Reported
Injection Site Rash;	Cetirizine			C	Unknown	Unk		Not Reported
Insomnia; Lip Swelling;	Demulen			C	Unknown	Unk		Not Reported
Mobility Decreased;	Fucidin			C	Unknown	Unk		Not Reported
Muscular Weakness;	Hydroxyzine			C	Unknown	Unk		Not Reported
Nasopharyngitis; Pain;	Metronidazole			C	Unknown	Unk		Not Reported
Pain In Extremity; Painful	Nystatin			C	Unknown	Unk		Not Reported
Respiration; Peripheral	Pantoprazole			C	Unknown	Unk		Not Reported
Swelling; Product Storage	Pepcid			C	Unknown	Unk		Not Reported
Error; Pruritus; Rash;	Prednisone			C	Unknown	Unk		Not Reported
Respiratory Tract	Reactine			C	Unknown	Unk		Not Reported
Congestion; Sensation Of	Sertraline			C	Unknown	Unk		Not Reported
Foreign Body; Stress;	Singulair			C	Unknown	Unk		Not Reported
Swelling; Tooth Fracture;	Ventolin			C	Unknown	Unk		Not Reported
Urticaria								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17192321	EXPEDITED (15-DAY)		OT	NVSC2019TR075664			Male	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Betamethasone			S	Transplacental	Maternal Dose-12 Mg		Novartis	
	Potassium Chloride			S	Transplacental			Not Reported	
	Azithromycin			S	Transplacental	Maternal Dose-500 Mg, Qd		Not Reported	
	Ampicillin			S	Transplacental	Maternal Dose- 2 Mg		Not Reported	
	Sulbactam			S	Transplacental	Maternal Dose-375 Mg		Not Reported	
	Indomethacin			S	Transplacental	Maternal Dose-100 Mg		Not Reported	
	Indomethacin			S	Unknown	25 Mg		Not Reported	
	Magnesium			S	Transplacental	Maternal Dose-4 Mg		Not Reported	
	Magnesium			S	Transplacental	Maternal Dose-2 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17192599	EXPEDITED (15-DAY)		HO, OT	GB-PFIZER INC-2019550191		66 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Alanine Aminotransferase Increased; Drug-Induced Liver Injury; Off Label Use; Product Use Issue; Serum Ferritin Increased	Azithromycin			S		Unk Unk, Weekly		Pfizer	
	Omeprazole			C		Unk		Not Reported	
	Flixotide			C		Unk		Not Reported	
	Losartan			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Dec-2019	17193966	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-120867			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular	Amoxicillin			S	Unknown			Bristol Myers Squibb	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Degeneration	Kenalog	S	Unknown	Bristol Myers Squibb
	Acetaminophene	S	Unknown	Not Reported
	Alprazolam	S	Unknown	Not Reported
	Apo Hydro	S	Unknown	Not Reported
	Atorvastatin	S	Unknown	Not Reported
	Avamys	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Betamethasone Dipropionate	S	Unknown	Not Reported
	Betamethasone Valerate	S	Unknown	Not Reported
	Biaxin XI	S	Unknown	Not Reported
	Bisacodyl	S	Unknown	Not Reported
	Calcium Carbonate And Vitamin D	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Clarithromycin	S	Unknown	Not Reported
	Clotrimazole	S	Unknown	Not Reported
	Desonide	S	Unknown	Not Reported
	Diphenhydramine	S	Unknown	Not Reported
	Entocort	S	Unknown	Not Reported
	Ertapenem Sodium	S	Unknown	Not Reported
	Flovent	S	Unknown	Not Reported
	Glycerine	S	Unknown	Not Reported
	Neomycin/Polymyxin/Gramicidin	S	Unknown	Not Reported
	Habitrol [Nicotine Polacrilex]	S	Unknown	Not Reported
	Humira	S	Subcutaneous	Not Reported
	Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;So	S	Unknown	Not Reported
	Metronidazole	S	Unknown	Not Reported
	Ms Ir	S	Unknown	Not Reported
	Mupirocin	S	Topical	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mupirocin	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Nicotine Polacrilex	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sinus Rinse	S	Unknown	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Vitamin D3	S	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	15761325	EXPEDITED (15-DAY)		HO, OT	PHHY2018CA191163		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Cough;	Xolair			S	Subcutaneous	225 Mg, Unk		Not Reported
Dizziness; Drug Ineffective; Dyspnoea;	Amlodipine Besylate			S	Oral	10.0 Mg, Qd		Novartis
Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased;	Amlodipine Besylate			S	Oral	1.0 Df, Qd		Novartis
Headache; Lung Disorder; Malaise; Nasopharyngitis;	Azithromycin			S	Oral	3.0 Df, Unk		Not Reported
Oxygen Saturation Decreased; Sputum Discoloured	Azithromycin			S	Oral	250.0 Mg, Unk		Not Reported
	Advair			C	Unknown	1.0 Df, Unk (2 Every 1 Day (S))		Not Reported
	Asa			C	Oral	1.0 Df, Qd		Not Reported
	Brilinta			C	Oral	1.0 Df, Qd		Not Reported
	Hydrochlorothiazide			C	Oral	1.0 Df, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Mylan Pantoprazole	C	Oral	1.0 Df, Qd	Not Reported
	Singulair	C	Oral	1.0 Df, Qd	Not Reported
	Spiriva	C	Other	1.0 Df, Qd	Not Reported
	Ventolin	C	Other	2.0 Df, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	16959312	EXPEDITED (15-DAY)		HO, OT	GR-ADVANZ PHARMA-201910001245			Unknown	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Pneumocystis Jirovecii Pneumonia	Prednisolone			S		5 Mg, Qd (5 Mg/Day Per Os)		Concordia
	Tofacitinib			S		5 Mg, Bid (5 Mg Per Os Twice A Day)		Not Reported
	Methotrexate			S		(15 Mg Per Os Once A Week)		Not Reported
	Moxifloxacin			S		Unk		Not Reported
	Azithromycin			S		Unk		Not Reported
	Oseltamivir			S		Unk		Not Reported
	Levofloxacin			S		Unk		Not Reported
	Cefixime			S		Unk		Not Reported
	Meropenem			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	17088194	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2019512453		59 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Increased; Fatigue; Headache; Hemiparesis; Neurological Symptom; Paraesthesia; Vision Blurred	Azithromycin			S	Oral	500 Mg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Panadol			S	Oral	2 Df Of [Paracetamol 500 Mg]/[Phenylephrine Hydrochloride5 Mg] Every 4-6 Hours As Needed		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Panadol		S		100 Mg, Daily		Not Reported	
Losartan		C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	17195423	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1156778		52 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Hypotension	Metformine Arrow 1000 Mg, Comprime Pellicule Secable			S	Oral	3 Dosage Forms		Actavis
	Aciclovir			S	Intravenous (not otherwise specified)	10 Mg/Kg		Not Reported
	Malocide 50 Mg, Comprime			S		50 Mg		Not Reported
	Zithromax 250 Mg, Comprime Pellicule			S	Oral	1 Dosage Forms		Not Reported
	Sertide			C				Not Reported
	Pantoprazole			C				Not Reported
	Novorapid			C				Not Reported
	Atorvastatine			C				Not Reported
	Moxonidine			C				Not Reported
	Lantus			C				Not Reported
	Nebivolol			C				Not Reported
	Galvus 50 Mg, Comprimé			C				Not Reported
	Furosemide			C				Not Reported
	Tarka			C				Not Reported
	Montelukast Acide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	17196042	EXPEDITED (15-DAY)		OT	CA-009507513-1912CAN008936		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchiectasis; Bronchomalacia; Cataract; Dyspnoea; Dyspnoea Exertional; Eosinophil Count Increased; Gastrooesophageal Reflux Disease; Hypertension;	Ezetrol			S	Unknown	Unk		Merck
	Zenhale			S	Unknown	Dosage Form: Aerosol, Dose		Merck
	Prednisone			S	Unknown	Dosage Form: Not Specified		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Osteoporosis; Productive Cough; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Tooth Disorder; Wheezing	Aspirin	S	Unknown	Dosage Form: Not Specified	Not Reported
	Azithromycin	S	Unknown	Dosage Form: Not Specified	Not Reported
	Advair	S	Unknown	Dosage Form: Not Specified	Not Reported
	Alvesco	S	Unknown	Unk	Not Reported
	Esomeprazole Magnesium	S	Unknown	Unk	Not Reported
	Fluticasone Propionate (+) Salmeterol Xinafoate	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Pantoprazole Sodium	S	Unknown	Unk	Not Reported
	Quinapril Hydrochloride	S	Unknown	Unk	Not Reported
	Rhinocort (Beclomethasone Dipropionate)	S	Unknown	Unk	Not Reported
	Risedronate Sodium	S	Unknown	Dosage Form: Not Specified	Not Reported
	Ventolin (Albuterol Sulfate)	S	Unknown	Dosage Form: Not Specified	Not Reported
	Zantac	S	Unknown	Dosage Form: Not Specified	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	17197303	EXPEDITED (15-DAY)		HO, OT	NVSC2019CA076155		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Gait Disturbance; Headache; Influenza Like Illness; Malaise; Musculoskeletal Pain; Nasopharyngitis; Neck Pain; Pneumonia; Pyrexia; Seasonal Allergy	Xolair			S	Subcutaneous	300 Mg, Biw		Not Reported
	Azithromycin			S	Oral	250 Mg		Novartis
	Advair			C	Unknown			Not Reported
	Ipratropium			C	Unknown			Not Reported
	Clarithromycin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spiriva	C	Unknown	Not Reported
Symbicort	C	Unknown	Not Reported
Synthroid	C	Unknown	Not Reported
Ventolin	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Dec-2019	17197434	EXPEDITED (15-DAY)		OT	NVSC2019BR077592			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anxiety; Blood Pressure Fluctuation; Confusional State; Constipation; Cystitis; Dizziness; Dysphagia; Dyspnoea; Ear Pain; Extrapyrimal Disorder; Fatigue; Head Discomfort; Hypertension; Infection; Malaise; Musculoskeletal Chest Pain; Musculoskeletal Discomfort; Musculoskeletal Pain; Myalgia; Nervousness; Poisoning; Procedural Pain; Reflux Gastritis; Sinusitis; Spinal Pain; Thirst; Tinnitus; Wheezing	Azithromycin			S	Unknown	Unk		Novartis
	Clenil			S	Unknown	Unk (Strength: 200)		Not Reported
	Clenil			S	Unknown	Unk (Strength: 50)		Not Reported
	Beclometasone Dipropionate			S	Unknown	Unk		Not Reported
	Plasil			S	Unknown	Unk		Not Reported
	Rilan [Cromoglicate Sodium]			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2019	17198301	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2019-067505		66 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Abdominal Pain; Adverse Drug Reaction; Adverse Food Reaction; Anxiety;	Azithromycin			S	Oral	3 Dosage Form, Once A Day		Aurobindo
	Duodopa			S	Other	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Device Dislocation; Discomfort; Dyskinesia; Dyspnoea; Emotional Distress; Fatigue; Feeling Abnormal; Gingival Pain; Muscle Spasms; Nausea; Nervousness; Rash; Swollen Tongue; Therapeutic Response Shortened	Amoxicillin	S	Oral	3 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2019	17198926	EXPEDITED (15-DAY)		OT	NVSC2019CA075896		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Accidental Exposure To Product; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Respiratory Tract Infection; Speech Disorder; Stomatitis; Urticaria	Xolair			S	Unknown	300 Mg		Not Reported
	Azithromycin			S	Unknown	250 Mg		Novartis
	Benadryl			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Reactine			C	Unknown			Not Reported
	Singulair			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Dec-2019	17198980	EXPEDITED (15-DAY)		OT	NVSC2019CA075364		25 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Azithromycin			S	Unknown	Unk		Novartis
	Levofloxacin			S	Unknown			Not Reported
	Xolair			S	Subcutaneous	300 Mg, Q2w (1 Every 2 Weeks)		Not Reported
	Xolair			S	Subcutaneous	150 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Reactine (Cetirizine Hydrochloride)	S	Unknown	10 Mg	Not Reported
	Reactine (Cetirizine Hydrochloride)	S	Unknown	20 Mg, Bid	Not Reported
	Rifampin	S	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	16993667	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019AMR197299			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Eosinophil Count Increased; Hospitalisation; Therapeutic Product Effect Incomplete	Mepolizumab			S		100 Mg, Z(Monthly)		Glaxosmithkline	
	Ventolin			S		Unk, (Prn Or 4x Daily)		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Alvesco			S		2 Puff(S), Qd		Not Reported	
	Inspiolto			S		2 Puff(S), Qd		Not Reported	
	Prednisone			S		10 Mg, Qd(Tapering For 2 Months)		Not Reported	
	Metoprolol			S		25 Mg, Bid		Not Reported	
	Propranolol			S		Unk		Not Reported	
	Fluoride			S		1 Df(Pill), Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17140598	EXPEDITED (15-DAY)		OT	NVSC2019UA060488		60 YR	Female	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enuresis; Headache; Pyelonephritis; Renal Pain; Tremor	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Lisinopril			C	Oral	5 Mg, Qd In The Evening (From Long Time)		Not Reported	
	Nolpaza			C	Oral	40 Mg, Periodically		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17200194	EXPEDITED (15-DAY)		OT	CA-DRREDDYS- USA/CAN/19/0117732			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atorvastatin			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Not Reported
	Amoxicillin Trihydrate			S	Unknown			Not Reported
	Acetaminophen			S	Unknown			Not Reported
	Apo Hydro			S	Unknown			Not Reported
	Avamys			S	Unknown	Spray, Metered Dose		Not Reported
	Azithromycin Dihydrate			S	Unknown			Not Reported
	Bactroban			S	Unknown			Not Reported
	Betaderm			S	Unknown			Not Reported
	Betamethasone Dipropionate			S	Unknown			Not Reported
	Biaxin XI			S	Unknown			Not Reported
	Bisacodyl			S	Unknown			Not Reported
	Cetirizine			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Clotrimazole			S	Unknown			Not Reported
	Desonide			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Diphenhydramine			S	Unknown			Not Reported
	Entocort			S	Unknown			Not Reported
	Ertapenem Sodium			S	Unknown			Not Reported
	Flovent			S	Unknown			Not Reported
	Glycerine			S	Oral	Liquid Oral		Not Reported
	Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate			S	Unknown			Not Reported
	Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Habitrol	S	Unknown		Not Reported
Humira	S	Subcutaneous	Solution Subcutaneous	Not Reported
Kenalog	S	Unknown	Suspension Intra- Articular	Not Reported
Lomotil	S	Oral		Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride/So Metronidazole	S	Unknown		Not Reported
Ms Ir	S	Unknown		Not Reported
Mupirocin	S	Topical	Ointment Topical	Not Reported
Nadolol	S	Unknown		Not Reported
Nicoderm	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pentasa	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pulmicort	S	Unknown		Not Reported
Refresh Tears	S	Unknown	Drops Ophthalmic	Not Reported
Salinex [Sodium Chloride]	S	Unknown	Solution Nasal	Not Reported
Statex (Morphine Sulfate)	S	Unknown		Not Reported
Sulfamethoxazole/Tri Methoprim	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Vitamin D3	S	Unknown		Not Reported
Calcium Carbonate/Vitamin D3	S			Not Reported
Valsartan	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17200582	EXPEDITED (15-DAY)		HO, OT	US-ALKEM LABORATORIES LIMITED-US-ALKEM- 2019-06492		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cryptococcosis; Drug Ineffective; Leukopenia; Pericarditis Fungal	Mycophenolate Mofetil	S	Unknown	250 Milligram, Bid	Alkem
	Mycophenolate Mofetil	S	Unknown	500 Unk	Alkem
	Tacrolimus	S	Unknown	3 Milligram, Bid	Not Reported
	Tacrolimus	S	Unknown	3 Milligram	Not Reported
	Fluconazole	S	Oral	Unk	Not Reported
	Fluconazole	S	Oral	400 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	10 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	15 Milligram, Qd	Not Reported
	Prednisone	S	Unknown	30 Milligram, Qd	Not Reported
	Trimethoprim-Sulfamethoxazole	S	Unknown	Double-Strength 3 Times Weekly	Not Reported
	Valganciclovir	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	250 Milligram, 3 Times Weekly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17201613	NON-EXPEDITED			CN-LUPIN PHARMACEUTICALS INC.-2019-07962		63 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Allergic; Gastrointestinal Disorder	Rifabutin			S	Unknown	Unk		Lupin	
	Rifabutin			S	Unknown	Unk		Lupin	
	Ethambutol			S	Unknown	Unk		Lupin	
	Ethambutol			S	Unknown	Unk		Lupin	
	Moxifloxacin			S	Unknown	Unk		Lupin	
	Moxifloxacin			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17201714	EXPEDITED (15-DAY)		DE, OT	TH-PFIZER INC- 2019551145		25 YR	Male	THA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Hemiparesis	Azithromycin			S		Unk		Pfizer	
	Ethambutol			S		Unk		Not Reported	
	Levofloxacin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17201805	NON-EXPEDITED			US-PFIZER INC- 2019550489			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17201862	NON-EXPEDITED			US-PFIZER INC- 2019551729			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Bactrim			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17202674	EXPEDITED (15-DAY)		OT	NVSC2019CA077472		34 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chapped Lips; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder;	Azithromycin			S	Unknown	250 Mg, Unknown		Novartis	
	Xolair			S	Subcutaneous	300 Mg, Unknown		Not Reported	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Benadryl			C	Unknown	Unk		Not Reported	
	Cetirizine Hydrochloride			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Stomatitis; Urticaria	Prednisone	C	Unknown	Unk	Not Reported
	Singulair	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17202838	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019550697			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate Sodium Sulfasalazine Azithromycin Xeljanz Azathioprine Humira Metoprolol Naproxen Plaquenil [Hydroxychloroquine Sulfate]			S S S S S S S S S		5 Mg, 2x/Day Subcutaneous		Pfizer Pfizer Pfizer Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17203526	EXPEDITED (15-DAY)		HO	US-CATALYST PHARMACEUTICALS, INC-2019CAT00601		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dyspnoea; Influenza; Nasopharyngitis; Secretion Discharge	Firdapse Firdapse Z-Pak Unspecified Piills Mestinon Methotrexate Unspecified Thyroid Medications Unspecified Diabetes Medications Unspecified Blood Pressure Medications			S S S S C C C C C	Oral	20 Mg, 3x/Day Unk		Catalyst Pharma Catalyst Pharma Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17203827	EXPEDITED (15-DAY)		DE, OT	NVSC2019TH079470		25 YR	Male	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Condition Aggravated; Hemiparesis; Pneumonia Aspiration	Azithromycin			S	Unknown	Unk		Novartis	
	Levofloxacin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Dec-2019	17204458	EXPEDITED (15-DAY)		DS	NVSC2019CA012574			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Therapy Non-Responder	Mycophenolate Mofetil			S	Oral	720 Mg, Bid		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Montelukast			S	Unknown	Unk		Not Reported	
	Fluticasone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	11681550	NON-EXPEDITED			US-PFIZER INC- 2015362254		86 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Hypoacusis	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	15736265	NON-EXPEDITED			US-PFIZER INC- 2018521343		46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Pruritus	Zithromax			S		Unk		Pfizer	
	Hydrocodone Bitartrate			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Benadryl	S	Unk	Not Reported
Tramadol	S	Unk	Not Reported
Norco	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	16945518	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1099035		34 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Maternal Exposure During Pregnancy; Pregnancy On Oral Contraceptive	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Klaira			S	Oral	1 Dosage Form, Qd		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17205601	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2019-107142		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Tract Infection	Prednisolone			S	Oral	Variable		Aurobindo	
	Esomeprazole			S	Oral	1 Dosage Form, Once A Day		Aurobindo	
	Novatrex			S	Oral	4 Dosage Form, Every Week		Not Reported	
	Aclasta			C	Intravenous drip	1 Dosage Form, 1 Year		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17206344	EXPEDITED (15-DAY)		HO, LT, OT	GB-AUROBINDO-AUR-APL-2019-107780		52 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Drug-Induced Liver Injury; Faeces Pale; Hepatitis Cholestatic; Jaundice	Azithromycin Film-Coated Tablets			S	Unknown	1500 Milligram, Every Week		Aurobindo	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17207996	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2019556244		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Blood Lactic Acid Increased; Blood Potassium Decreased; Breath Sounds Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Cough; Dyspnoea; Ear Pruritus; Eosinophilia; Eye Pruritus; Lacrimation Increased; Loss Of Personal Independence In Daily Activities; Nasal Congestion; Nasal Polyps; Platelet Count Increased; Pulmonary Function Test Abnormal; Rhinitis Allergic; Rhinorrhoea; Sneezing; Upper-Airway Cough Syndrome; Urticaria; Vasculitis; Wheezing	Ceftriaxone Sodium			S	Unknown	Unk		Pfizer
	Azithromycin			S	Unknown	Unk		Pfizer
	Nucala			S	Unknown	100 Mg, Unk		Not Reported
	Omalizumab			S	Unknown	150 Mg, Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Pulmicort			S	Unknown	Unk		Not Reported
	Rupatadine			S	Unknown	10 Mg, Unk		Not Reported
	Rupatadine Fumarate			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	10 Mg, Unk		Not Reported
	Symbicort Turbohaler			S	Unknown	2 Mg, Unk		Not Reported
	Tamiflu			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17208104	NON-EXPEDITED			US-UCBSA-2017011447		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zyrtec			S		Unknown Dose		Not Reported
	Certolizumab Pegol			S		Unknown Dose		Not Reported
	Acetaminophen			S		Unknown Dose		Not Reported
	Golimumab			S		Unknown Dose		Not Reported
	Levofloxacin			S		Unknown Dose		Not Reported

FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Diphenhydramine Hcl	S	Unknown Dose	Not Reported
Tramadol	S	Unknown Dose	Not Reported
Hydromorphone	S	Unknown Dose	Not Reported
Morphine	S	Unknown Dose	Not Reported
Salicylate Sodium	S	Unknown Dose	Not Reported
Diclofenac	S	Unknown Dose	Not Reported
Oxycodone	S	Unknown Dose	Not Reported
Hydrocodone	S	Unknown Dose	Not Reported
Naproxen	S	Unknown Dose	Not Reported
Clonidine	S	Unknown Dose	Not Reported
Amlodipine	S	Unknown Dose	Not Reported
Methylprednisolone	S	Unknown Dose	Not Reported
Budesonide	S	Unknown Dose	Not Reported
Nedocromil	S	Unknown Dose	Not Reported
Cromolyn	S		Not Reported
Montelukast	S	Unknown Dose	Not Reported
Abatacept	S	Unknown Dose	Not Reported
Adalimumab	S	Unknown Dose	Not Reported
Methotrexate	S	Unknown Dose	Not Reported
Dapsone	S	Unknown Dose	Not Reported
Amoxicillin And Clavulanate	S	Unknown Dose	Not Reported
Potassium			
Benzoic Acid	S	Unknown Dose	Not Reported
Azithromycin	S	Unknown Dose	Not Reported
Fluconazole	S	Unknown Dose	Not Reported
Clindamycin	S	Unknown Dose	Not Reported
Linezolid	S	Unknown Dose	Not Reported
Vancomycin	S	Unknown Dose	Not Reported
Ciprofloxacin	S	Unknown Dose	Not Reported
Cefdinir	S	Unknown Dose	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Macrodantin	S	Unknown Dose	Not Reported
Heparin	S	Unknown Dose	Not Reported
Pantoprazole	S	Unknown Dose	Not Reported
Milk Of Magnesia	S	Unknown Dose	Not Reported
Fexofenadine	S	Unknown Dose	Not Reported
Sodium Hypochlorite	S	Unknown Dose	Not Reported
Prednisone	S	17 Mg Daily	Not Reported
Hydroxychloroquine	S	Unk	Not Reported
Sulindac	S		Not Reported
Albuterol	S		Not Reported
Gabapentin	S	Unk	Not Reported
Ramipril	S	Unk	Not Reported
Misoprostol	S	Unk	Not Reported
Rosuvastatin	S	Unknown Dose	Not Reported
Ranitidine	S	Unknown Dose	Not Reported
Teriparatide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17208616	NON-EXPEDITED			US-PFIZER INC-2019554918		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash; Swelling	Clindamycin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17208828	EXPEDITED (15-DAY)		DE, HO	MY-MYLANLABS-2019M1130013		1 YR	Female	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Ceftriaxone			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Vancomycin	S	Intravenous (not otherwise specified)	Two Doses On Day 2 And Day 3	Not Reported
Normal Saline	S	Intravenous (not otherwise specified)	30 MI/Kg	Mylan
Normal Saline	S			Mylan
Vitamin K /00032401/	S	Intravenous (not otherwise specified)		Mylan
Vitamin K /00032401/	S			Mylan
Fresh Frozen Plasma	S	Intravenous (not otherwise specified)	15 MI/Kg	Mylan
Fresh Frozen Plasma	S			Mylan
Nitric Oxide	S	Respiratory (inhalation)	20 Ppm, Inhalation	Mylan
Noradrenaline /00127501/	S	Intravenous (not otherwise specified)		Mylan
Dopamine	S	Intravenous (not otherwise specified)		Mylan
Dobutamine	S	Intravenous (not otherwise specified)		Mylan
Immunoglobulin /00025201/	S	Intravenous (not otherwise specified)	Twice On Day 2 And Day 4	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17209141	EXPEDITED (15-DAY)		OT	JP-GLAXOSMITHKLINE-JP2019JPN157812		51 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Drug-Induced Liver Injury; Pyrexia; Renal Disorder	Samtirel			S	Oral	10 MI, Bid		Glaxosmithkline	
	Vfend			S	Oral	600 Mg, 1d		Not Reported	
	Vfend			S	Oral	200 Mg, Bid		Not Reported	
	Zithromac			S	Oral	600 Mg, Qd		Not Reported	
	Calonal Tablet			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Rabeprazole Na Tablets			C		Unk			Not Reported
	Ambisome Injection			C		Unk			Not Reported
	Fluconazole Capsule			C		Unk			Not Reported
	Sulfamethoxazole/Trimethoprim Tablets			C		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2019	17210565	NON-EXPEDITED			NVSC2019US079324		90 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk, Unknown			Novartis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2019	17207244	NON-EXPEDITED		OT	NVSC2019US080310		2 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatosplenomegaly; Lymphadenopathy; Pyrexia	Azithromycin			S	Unknown	Unk			Novartis
	Cefdinir			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2019	17214353	DIRECT		DS			87 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Peripheral Swelling	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Dec-2019	17214623	DIRECT	Y	HO, LT			64 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardiac Arrest	Azithromycin	S	Oral	Unknown
	Hydrocodone Acetamin 10-325mg 1/2-0-1/2	C		Not Reported
	Zolpidem 10mg 0-0-1	C		Not Reported
	Co Q10 200mg 1-0-1	C		Not Reported
	Magnesium Ca. 350 Mg/D	C		Not Reported
	Taurin 1-1-1	C		Not Reported
	Lovaza 1g 1-0-1	C		Not Reported
	Vit. B Complex	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	12949107	NON-EXPEDITED			US-PFIZER INC-2016531943			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Urticaria	Zithromax			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	15284316	EXPEDITED (15-DAY)		OT	US-SUNOVION-2018SUN003172		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact; Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Glycopyrrolate			S	Unknown	1 Df, Qd		Sunovion	
	Omalizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Ipratropium/Albuterol			S	Unknown			Not Reported	
	Theophylline			S	Oral	450 Mg, Qd		Not Reported	
	Atrovent			S	Unknown			Not Reported	
	Breo Ellipta			S	Unknown	1 Df, Qd		Not Reported	
	Prednisone			S	Oral	45 Mg, Unk		Not Reported	
	Singulair			S	Oral	10 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	16922521	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2019-066859			Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Neutropenia; Pyrexia	Azithromycin			S	Unknown	500 Milligram, Once A Day		Aurobindo
	Idelalisib			S	Oral	300 Milligram, Once A Day		Not Reported
	Idelalisib			S	Oral	300 Milligram, Once A Day		Not Reported
	Idelalisib			S	Oral	300 Milligram, Once A Day		Not Reported
	Idelalisib			S	Oral	200 Milligram, Once A Day		Not Reported
	Idelalisib			S	Oral	200 Milligram, Once A Day		Not Reported
	Idelalisib			S	Oral	200 Milligram, Once A Day		Not Reported
	Idelalisib			S	Oral	200 Milligram, Once A Day		Not Reported
	Filgrastim			C	Unknown	Unk		Not Reported
	Arixtra			C	Subcutaneous	Unk		Not Reported
	Zeffix			C	Oral	Unk		Not Reported
	Bactrim Forte			C	Oral	Unk		Not Reported
	Zelitrex			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17213121	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2019-6119			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dizziness; Drug Ineffective; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Nausea; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous	Not Reported
Metoprolol	S	Unknown	Not Reported
Naproxen	S	Unknown	Not Reported
Plaquenil	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17213592	EXPEDITED (15-DAY)	HO		CA-MYLANLABS-2019M1126867		72 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Chest Discomfort; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Gastroesophageal Reflux Disease; Lung Disorder; Lung Hyperinflation; Lung Opacity; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pain In Extremity; Rhinorrhoea; Sputum Discoloured; Therapeutic Product Effect Incomplete; Total Lung Capacity Abnormal; Weight Increased; Wheezing	Synthroid			S		Unk		Mylan
	Amlodipine			S		Unk		Mylan
	Atrovent			S		Unk		Mylan
	Breo Ellipta			S		Unk		Mylan
	Cipralex /01588501/			S		Unk		Mylan
	Escitalopram Oxalate			S		Unk		Mylan
	Piperacillin Sodium And Tazobactam Sodium			S		Unk		Mylan
	Prednisone			S		Unk		Mylan
	Salbutamol Sulfate			S		Unk		Mylan
	Singular			S		Unk		Mylan
	Solu-Medrol			S		Unk		Mylan
	Spiriva			S		Unk		Mylan
	Theophylline			S		Unk		Mylan
	Uniphyl			S		Unk		Mylan
	Zantac			S		Unk		Mylan
	Zithromax			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17214051	NON-EXPEDITED			US-PFIZER INC-2019557489		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity; Dyspnoea; Pruritus	Azithromycin	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17214693	EXPEDITED (15-DAY)		OT	CA-ROCHE-2507614		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Stress	Xolair			S	Subcutaneous	300 Mg, Unknown		Not Reported
	Xolair			S	Subcutaneous	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg, 1 Every Three Weeks		Not Reported
	Prednisone			C	Unknown			Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17214943	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2019M1128576		81 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Loss Of Consciousness; Torsade De Pointes	Sotalol			S	Oral	80 Milligram, Qd		Not Reported
	Zitromax			S		500 Milligram, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17215640	NON-EXPEDITED			US-PFIZER INC-2019559802			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2019	17216508	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2019-107940		48 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Diarrhoea; Jaundice; Liver Disorder	Azithromycin			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Augmentin			S	Oral	2 Gram, Once A Day		Not Reported
	Fidato			S	Intramuscular	1 Dosage Form, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	12892508	NON-EXPEDITED			US-PFIZER INC- 2016497774		66 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Darvocet A500			S		Unk		Not Reported
	Tamiflu			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	13022205	NON-EXPEDITED			US-PFIZER INC- 2016565989		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Hydrocortisone Acetate			S		Unk		Pfizer
	Sumatriptan Succinate			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Caumadin			S		Unk		Not Reported
	Cymbalta			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	14553141	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-APOTEX- 2018AP006524		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Alveolitis; Atrial Fibrillation; Hypoxia	Amiodarone	S	Unknown	Unk	Apotex
	Amiodarone	S	Unknown	Unk	Apotex
	Diltiazem	S	Oral	180 Mg, Unk	Apotex
	Diltiazem	S	Oral	180 Mg, Unk	Apotex
	Furosemide	S	Oral	40 Mg, Qd	Not Reported
	Furosemide	S	Oral	40 Mg, Qd	Not Reported
	Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk, Once Every 14 Days	Not Reported
	Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk	Not Reported
	Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Q.H.	Apotex
	Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Unk	Apotex
	Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd	Apotex
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 G, Qd	Apotex
	Ceftriaxone	S	Intravenous (not otherwise specified)	1 G, Qd	Apotex
	Digoxin	S	Intravenous (not otherwise specified)	10 Mg, Q.H.	Not Reported
	Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg, Q.4h.	Not Reported
	Digoxin	S	Intravenous (not otherwise specified)	10 Mg, Unk	Not Reported
	Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg, Six Every One Day	Not Reported
	Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Q.4h.	Not Reported
	Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Six Every One Day	Not Reported
	Dimenhydrinate	S	Intravenous (not	1 Df, Q.6h	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg, Once Every 14 Days,Unk	Not Reported
Doxorubicin Hydrochloride	S	Intravenous (not otherwise specified)	106 Mg, Unk	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Q.O.Wk.	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Cyclical	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, Qd	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, Qd	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q.4h. (Six Every One Day)	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q.6h	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Unk	Not Reported
Hydromorphone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydromorphone	S	Intravenous (not otherwise specified)	Unk	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Unk	Not Reported
Adriamycin /00330901/	S	Intravenous (not otherwise specified)	106 Mg, Q.O.Wk.	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Q.6h	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Qid	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Mg, Q.6h (Four Every One Day)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Mg, Q.6h (4 Every One Day)	Not Reported
Morphine	S	Intravenous (not	Unk, One Every 10	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine Sulphate	S	otherwise specified)	Minutes	Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified)	Unk	Not Reported
Procytox	S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Unk, Once Every 14 Days	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Unk	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Qd	Not Reported
Trastuzumab	S	Unknown	Unk	Not Reported
Aprepitant	C	Oral	125 Mg, Unk	Not Reported
Dexamethasone	C	Oral	20 Mg, Qd	Not Reported
Filgrastim	C	Subcutaneous	300 Mg, Qd	Not Reported
Gabapentin	C	Oral	100 Mg, Tid	Not Reported
Metoclopramide	C	Oral	10 Mg, Qid	Not Reported
Metoclopramide	C	Oral	10 Mg, Unk	Not Reported
Ondansetron	C	Oral	8 Mg, Bid	Not Reported
Dexamethasone	C	Unknown	Unk	Not Reported
Emend /01627301/	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17075406	NON-EXPEDITED			US-PFIZER INC-2019505808		47 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer
	Levaquin			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17147682	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-MYLANLABS-2019M1122198			Male	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Brain Abscess; Iris Adhesions; Multiple Allergies; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Levetiracetam			S	Unknown	1000 Dosage Form, Qd (1000 Qd)		Not Reported	
	Levetiracetam			S				Not Reported	
	Nivolumab			S	Intravenous (not otherwise specified)	1 Milligram/Kilogram, Q3cycles		Mylan	
	Ipilimumab			S	Intravenous (not otherwise specified)	Unk Q3cycles		Mylan	
	Novalglin /06276704/			S	Unknown	Unk		Mylan	
	Azithromycin			S		Unk		Mylan	
	Ranitidine			C		300 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17151266	NON-EXPEDITED			US-PFIZER INC- 2019538864		77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17217027	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508849		25 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S	Subcutaneous	150 Mg		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported	
	Reactine [Cetirizine Hydrochloride]			S	Unknown			Not Reported	
	Rifampin			S	Unknown			Not Reported	
	Diphenhydramine Hydrochloride			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17217136	EXPEDITED (15-DAY)		DE	CA-ROCHE-2506039		74 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Xolair			S	Subcutaneous	Unk		Not Reported	
Asthma; Blood Pressure	Xolair			S	Subcutaneous	150 Mg		Not Reported	
Increased; Decreased	Xolair			S	Subcutaneous	150 Mg		Not Reported	
Appetite; Dyspnoea;	Azithromycin			S	Oral			Not Reported	
Forced Expiratory Volume									
Decreased; Forced Vital									
Capacity Decreased;									
Heart Rate Increased;									
Inappropriate Schedule Of									
Product Administration;									
Influenza; Malaise;									
Obstructive Airways									
Disorder; Off Label Use;									
Oxygen Saturation									
Decreased; Product Use									
In Unapproved Indication									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17217340	EXPEDITED (15-DAY)		HO	CA-ROCHE-2508596		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchospasm;	Xolair			S	Subcutaneous			Not Reported	
Candida Infection;	Xolair			S	Subcutaneous			Not Reported	
Cerebrovascular Accident;	Potassium Acetate			S	Unknown			Not Reported	
Dyspnoea; Heart Rate	Azithromycin			S	Unknown			Not Reported	
Increased; Hemiplegia;	Levaquin			C	Unknown			Not Reported	
Inappropriate Schedule Of	Prednisone			C	Unknown			Not Reported	
Product Administration;	Singulair			C	Unknown			Not Reported	
Oxygen Saturation	Spiriva			C	Unknown			Not Reported	
Decreased; Peritonsillar	Ventolin [Salbutamol]			C	Unknown			Not Reported	
Abscess; Pharyngeal									
Inflammation; Pilonidal									
Cyst; Postoperative									
Wound Complication;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Productive Cough; Pulmonary Pain; Respiratory Rate Increased; Rhonchi; Therapy Partial Responder; Wheezing	Zenhale	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17217703	EXPEDITED (15-DAY)		HO	CA-ROCHE-2508387		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Sputum Discoloured	Xolair			S	Subcutaneous			Not Reported
	Amlodipine Besylate			S	Oral			Not Reported
	Amlodipine Besylate			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported
	Azithromycin			S	Oral	250.0 Mg, Unk		Not Reported
	Advair			C	Unknown	1.0 Df, Unk (2 Every 1 Day (S))		Not Reported
	Asa			C	Oral	1.0 Df, Qd		Not Reported
	Brilinta			C	Oral	1.0 Df, Qd		Not Reported
	Hydrochlorothiazide			C	Oral	1.0 Df, Qd		Not Reported
	Mylan Pantoprazole			C	Oral	1.0 Df, Qd		Not Reported
Singulair			C	Oral	1.0 Df, Qd		Not Reported	
Spiriva			C	Other	1.0 Df, Qd		Not Reported	
Ventolin [Salbutamol]			C	Other	2.0 Df, Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17218025	EXPEDITED (15-DAY)		OT	CA-ROCHE-2507188		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Off Label Use; Stress	Xolair			S	Subcutaneous			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	C	Unknown	Not Reported
Salbutamol	C	Unknown	Not Reported
Spiriva	C	Unknown	Not Reported
Symbicort	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17218830	EXPEDITED (15-DAY)		OT	CA-ROCHE-2507092		41 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthropathy;	Xolair			S	Subcutaneous	225 Mg, Q2w		Not Reported
Blister; Burning Sensation;	Xolair			S	Subcutaneous	300 Mg, Q2w		Not Reported
Chest Pain; Cough;	Xolair			S	Subcutaneous	150 Mg, Q2w		Not Reported
Cystitis; Dizziness; Drug	Xolair			S	Subcutaneous	200 Mg, Q2w		Not Reported
Ineffective; Fall; Feeling	Xolair			S	Subcutaneous	300 Mg		Not Reported
Abnormal; Gait	Xolair			S	Subcutaneous	Unk		Not Reported
Disturbance; Headache;	Xolair			S	Subcutaneous	250 Mg		Not Reported
Heart Rate Increased;	Xolair			S	Subcutaneous			Not Reported
Hypertension; Incorrect	Azithromycin			S	Unknown			Not Reported
Dose Administered;	Azithromycin			S				Not Reported
Influenza Like Illness;	Azithromycin			S				Not Reported
Injection Site Rash;	Azithromycin			S				Not Reported
Insomnia; Lip Swelling;	Azithromycin			S				Not Reported
Mobility Decreased;	Azithromycin			S				Not Reported
Muscular Weakness;	Cetirizine			C	Unknown	Unk		Not Reported
Nasopharyngitis; Pain;	Demulen-28			C	Unknown	Unk		Not Reported
Pain In Extremity; Painful	Fucidin [Fusidic Acid]			C	Unknown	Unk		Not Reported
Respiration; Peripheral	Hydroxyzine			C	Unknown	Unk		Not Reported
Swelling; Product Storage	Metronidazole			C	Unknown	Unk		Not Reported
Error; Pruritus; Rash;	Nystatin			C	Unknown	Unk		Not Reported
Respiratory Tract	Pantoprazole			C	Unknown	Unk		Not Reported
Congestion; Sensation Of	Pepcid [Famotidine]			C	Unknown	Unk		Not Reported
Foreign Body; Stress;	Prednisone			C	Unknown	Unk		Not Reported
Swelling; Tooth Fracture;	Reactine [Cetirizine			C	Unknown	Unk		Not Reported
Urticaria	Hydrochloride]							

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sertraline	C	Unknown	Unk	Not Reported
Singulair	C	Unknown	Unk	Not Reported
Ventolin [Salbutamol]	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17218849	EXPEDITED (15-DAY)		HO	CA-ROCHE-2508142		51 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Gait Disturbance; Headache; Influenza Like Illness; Malaise; Musculoskeletal Pain; Nasopharyngitis; Neck Pain; Pneumonia; Pyrexia; Seasonal Allergy	Xolair			S	Subcutaneous			Not Reported
	Azithromycin			S	Oral			Not Reported
	Advair			C	Unknown			Not Reported
	Ipratropium			C	Unknown			Not Reported
	Clarithromycin			C	Unknown			Not Reported
	Prednisone			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Ventolin [Salbutamol]			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17218992	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191243319		56 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Foetal Exposure During Pregnancy	Intelence			S	Transplacental			Not Reported
	Prezista			S	Transplacental			Not Reported
	Acyclovir /00587301/			S	Transplacental			Not Reported
	Azithromycin			S	Transplacental			Not Reported
	Bactrim			S	Transplacental			Not Reported
	Isentress			S	Transplacental			Not Reported
	Lamivudine			S	Transplacental			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ritonavir	S	Transplacental	Not Reported
Tenofovir	S	Transplacental	Not Reported
Zidovudine	S	Transplacental	Not Reported
Abacavir	C		Not Reported
Folic Acid	C		Not Reported
Iron	C		Not Reported
Magnesium Gluconate	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17218993	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20191243311		19 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Intelence			S	Unknown			Not Reported
	Prezista			S	Oral			Not Reported
	Abacavir			S	Unknown			Not Reported
	Acyclovir			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Isentress			S	Oral			Not Reported
	Lamivudine			S	Unknown			Not Reported
	Ritonavir			S	Unknown			Not Reported
	Tenofovir			S	Unknown			Not Reported
	Zidovudine			S	Unknown			Not Reported
	Folic Acid			C				Not Reported
	Iron			C				Not Reported
	Magnesium Gluconate			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17219379	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2019AP026776		2 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Reaction With	Azithromycin			S	Unknown	Unk		Apotex

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eosinophilia And Systemic Symptoms	Cefdinir	S	Unknown	Unk				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17219553	NON-EXPEDITED			US-PFIZER INC-2019560125			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17219740	EXPEDITED (15-DAY)		OT	CA-ROCHE-2510045		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chapped Lips; Cough; Dry Mouth; Dysphagia;	Xolair			S	Unknown	300 Mg, Unknown		Not Reported
Fatigue; Hypoaesthesia;	Xolair			S	Unknown	Unk		Not Reported
Lip Dry; Lip Swelling;	Azithromycin			S	Unknown	250 Mg, Unknown		Not Reported
Pruritus; Psoriasis;	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown	Unk		Not Reported
Respiratory Tract Infection; Skin Exfoliation;	Cetirizine Hydrochloride			C	Unknown	Unk		Not Reported
Speech Disorder;	Prednisone			C	Unknown	Unk		Not Reported
Stomatitis; Urticaria	Singulair			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17219773	EXPEDITED (15-DAY)		HO	EG-PFIZER INC-2019538828		50 YR	Female	EGY

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Condition Aggravated; Dyspnoea; Prescribed Underdose	Zithromax			S		500 Mg, Single		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Dec-2019	17221283	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2019SF90908		7 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Headache; Intracranial Pressure Increased; Papilloedema; Strabismus; Visual Acuity Reduced; Vith Nerve Paralysis	Symbicort Turbuhaler			S	Respiratory (inhalation)			Astrazeneca	
	Zithromax			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2020	17198445	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-107223		83 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Abdomen; Drug Ineffective; Incarcerated Hernia; Pneumonia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2020	17221881	EXPEDITED (15-DAY)		OT	CA-ROCHE-2508485		34 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Cough; Dry Mouth; Dysphagia; Fatigue; Hypoaesthesia Oral; Lip Dry; Lip Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder; Stomatitis; Urticaria	Xolair			S	Unknown	300 Mg		Not Reported	
	Azithromycin			S	Unknown	250 Mg		Not Reported	
	Benadryl [Diphenhydramine Hydrochloride]			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Reactine [Cetirizine Hydrochloride]			C	Unknown			Not Reported	
	Singulair			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jan-2020	17222176	EXPEDITED (15-DAY)		OT	FR-ASTRAZENECA-2019SF87284		80 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Respiratory Tract Infection	Esomeprazole			S	Oral			Astrazeneca	
	Novatrex			S	Oral			Not Reported	
	Prednisolone			S	Oral	Variable		Not Reported	
	Aclasta			C	Intravenous drip			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224089	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2019552293		23 YR	Female	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Off Label Use; Product Use In Unapproved Indication; Rash; Uterine Contractions During Pregnancy	Azithromycin			S		Unk		Pfizer	
	Ampicillin Trihydrate			S		Unk		Not Reported	
	Gentamicin Sulfate			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224632	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019560432		1 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Anuria	Zithromax			S	Oral	0.05 G, 1x/Day		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
02-Jan-2020	17224973	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2019M1132828		2 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Autoimmune Thyroiditis; Drug Reaction With	Azithromycin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eosinophilia And Systemic Symptoms		Cefdinir	S	Unknown				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2020	17226654	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2019-109187		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Amoxicillin			S	Oral	3 Gram, Once A Day		Aurobindo	
	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2020	17226690	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-108142		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Frequent Bowel Movements; Nausea; Pneumonia; Vomiting	Azithromycin			S	Unknown	Unk		Aurobindo	
	Remicade			S	Intravenous (not otherwise specified)	500 Milligram, 1 Every 8 Weeks		Not Reported	
	Remicade			S				Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	5.0 Milligram/Kilogram, 1 Every 8 Weeks		Not Reported	
	Remicade			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Jan-2020	17229275	DIRECT	Y	LT, OT			59 YR	Transgender	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Torsade De Pointes; Ventricular Tachyarrhythmia	Azithromycin 500 Mg Iv In 250 MI	Y		S	Intravenous drip			Fresenius Kabi	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	14910221	EXPEDITED (15-DAY)		DS, HO, OT	US-ACTELION-A-US2016-135717		62 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension;	Uptravi			S	Oral	800 Mcg, Qam		Actelion
Arthralgia; Blood Disorder;	Uptravi			S	Oral	800 Mcg, Bid		Actelion
Coagulopathy; Condition	Uptravi			S	Oral	200 Mcg, Bid		Actelion
Aggravated; Diarrhoea;	Uptravi			S	Oral	200 Mcg, Tid		Actelion
Dizziness; Dyspnoea;	Uptravi			S	Oral	1000 Mcg, Qam		Actelion
Dyspnoea Exertional;	Uptravi			S	Oral	800 Mcg, Qam		Actelion
Epistaxis; Fatigue;	Uptravi			S	Oral	10 Mg, Qd		Actelion
Hereditary Haemorrhagic	Opsumit			S	Oral			Actelion
Telangiectasia;	Zithromax			S	Unknown			Not Reported
Hypersensitivity; Liver	Riociguat			C	Oral	2 Mg, Tid		Not Reported
Disorder; Memory	Revatio			C				Not Reported
Impairment; Myalgia;	Levofloxacin			C				Not Reported
Nasopharyngitis; Nausea;	Aldactone			C				Not Reported
Neuralgia; Pain; Product	Gabapentin			C				Not Reported
Dose Omission;	Digoxin			C				Not Reported
Pulmonary Arterial								Not Reported
Hypertension; Sleep								Not Reported
Disorder; Swelling Face;								Not Reported
Unevaluable Event								Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17099458	NON-EXPEDITED			US-PFIZER INC-2019519961		65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Fatigue	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17227464	EXPEDITED (15-DAY)		HO	FR-TEVA-2019-FR-1162051		58 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Pyrexia	Azithromycin			S	Unknown	Unspecified Dosage Regimen		Not Reported
	Furadantine			S	Unknown	Unspecified Dosage Regimen		Actavis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tavanic	S	Unknown	Unspecified Dosage Regimen	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17227555	NON-EXPEDITED		OT	NVSC2019US083463		24 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia	Azithromycin			S	Unknown	250 Mg, Qd		Novartis
	Rifabutin			S	Unknown	300 Mg, Qd On Day 1		Not Reported
	Clofazimine			C	Unknown	50 Mg, Qd On Day 7		Not Reported
	Amikacin			C	Unknown	22 Mg/Kg, Q2w On Day 3		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17227571	NON-EXPEDITED			US-TEVA-2020-US-1163701			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Product Packaging Difficult To Open; Product Prescribing Error; Product Use In Unapproved Indication	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17230325	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2019-066636		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Tract Infection	Prednisolone			S	Oral	Variable		Not Reported
	Novatrex			S	Oral			Not Reported
	Esomeprazole			S	Oral			Not Reported
	Aclasta			C	Intravenous drip			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17231315	NON-EXPEDITED			US-PFIZER INC-2019563069		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celebrex			S		Unk		Pfizer	
	Zoloft			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Amlodipine Besilate			S		5 Mg, Unk		Pfizer	
	Ampicillin Sodium			S		Unk		Unknown	
	Erythromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Not Reported	
	Codeine			S		Unk		Not Reported	
	Flexeril [Cefixime]			S		Unk		Not Reported	
	Macrobid [Nitrofurantoin]			S		Unk		Not Reported	
	Robaxin			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17232998	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR-APL-2019-109421		83 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diaphragmatic Hernia	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2020	17233009	NON-EXPEDITED			NVSC2019US079299			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin			S	Unknown			Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Meclizine	S	Unknown	Unk		Not Reported
	Septra Ds	S	Unknown	Unk		Not Reported
	Soma	S	Unknown	Unk		Not Reported
	Cafergot	S	Unknown	Unk		Not Reported
	Tylenol With Codeine	S	Unknown	Unk		Not Reported
	Paxil	S	Unknown	Unk		Not Reported
	Bactroban	S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2020	15577844	NON-EXPEDITED			US-PFIZER INC-2018448160		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Ciprofloxacin			S		Unk		Unknown	
	Biaxin			S		Unk		Not Reported	
	Cipro [Ciprofloxacin Hydrochloride Monohydrate]			S				Not Reported	
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
	Phenergan			S		Unk		Not Reported	
	Chloral Hydrate			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2020	17235201	EXPEDITED (15-DAY)		HO, LT	GB-TEVA-2019-GB-1161860		52 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Drug-Induced Liver Injury; Faeces Pale; Hepatitis Cholestatic; Jaundice	Azithromycin			S		1500 Mg, Weekly		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2020	17235562	EXPEDITED (15-DAY)		OT	ES-TEVA-2019-ES-1161940		35 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Azitromicina (7019a)			S	Oral	500 Mg Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2020	17236233	NON-EXPEDITED			US-GLAXOSMITHKLINE-US2019AMR207623			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Chills; Cough; Dyspnoea; Headache; Heart Rate Increased; Malaise; Oral Discomfort; Productive Cough; Toothache	Trelegy Ellipta Inhalation Powder			S	Unknown	Unk		Glaxosmithkline	
	Ventolin Hfa Inhalation Powder			S	Unknown	Prn		Glaxosmithkline	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2020	17237131	NON-EXPEDITED			US-PFIZER INC-2020000606		63 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Atorvastatin Calcium			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Acetaminophen			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2020	17305901	DIRECT	Y	HO			83 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection; Diarrhoea;	Moxifloxacin (Moxifloxacin Hcl 400mg Tab)			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pneumonia	Azithromycin (Azithromycin 250mg Cap)		S		Oral		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2020	17240966	EXPEDITED (15-DAY)		HO	FR-ZYDUS-046238		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Amoxicillin			S	Oral				Not Reported
	Azithromycin			S	Oral				Zydus Pharm
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2020	17241596	EXPEDITED (15-DAY)		HO	IT-TEVA-2019-IT-1162453		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Diarrhoea; Jaundice; Liver Disorder	Azithromycin			S	Oral	1 Dosage Form			Not Reported
	Fidato 1 G/3,5 MI Polvere E Solvente Per Soluzione Iniettabile Per Uso Augmentin			S	Intramuscular	1 Dosage Form			Not Reported
				S	Oral	2 Gm			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2020	17241924	EXPEDITED (15-DAY)		OT	CA-DRREDDYS-USA/CAN/20/0118256		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder;	Fluoxetine			S	Unknown				Not Reported
	Azithromycin			S	Oral				Not Reported
	Omalizumab			S	Unknown				Not Reported
	Avamys			C	Unknown	Spray, Metered Dose			Not Reported
	Prozac			C	Unknown				Not Reported
	Quetiapine			C	Oral				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Oropharyngeal Pain;
Pharyngeal Paraesthesia;
Rash Pustular;
Staphylococcal Infection;
Syncope

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2020	17242247	EXPEDITED (15-DAY)		DE	US-PFIZER INC-2020000911		64 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Sulfamethoxazole/Trimethoprim			S		Unk		Pfizer	
	Sulfamethoxazole/Trimethoprim			S				Pfizer	
	Alectinib			C		Unk, Cyclic		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2020	17243565	EXPEDITED (15-DAY)		HO, OT	US-TEVA-2020-US-1163153		2 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Thyroiditis; Drug Reaction With Eosinophilia And Systemic Symptoms	Cefdinir			S	Unknown			Teva	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2020	14603868	EXPEDITED (15-DAY)		DE, HO	US-PFIZER INC-2018087948		66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depressed Level Of Consciousness; Diarrhoea; Haemorrhage Intracranial; Neutrophil Count Decreased; Platelet Count Decreased; Respiratory Failure; Septic	Dacarbazine			S	Intravenous (not otherwise specified)	375 Mg/M2, On Days 1 And 15		Unknown	
	Doxorubicin Hcl			S	Intravenous (not otherwise specified)	25 Mg/M2, On Days 1 And 15		Pfizer	
	Azithromycin			S		1200 Mg, Cyclic		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Shock; White Blood Cell Count Decreased	Brentuximab Vedotin Recombinant	S	Intravenous (not otherwise specified)	1.2 Mg/Kg, On Days 1 And 15	Not Reported
	Vinblastine	S	Intravenous (not otherwise specified)	6 Mg/M2, On Days 1 And 15	Not Reported
	Mepron	S		1500 Mg	Not Reported
	Triumeq	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2020	17245855	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-001774		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Ibuprofen			S	Oral	600 Milligram, Four Times/Day (1-1-1-1)		Aurobindo	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2020	17246309	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020002376		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Retinal Artery Occlusion	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Rifabutin			S	Oral	600 Mg, 1x/Day		Not Reported	
	Lamprene [Clofazimine]			S	Oral	1 Df, 1x/Day		Not Reported	
	Amikacin			S		500 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2020	17246841	NON-EXPEDITED			US-PFIZER INC-2020005659		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Flagyl			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cipro			S			Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Jan-2020	17247125	NON-EXPEDITED			US-PFIZER INC-2020007173		11 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective	Zithromax			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Jan-2020	17247566	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1001859		59 YR	Male	FRA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Aplasia	Azithromycin			S	Oral	500 Milligram, Qd			Not Reported	
	Soliris			S	Intravenous (not otherwise specified)	1200 Milligram, Q21d			Mylan	
	Cellcept /01275102/			S	Intravenous (not otherwise specified)	2 Gram, Qd			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Jan-2020	17248256	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020004074			Female	JPN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Anaphylactic Reaction; Loss Of Consciousness	Zithromac 250mg			S	Oral			Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
08-Jan-2020	17251967	DIRECT					38 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hypersensitivity; Urticaria	Zithromax			S	Oral	Other Frequency:X 1 Dose;			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Jan-2020	17252283	DIRECT		DS			21 YR	Male	SWE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Use; Application Site Erythema; Application Site Reaction; Application Site Warmth; Drug Interaction; Headache; Hypersensitivity; Pigmentation Disorder; Product Use Issue; Rash; Rash; Rash Pruritic; Scar; Skull Malformation; Vision Blurred	Elidel (Pimecrolimus)	Y		S	Topical			Not Reported	
	Azithromycin			S				Not Reported	
	Daktar			C				Not Reported	
	Multivitamins			C				Not Reported	
	Vitamin D			C				Not Reported	
	Omega-3			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	16830478	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-221135		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
Abdominal Pain;	Coumadin 5 Mg Compresse			S	Oral	5 Milligrams, Prn		Not Reported	
Anaesthesia; Dysentery; Nausea	Paracetamol			C	Oral	1 Gram, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	17124079	EXPEDITED (15-DAY)		HO	DE-PFIZER INC- 2019527651			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
B-Lymphocyte Count Decreased; Off Label Use;	Azithromycin			S		Unk		Pfizer	
Product Use In	Fluconazole			S		Unk		Pfizer	
Unapproved Indication	Cefotaxim			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eremfat [Rifampicin]	S	Oral	Unk	Not Reported
Duloxetine	C		Unk	Not Reported
Zopiclone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	17214407	EXPEDITED (15-DAY)		OT	FR-REGENERON PHARMACEUTICALS, INC.-2019-75780			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact	Eylea			S	Intraocular	Dosing Information Not Reported. Patient Had Event Onset Twenty-Four Hours After The 4th And 5th Inj		Regeneron	
	Tetracaine			S				Not Reported	
	Azyter			S		Unk		Not Reported	
	Povidone-Iodine			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	17221404	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR- APL-2019-108645		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; General Physical Health Deterioration; Pyrexia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Tavanic			S	Unknown	Unk		Not Reported	
	Furadantine			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	17251216	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2019- 066918		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact	Tetracaine			S	Unknown			Bausch And Lomb	
	Eylea			S	Intraocular			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azyter			S	Unknown					Not Reported
Povidone-Iodine			C						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	17251849	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1001647		64 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urethral Stenosis	Azithromycin			S	Oral	250 Milligram, Qd			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2020	17254128	EXPEDITED (15-DAY)		OT	AT-MYLANLABS-2020M1002071			Unknown	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		500 Mg, 1x/Day (For 3 Days)			Not Reported
	Azithromycin			S		Unk			Not Reported
	Azithromycin			S					Not Reported
	Rifaximin			S		200 Mg, 3x/Day (For 10days)			Mylan
	Rifaximin			S		Unk			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2020	17210800	EXPEDITED (15-DAY)		OT	FR-REGENERON PHARMACEUTICALS, INC.-2019-73789			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Dermatitis; Drug Hypersensitivity	Eylea			S	Intraocular				Regeneron
	Tetracaine			S	Ophthalmic	Eye Drops			Not Reported
	Azithromycin			S	Ophthalmic	Unk			Not Reported
	Povidone Iodine			C					Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2020	17257604	NON-EXPEDITED			US-PFIZER INC-2020011689		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2020	17259219	EXPEDITED (15-DAY)		OT	US-LANNETT COMPANY, INC.-US-2019LAN001233			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Faeces; Clostridium Difficile Infection; Respiratory Syncytial Virus Infection; Seizure	Levetiracetam			S	Unknown	12 MI, Unk		Lannett	
	Levetiracetam			S	Other	14 MI, Bid, G-Tube		Lannett	
	Zithromax			S	Unknown	Unk, 3 Times A Week		Not Reported	
	Lamictal			C	Unknown	Unk		Not Reported	
	Klonopin			C	Unknown	Unk		Not Reported	
	Senna /00142201/			C	Unknown	Unk		Not Reported	
	Iron /00023503/			C	Unknown	Unk		Not Reported	
	Vitamin D /00107901/			C	Unknown	Unk		Not Reported	
	Calcium			C	Unknown	Unk		Not Reported	
	Melatonin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2020	17260112	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1165252		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Amoxicilline			S	Oral	3 Gram		Teva	
	Azithromycine Anhydre			S	Oral	500 Mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jan-2020	17263271	DIRECT		OT			58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Hyposmia	Azithromycin Tablets 250mg 6 Tablets	Y		S	Oral	Quantity:6 Tablet(S);		Aurobindo	
	Mucinex Dm Liquid			C				Not Reported	
	Ibuprofen			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2020	14122156	EXPEDITED (15-DAY)		HO	JP-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2017- NB-00		76 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure;	Bibf 1120			S	Unknown			Boehringer Ingelheim	
Constipation; Deep Vein	Bibf 1120			S	Unknown			Boehringer Ingelheim	
Thrombosis; Hepatic	Bibf 1120			S	Unknown			Boehringer Ingelheim	
Function Abnormal;	Picillibacta			S	Unknown			Not Reported	
Idiopathic Pulmonary	Zithromac			S	Intravenous (not otherwise specified)			Not Reported	
Fibrosis; Pneumonia	Rabeprazole Na			C	Unknown			Not Reported	
	Clarithromycin			C	Unknown			Not Reported	
	Medicon [Dextromethorphan Hydrobromide]			C	Unknown			Not Reported	
	Bayaspirin			C	Unknown			Not Reported	
	Olmotec			C	Unknown			Not Reported	
	Amlodipine [Amlodipine Besilate]			C	Unknown			Not Reported	
	Neurotropin [Rabbit Vaccinia Extract]			C	Unknown			Not Reported	
	Glycyron [DI- Methionine;Glycine;Glycyrrhizic Acid, Ammonium Salt]			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Talion [Bepotastine Besilate]	C	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	C	Unknown	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17235849	NON-EXPEDITED			US-TEVA-2020-US-1163745			Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Epistaxis; Product Odour Abnormal; Product Quality Issue; Product Taste Abnormal	Azithromycin			S	Unknown	200mg/5ml		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17261653	NON-EXPEDITED			US-TEVA-2020-US-1167394			Unknown	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Hypersensitivity	Azithromycin			S	Unknown			Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17262391	NON-EXPEDITED			US-PFIZER INC-2020013015		75 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
13-Jan-2020	17263983	DIRECT					66 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chills; Diarrhoea; Muscle Spasms; Syncope	Azithromycin			S	Oral	Quantity:1 Tablet(S);	5 DAY	Cspc Ouyi Pharmaceutical
	Citalopram			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2020	17264306	EXPEDITED (15-DAY)		OT	HU-MYLANLABS-2020M1003355		9 YR	Male	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Apathy; Brain Abscess; Drug Ineffective; Infection; Inflammatory Marker Increased; Partial Seizures; Product Use In Unapproved Indication; Sinusitis; Sinusitis Bacterial; Subdural Abscess; Vomiting	Azithromycin			S	Oral	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxone			S	Unknown	Unk		Mylan	
	Amoxicillin W/Clavulanate			S	Unknown	Unk		Mylan	
	Potassium Vancomycin			S	Unknown	Unk		Mylan	
	Vancomycin			S				Mylan	
	Vancomycin			S				Mylan	
	Metronidazole			S	Unknown	Unk		Mylan	
	Meropenem			S	Unknown	Unk		Mylan	
	Meropenem			S				Mylan	
	Meropenem			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2020	17265076	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-233033		35 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	15950550	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019GSK024159			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anaemia; Aspiration;	Mepolizumab			S	Intravenous (not	100 Mg, Z (Monthly)		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Asthma; Blood Calcium Increased; Blood Creatinine Increased; Blood Test Abnormal; Bronchiectasis; Bronchopulmonary Aspergillosis Allergic; Constipation; Cough; Drug Hypersensitivity; Drug Ineffective; Dyspnoea; Fatigue; Gastroesophageal Reflux Disease; Haemoptysis; Headache; Hypoxia; Liver Function Test Increased; Lower Respiratory Tract Infection; Lung Opacity; Musculoskeletal Stiffness; Obstructive Airways Disorder; Oedema	Mepolizumab	S	otherwise specified)	Intravenous (not otherwise specified)	100 Mg, Unk	Glaxosmithkline
Peripheral; Pain; Pleural Effusion; Pneumonia; Pulmonary Fibrosis; Pyrexia; Rales; Sputum Discoloured; Total Lung Capacity Decreased; Transaminases Increased; Tremor; Upper Respiratory Tract Infection; Wheezing	Mepolizumab	S		Intravenous (not otherwise specified)	100 Mg, Z	Glaxosmithkline
	Flu Vaccine	S				Glaxosmithkline
	Ventolin	S			100 Ug (As Needed)	Glaxosmithkline
	Singulair	S			100 Mg, Qd	Glaxosmithkline
	Nitroglycerin	S			Unk	Glaxosmithkline
	Lansoprazole	S			Unk	Glaxosmithkline
	Domperidone	S			Unk	Glaxosmithkline
	Budesonide	S			Unk	Glaxosmithkline
	Senna	S			Unk	Glaxosmithkline
	Quetiapine	S			Unk	Glaxosmithkline
	Zopiclone	S			Unk	Glaxosmithkline
	Rosuvastatin	S			Unk	Glaxosmithkline
	Senokot	S			Unk	Glaxosmithkline
	Acetaminophen	S			1000 Mg, Unk Q.H.S	Glaxosmithkline
	Azithromycin	S			Unk	Glaxosmithkline
	Levothyroxin	S			Unk	Glaxosmithkline
	Vitamin D	S	Oral		Unk 1000 Units	Glaxosmithkline
	Montelukast	S	Oral		10 Mg, 1d	Glaxosmithkline
	Ranitidine	S			Unk	Glaxosmithkline
	Atrovent	S			Unk	Not Reported
	Prevnar	S			Unk	Not Reported
	Spiriva	S			1 Puff(S), 1d	Not Reported
	Synthroid	S			Unk	Not Reported
	Candesartan	S	Oral		8 Mg, 1d	Not Reported
	Xolair	S			Unk	Not Reported
	Dexilant	S			Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Pramipexole	S	Oral	0.25 Mg, Unk Q.P.M	Not Reported
	Pramipexole	S	Oral	0.5 Mg, Unk	Not Reported
	Risedronate	S		Unk	Not Reported
	Symbicort	S		2 Puff(S), Bid	Not Reported
	Pregabalin	S	Oral	75 Mg, Unk Q.H.S	Not Reported
	Statex (Morphin)	S	Oral	10 Mg, Unk Q.H.S	Not Reported
	Efinaconazole	S		Unk 10 Percent Solution Apply At H.S	Not Reported
	Nasonex	S		Unk 50 Mcg Per Spary 2 Spary In Each Nostril Bid	Not Reported
	Morphine	S		10 Mg (Pnr As Needed Q4h)	Not Reported
	Morphine	S		Unk	Not Reported
	Trazodone	S		10 Mg As Needed	Not Reported
	Trazodone	S		12.5 Mg	Not Reported
	Pantoloc	S		Unk	Not Reported
	Pantoloc	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17265392	EXPEDITED (15-DAY)		DE, HO	US-APOTEX- 2020AP005810		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Drug Reaction	Azithromycin			S	Parenteral	Unk, Unknown		Apotex	
	Ceftriaxone			S	Parenteral	Unk, Unknown		Apotex	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17265649	EXPEDITED (15-DAY)		HO	ES-JNJFOC- 20200118787		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Ibuprofen			S	Oral	1-1-1-1		Not Reported	
	Azitromicina			S	Oral	500 Mg Dia		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266270	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-002545		2 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Reaction With Eosinophilia And Systemic Symptoms; Hepatosplenomegaly; Lymphadenopathy; Pyrexia; Rash Morbilliform	Azithromycin			S	Unknown	Unk		Aurobindo	
	Cefdinir			S	Unknown	Unk		Aurobindo	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266812	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020009201		65 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Abdominal Pain Lower; Aphonia; Cough; Intentional Product Use Issue; Vomiting	Gd-Azithromycin			S		250 Mg, Unk		Pfizer	
	Tylenol [Paracetamol]			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17266876	NON-EXPEDITED			NVSC2020US006789		33 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Product Use In Unapproved Indication; Treatment Failure	Azithromycin			S	Unknown	Unk		Novartis	
	Prednisone			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
14-Jan-2020	17267010	EXPEDITED (15-DAY)		HO	CN-PFIZER INC-2020014436		5 YR	Male	CHN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dermatitis Allergic; Rash	Zithromax			S	Oral	180 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Hua Chang			C	Oral	5 Mg, 1x/Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17269426	EXPEDITED (15-DAY)		OT	NVSC2020US006404		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Dysphagia; Dyspnoea; Dysuria; Feeling Hot; Foaming At Mouth; Hyperhidrosis; Hyporesponsive To Stimuli; Myasthenia Gravis Crisis; Paralysis; Respiratory Failure; Tachycardia	Azithromycin			S	Unknown	Unk		Novartis	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Flagyl			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17269549	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1003671		69 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Haematuria; Mouth Ulceration; Purpura; Thrombocytopenia	Azithromycin			S	Oral	1 Dosage Form		Not Reported	
	Nabucox			S	Oral	2 Dosage Form, Qd		Mylan	
	Loxen /00639802/			C	Oral	2 Dosage Form, Qd		Mylan	
	Ezetrol			C	Oral	1 Dosage Form, Qd		Mylan	
	Flector Tissugel Ep			C	Cutaneous	3 Dosage Form, Qd		Mylan	
	Ropinirole /01242902/			C	Oral	0.5 Milligram, Qd		Mylan	
	Bronchodual			C	Respiratory (inhalation)	2 Dosage Form, Qd		Mylan	
	Spasfon /00765801/			C	Oral	6 Dosage Form, Qd		Mylan	
	Aspirine Protect			C	Oral	1 Dosage Form, Qd		Mylan	
	Nebivolol			C	Oral	1 Dosage Form, Qd		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17269556	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SE05942		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoxia; Maternal Exposure During Pregnancy; Ventilation Perfusion Mismatch	Bupivacaine Hydrochloride			S	Unknown	1.8ml Unknown		Not Reported	
	Omeprazole			S	Oral			Not Reported	
	Levothyroxine Sodium Eli			S	Unknown			Not Reported	
	Fentanyl			S	Unknown	10.0mg Unknown		Not Reported	
	Fluticasone			S	Unknown			Not Reported	
	Morphine Sulfate			S	Unknown	100.0mg Unknown		Not Reported	
	Ondansetron			S	Intravenous (not otherwise specified)	4.0mg Unknown		Not Reported	
	Oxytocin			S	Intravenous (not otherwise specified)			Not Reported	
	Phenylephrine			S	Intravenous (not otherwise specified)	650.0ug Unknown		Not Reported	
	Pms Azithromycin			S	Respiratory (inhalation)			Not Reported	
	Salbutamol			S	Respiratory (inhalation)			Not Reported	
	Serevent			S	Respiratory (inhalation)			Not Reported	
	Tobramycin			S	Respiratory (inhalation)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jan-2020	17269607	EXPEDITED (15-DAY)		OT	CA-SA-2020SA006940			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial	Arava			S	Unknown	Unk Unk, Unk		Sanofi	
	Diphenhydramine Hydrochloride			S	Unknown	Unk Unk, Unk		Sanofi	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lung Disease; Rheumatoid Arthritis; Treatment Failure	Celecoxib	S	Oral	Unk Unk, Unk	Not Reported
	Demerol	S	Unknown	Unk Unk, Unk	Sanofi
	Levofloxacin	S	Unknown	Unk Unk, Unk	Not Reported
	Methotrexate	S	Unknown	Unk Unk, Unk	Not Reported
	Plaquenil	S			Sanofi
	Azithromycin	S	Unknown	250 Mg	Not Reported
	Cyclophosphamide	S	Unknown	Unk Unk, Unk	Not Reported
	Cimzia	S	Unknown	Unk Unk, Unk	Not Reported
	Humira	S	Unknown	Unk Unk, Unk	Not Reported
	Imuran [Azathioprine]	S	Unknown	Unk Unk, Unk	Not Reported
	Enbrel	S	Unknown	Unk Unk, Unk	Not Reported
	Simponi	S	Unknown	Unk Unk, Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Xeljanz	S	Oral	5 Mg, Bid	Not Reported
	Ezetrol	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2020	15932109	NON-EXPEDITED			US-PFIZER INC- 2019054031		92 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Celecoxib			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Gabapentin			S		Unk		Pfizer	
	Potassium Chloride			S		Unk		Unknown	
	Zithromax			S		Unk		Pfizer	
	Avelox			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Clarithromycin			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Citalopram	S	Unk	Not Reported
Cymbalta	S	Unk	Not Reported
Cipro	S	Unk	Not Reported
Glucosamine	S	Unk	Not Reported
Codeine Polistirex	S	Unk	Not Reported
Hydrocodone	S	Unk	Not Reported
Chondroitin	S	Unk	Not Reported
Flonase	S	Unk	Not Reported
Macrobid [Clarithromycin]	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2020	16970040	EXPEDITED (15-DAY)		OT	DE-DEXPHARM-20190907		29 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ulcerative Keratitis	Chlorhexidine 0.02% Drops			S	Ophthalmic	Every 2 Hours		Not Reported	
	Brolene 0.1%			S	Ophthalmic	Hourly		Not Reported	
	Azydrop			S	Ophthalmic	Single Dose Every 4 Hours		Not Reported	
	Azydrop			S	Ophthalmic	Single Dose Every 12 Hours		Not Reported	
	Dexafree			S	Ophthalmic	Every 6 Hours		Not Reported	
	Colircusi Gentadexa			S	Ophthalmic			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2020	17270889	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2019RR-233063		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Diarrhoea; Jaundice; Liver Disorder	Azithromycin			S	Oral	1 Dosage Form, Daily		Sun	
	Augmentin			S	Oral	2 Gram, Daily		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fidato 1 G/3,5 MI Polvere E Solvente Per Soluzione Iniettabile Per Uso	S	Intramuscular	1 Dosage Form, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Jan-2020	17274306	NON-EXPEDITED			US-PFIZER INC- 2020019362			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17267486	EXPEDITED (15-DAY)		DE, HO, OT	US-PFIZER INC- 2020015486		63 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Azithromycin			S	Parenteral	Unk		Pfizer
	Ceftriaxone Sodium			S	Parenteral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17275030	EXPEDITED (15-DAY)		OT	CA-DRREDDYS- USA/CAN/20/0118483		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased; Coccydynia; Contusion; Crying; Discomfort; Dizziness Exertional; Dry Skin; Dyspnoea; Dyspnoea Exertional; Ear Pain; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Headache; Heart Rate Increased; Myalgia; Nausea; Oxygen Saturation Decreased;	Atorvastatin			S	Oral			Not Reported
	Azithromycin Monohydrate			S				Not Reported
	Fentanyl Citrate			S	Epidural	Liquid Epidural		Not Reported
	Montelukast			S	Oral			Not Reported
	Pantoprazole			S	Oral			Not Reported
	Xolair			S	Subcutaneous			Not Reported
	Advair			C				Not Reported
	Prednisone			C				Not Reported
	Reactine			C				Not Reported
	Spiriva			C	Oral			Not Reported
	Ventolin			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pain In Extremity;
Respiratory Rate
Increased; Scratch; Vision
Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17275272	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2020-002539		24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Neutropenia	Azithromycin			S	Unknown	250 Milligram, Daily		Aurobindo	
	Rifabutin			S	Unknown	300 Milligram, Daily		Not Reported	
	Rifabutin			S	Unknown	600 Unk		Not Reported	
	Amikacin			S		22 Milligram/Kilogram, Every 2 Weeks (On Day 3)		Not Reported	
	Clofazimine			S	Unknown	50 Milligram, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17275722	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-00		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact; Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Atrovent			S	Unknown			Boehringer Ingelheim	
	Azithromycin			S	Oral			Not Reported	
	Breo Ellipta			S	Unknown	Dosage Form: Powder		Not Reported	
	Ipratropium;Salbutamol			S	Unknown			Not Reported	
	Prednisone			S	Oral			Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Seebri Breezhaler			S	Unknown			Not Reported	
	Singulair			S	Oral			Not Reported	
	Theophylline			S	Oral			Not Reported	
	Xolair			S	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17276591	EXPEDITED (15-DAY)		HO	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-00		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma	Atrovent			S	Unknown			Boehringer Ingelheim	
	Ciclesonide			S	Unknown			Not Reported	
	Rupatadine Fumarate			S	Unknown			Not Reported	
	Salbutamol			S	Respiratory (inhalation)			Not Reported	
	Salbutamol Sulfate			S	Unknown			Not Reported	
	Symbicort Turbuhaler			S	Unknown	Form Of Admin: Powder		Not Reported	
	Zithromax			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17278735	EXPEDITED (15-DAY)		OT	IT-PFIZER INC- 2020015815		34 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Oedema	Zitromax			S	Oral	500 Mg, Single		Pfizer	
	Dasatinib			C	Oral	100 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17278738	EXPEDITED (15-DAY)		HO	IT-PFIZER INC- 2020015812		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Diarrhoea; Jaundice; Liver Disorder	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Fidato			S	Intramuscular	1 Df, 1x/Day		Not Reported	
	Augmentin [Amoxicillin;Clavulanic Acid]			S	Oral	2 G, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Jan-2020	17279862	EXPEDITED (15-DAY)		HO, LT, OT	US-BAXTER-2020BAX000786		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Myasthenia Gravis Crisis	Ceftriaxone Injection, Usp (In Dextrose)			S	Unknown			Baxter	
	Flagyl			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	16024148	EXPEDITED (15-DAY)		HO	CA-GLAXOSMITHKLINE-CA2019GSK036799			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Dyspnoea; Therapeutic Product Effect Incomplete; Wheezing	Salbutamol Sulphate			S		Unk Unk, Prn (100mcg Prn And Nebs)		Glaxosmithkline	
	Salbutamol			S	Respiratory (inhalation)	100 ?G, Prn		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z(Monthly)		Glaxosmithkline	
	Nucala			S		100 Mg, Z, Monthly		Glaxosmithkline	
	Advair			S		Unk Unk, Bid		Glaxosmithkline	
	Symbicort			S		2 Puff(S), Bid(2 Puff At Am And 2 Puff At Pm)		Not Reported	
	Ciclesonide			S		200 ?G, Bid (2 Puff(S), (2 Puff At Am And 2 Puff At Pm)		Not Reported	
	Atrovent			S		20 Ug, Bid		Not Reported	
	Zithromax			S		Unk Unk, Z(Monday/Wednesday/Fri day)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Rupall		S			Unk			Not Reported
	Alvesco		S			200 Ug, Bid			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	16271132	EXPEDITED (15-DAY)		HO, LT	AU-009507513-1905AUS000209		5 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E Increased; Therapeutic Product Effect Incomplete	Singulair			S	Oral	Unk		Merck	
	Lukair			S	Oral	Unk		Merck	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	16309625	EXPEDITED (15-DAY)		LT, OT	AU-MYLANLABS-2019M1043114			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Immunoglobulin E Increased; Drug Ineffective; Mite Allergy	Azithromycin			S	Oral	Unk		Not Reported	
	Montelukast			S		Unk		Mylan	
	Omalizumab			S		150 Microgram, Qd (Monthly)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	16624385	EXPEDITED (15-DAY)		HO, OT	PHHY2019BR149201		62 YR	Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphthous Ulcer; Arthralgia; Bipolar Disorder; Bone Disorder; Cough; Decreased Immune Responsiveness; Depressed Mood; Depression; Dysgeusia; Fall; Inflammation; Influenza; Malaise;	Cosentyx			S	Unknown	Unk		Novartis	
	Cosentyx			S	Unknown	Unk		Novartis	
	Cosentyx			S	Unknown	Unk		Novartis	
	Cosentyx			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Movement Disorder;
Multiple Fractures;
Osteoarthritis; Pain;
Pneumonia; Pyrexia;
Pyrexia; Spinal Disorder;
Spinal Pain; Throat
Irritation; Visual
Impairment; Wheezing;
Wrist Fracture

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	17269576	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC- 2020015221		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Failure; Myasthenia Gravis Crisis	Ceftriaxone Sodium			S		Unk		Pfizer
	Flagyl			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	17280075	NON-EXPEDITED			US-TEVA-2020-US- 1165585			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Pruritus	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2020	17282760	EXPEDITED (15-DAY)		HO, LT, OT	US-APOTEX- 2020AP005173		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Myasthenia Gravis Crisis; Respiratory Failure	Azithromycin			S	Unknown	Unk		Apotex
	Azithromycin			S	Unknown	Unk		Apotex
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Flagyl /00012501/			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17283373	EXPEDITED (15-DAY)		OT	NG-PFIZER INC-2020019593			Unknown	NGA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Cough; Lower Respiratory Tract Infection Bacterial	Zithromax			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17284208	EXPEDITED (15-DAY)		OT	NVSC2020GB009039		66 YR	Male	GBR
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Myalgia; Visual Impairment	Azithromycin			S	Oral	2250 Mg, Qw (Patient Took 3 Tablets On Monday, Wednesday And Friday Then 3 Extra On Monday)		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
17-Jan-2020	17361339	DIRECT	Y					Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Intercepted Product Selection Error; Product Packaging Confusion	Protonix Zithromax			S S				Not Reported Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
18-Jan-2020	17285779	EXPEDITED (15-DAY)		HO, OT	CA-009507513-2001CAN005129		58 YR	Male	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma;	Zenhale			S	Unknown	2 Dosage Form, 2 Every 1 Days, Dosage Form : Aerosol, Metered Dose		Merck	
	Alvesco			S	Unknown	2 Dosage Form, 1 Every 1		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Wheezing									
	Albuterol Sulfate		S	Unknown	Days, Dosage Form: Aerosol, Metered Dose				Not Reported
	Spiriva		S	Unknown	100 Microgram, 1 Every 1 Days				Not Reported
	Zithromax		S	Unknown	2 Dosage Form, 2 Every 1 Days				Not Reported
	Prednisone		C	Unknown	Unk				Merck
					Unk				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2020	17285794	NON-EXPEDITED		DE, HO, OT	US-APOTEX-2020AP005174		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pancreatitis Acute	Tigecycline			S	Intravenous (not otherwise specified)	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	
	Amikacin			S	Unknown	Unk		Not Reported	
	Clofazimine			S	Oral	Unk		Not Reported	
	Azithromycin			S	Nasal	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2020	17286025	EXPEDITED (15-DAY)		HO	IT-AUROBINDO-AUR-APL-2020-002699		15 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Medication Error	Azithromycin			S	Oral	1.5 Gram, Once A Day		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2020	17291864	DIRECT		DS			70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Azithromycin	Y		S	Oral	Quantity:250 Tablet(S);		Wockhardt	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper; Lisinopril C Not Reported
Anal Incontinence;
Diarrhoea; Eye Pain; Eye
Pain; Fatigue; Headache

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2020	17286529	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1169385		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Salbutamol Sulfate			S	Unknown	100 Microgram Daily;		Barr	
	Alvesco			S	Unknown	2 Dosage Forms Daily;		Not Reported	
	Spiriva			S	Unknown	4 Dosage Forms Daily;		Not Reported	
	Zenhale			S	Unknown	4 Dosage Forms Daily;		Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	16081398	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-012932		48 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterovirus Infection; Transplant Rejection	Azithromycin			S	Unknown	250 Milligram		Aurobindo	
	Valganciclovir			S	Unknown	900 Milligram		Aurobindo	
	Abacavir			S	Unknown	Unk		Not Reported	
	Mycophenolic Acid			S	Unknown	1 Gram, Two Times A Day		Not Reported	
	Prednisone			S	Unknown	15 Milligram, Once A Day		Not Reported	
	Sulfamethoxazole			S	Unknown	800 Milligram		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Tivicay			S	Unknown	Unk		Not Reported	
	Trimethoprim			S	Unknown	160 Milligram		Not Reported	
	Pms Azithromycin			S	Unknown	250 Milligram		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	6425470	EXPEDITED (15-DAY)		OT	GB-JNJFOC-20070904046		21 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Drug Interaction; Dyspepsia; Hypophagia; Vomiting; Weight Decreased	Ibuprofen			S	Unknown	Dose And Frequency Unknown		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Colomycin (Colistimethate Sodium)			S	Intravenous (not otherwise specified)			Not Reported	
	Tobramycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17287305	NON-EXPEDITED			US-APOTEX-2020AP006500			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash; Swelling	Azithromycin			S	Unknown	Unk		Apotex	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17287681	NON-EXPEDITED			US-ASTRAZENECA-2020SE04120			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction	Omeprazole			S	Oral			Not Reported	
	Clopidogrel			S	Unknown			Not Reported	
	Pantoprazole			S	Oral	1 Tab By Mouth Once A Day		Not Reported	
	Azithromycin			S	Oral	1 Tab By Mouth Once A Day, X 30 Day (S)		Not Reported	
	Nitroglycerin			S	Oral	1 Tab Sublingual Q 5 Minutes		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17287774	EXPEDITED (15-DAY)		OT	US-INSMED, INC.-US-INS-20-00064		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adverse Drug Reaction; Off Label Use	Amikacin			S	Respiratory (inhalation)			Insmed
	Nitric Oxide			S				Not Reported
	Nitric Oxide			S				Not Reported
	Cefoxitin			S	Intravenous (not otherwise specified)			Not Reported
	Cefoxitin			S				Not Reported
	Clofazimine			S				Not Reported
	Clofazimine			S				Not Reported
	Azithromycin			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17287823	EXPEDITED (15-DAY)		HO	US-STRIDES ARCOLAB LIMITED-2020SP000458		58 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Altered State Of Consciousness; Dysphagia; Dyspnoea; Facial Paresis; Feeling Hot; Foaming At Mouth; Hyperhidrosis; Malaise; Myasthenia Gravis; Paralysis; Productive Cough; Respiratory Failure; Tachycardia; Unresponsive To Stimuli; Urinary Incontinence	Metronidazole			S	Unknown	Unk		Strides
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S				Not Reported
	Ceftriaxone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17288060	NON-EXPEDITED			US-TEVA-2020-US-1168551			Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Product Taste Abnormal	Azithromycin Teva			S	Unknown	250 Milligram Daily; For 6 Days		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17288548	EXPEDITED (15-DAY)		OT	AT-PFIZER INC-2020020286		52 YR	Female	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Depersonalisation/Dereali sation Disorder; Drug Interaction; Transient Global Amnesia	Azithromycin			S	Oral	Unk		Pfizer	
	Hydal			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17289107	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020025406		24 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Hyperhidrosis; Hypoaesthesia; Pallor; Ventricular Extrasystoles; Ventricular Tachycardia	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17289253	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1005674		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Myasthenia Gravis	Azithromycin			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Mylan	
	Flagyl /00012501/			S	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17290168	NON-EXPEDITED			PHHY2019US103246		65 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Hypersensitivity; Nausea; Skin Discolouration	Lamprene			S	Oral	50 Ot, Qd		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Amikacin			C	Respiratory (inhalation)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2020	17293361	DIRECT						Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Urticaria	Azithromycin			S				Not Reported	
	Norco 5-325			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	16899175	NON-EXPEDITED			US-PFIZER INC-2019434666			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Levofloxacin			S		Unk		Pfizer	
	Cipro			S		Unk		Not Reported	
	Keflex			S		Unk		Not Reported	
	Tequin			S		Unk		Not Reported	
	Acetaminophen			S		Unk		Not Reported	
	Tylenol			S		Unk		Not Reported	
	Sulfonamide			S		Unk		Not Reported	
	Bactrim			S		Unk		Not Reported	
	Nitrofurantoin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17275700	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2020AMR006357			Male	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Diabetes Mellitus; Dyspnoea; Loss Of Personal Independence In Daily Activities; Renal Failure; Sleep Disorder Due To A General Medical Condition; Therapeutic Product Effect Incomplete; Wheezing	Salbutamol Sulphate			S		Unk, Prn(Monthly)		Glaxosmithkline
	Breo Ellipta			S		Unk Unk, Prn		Glaxosmithkline
	Incruse Ellipta			S		Unk Unk, Prn		Glaxosmithkline
	Alvesco			S		Unk Unk, Prn		Not Reported
	Azithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17291396	EXPEDITED (15-DAY)		DE, HO, OT	US-EMCURE PHARMACEUTICALS LTD-2020-EPL-0037		210 DAY	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Foetal Exposure During Pregnancy; Neonatal Pneumonia; Neonatal Respiratory Acidosis; Sepsis Neonatal	Ampicillin			S		Unk		Heritage
	Ampicillin			S	Transplacental	2 Gram Q 6 × 48 Hours		Heritage
	Ampicillin			S	Transplacental	Unk		Heritage
	Azithromycin			S	Transplacental	500 Mg Q 6 X 48 Hours		Not Reported
	Erythromycin			S	Transplacental	Unk		Not Reported
	Gentamycine			C		Unk		Not Reported
	Penicillin /00000901/			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17291760	EXPEDITED (15-DAY)		HO	CA- GLAXOSMITHKLINE- CA2020AMR007263		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma	Salbutamol			S		100 Ug		Glaxosmithkline
	Salbutamol Sulphate			S		Unk		Glaxosmithkline
	Atrovent			S		20 Ug		Not Reported
	Ciclesonide			S	Respiratory	2 Puff(S), Qd,200mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		(inhalation)			
Rupatadine	S		Unk		Not Reported
Symbicort Turbuhaler	S	Respiratory (inhalation)	Unk		Not Reported
Zithromax	S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17293250	NON-EXPEDITED		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00104		59 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia	Azithromycin			S	Unknown	Unk		Lupin
	Cefoxitin			S	Intravenous (not otherwise specified)	6 Gram, Qd		Not Reported
	Clofazimine			S	Unknown	Unk		Not Reported
	Amikacin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17294848	NON-EXPEDITED			US-MYLANLABS- 2020M1001979			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Drug Interaction	Esomeprazole Magnesium Delayed-Release Capsules			S	Oral	Twice Daily Before Meals		Mylan
	Prednisone Tablets Usp			S	Oral	Tapered Dosing From 50mg For 5 Days, Decreasing By 10mg Daily To Final 10mg Dose On The 9th Day		Mylan
	Amoxicillin Aurobindo			S		Taking 2 Tablets Daily For 7 Days		Mylan
	Azithromycin			S		Two Tablets On The First Day Followed By 1 Tablet Daily For Four Days		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17295316	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1004834		64 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest	Azithromycin			S		Unk		Not Reported	
	Amoxicillin/Clavulanic Acid			S		Unk		Not Reported	
	Oseltamivir			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17295329	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1004869		92 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Piperacillin/Tazobactam			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Ceftriaxona /00672201/			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17295444	EXPEDITED (15-DAY)		OT	MY-PFIZER INC-2020026434		2 YR	Unknown	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Resistance; Pneumonia	Zithromax			S	Oral	10mg/Kg, Daily		Pfizer	
	Ceftriaxone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jan-2020	17295802	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020024331		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Off Label Use; Product Use Issue	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Amoxicillin			S	Oral	3 G, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17295805	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020026714		37 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Toxicity To Various Agents; Transaminases Increased; Vomiting	Neurontin			S		Unk		Pfizer	
	Zitromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Tenofovir Disoproxil Accord [Tenofovir Disoproxil Fumarate]			S	Oral	Unk		Not Reported	
	Isentress			S	Oral	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17296074	NON-EXPEDITED			NVSC2020US013063			Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective	Azithromycin			S	Unknown	250 Mg		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
21-Jan-2020	17298555	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2020M1004411		72 YR	Female	PRT
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Dermatosis; Erythema; Malaise; Pharyngeal Enanthema; Pruritus; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	16428261	EXPEDITED (15-DAY)		OT	FR-BAUSCH-BL-2019-016834		58 YR	Female	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Burn Oesophageal; Cough	Doxycycline			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zithromax			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17070590	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2019499284		65 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alcohol Poisoning	Zithromac 250mg			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromac 250mg			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17296834	EXPEDITED (15-DAY)		OT	US-ACS-001618		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myasthenia Gravis Crisis	Ceftriaxone			S	Unknown			Not Reported	
	Flagyl			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17297921	EXPEDITED (15-DAY)		HO	ES-ZYDUS-046713		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Ibuprofen			S	Oral			Not Reported	
	Azithromycin			S	Oral			Zydus Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17298778	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001-20-504		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Myasthenia Gravis Crisis	Ceftriaxone			S	Unknown	()		Hikma	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Flagyl		S	Unknown	()			Not Reported	
	Azithromycin		S	Unknown	()			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17299026	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1171721		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azitromicina (7019a)			S	Oral	500 Mg Dia			Not Reported
	Ibuprofeno (1769a)			S	Oral	1-1-1-1 600 Mg			Actavis
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17299234	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1005707		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Pneumonia	Azithromycin			S	Unknown	Unk			Not Reported
	Prednisone			S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17299406	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020008437		66 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Anxiety; Device Dislocation; Discomfort; Dyskinesia; Dyspnoea; Emotional Distress; Fatigue; Feeling Abnormal; Muscle Spasms; Nausea; Nervousness; Off Label Use; Product Use In Unapproved Indication; Rash; Swollen Tongue; Therapeutic Response	Azithromycin			S	Oral	3 Ot, Daily			Pfizer
	Amoxicillin			S	Oral	3 Ot, Daily			Not Reported
	Duodopa			S	Other	Unk			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Shortened

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17300533	NON-EXPEDITED			US-ALLERGAN-1942890US		66 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eye Irritation; Eye Pruritus; Eye Swelling; Ocular Hyperaemia; Sjogren'S Syndrome	Restasis			S	Ophthalmic	2 Gtt, Bid		Allergan	
	Azasite			S	Ophthalmic	Unk		Not Reported	
	Unspecified Medications			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17300883	NON-EXPEDITED		OT	NVSC2020US015256			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridium Difficile Infection	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17300919	NON-EXPEDITED			US-PFIZER INC-2020028300		31 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Amoxicillin			S		Unk		Pfizer	
	Clarithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17301247	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020026515		17 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Altered State Of Consciousness;	Zithromax			S	Oral	2 Df, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Dysuria; Fatigue

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17301248	EXPEDITED (15-DAY)		OT	NVSC2020CA013507			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis;	Azithromycin			S	Unknown			Novartis
Atypical Mycobacterial	Methotrexate			S	Unknown			Not Reported
Infection; Bacterial	Leflunomide			S	Unknown			Not Reported
Infection; Bronchiectasis;	Depomedrol			S	Unknown			Not Reported
C-Reactive Protein	Plaquenil			S	Unknown	Unk (200 Mg Od)		Not Reported
Increased; Cellulitis; Chest								
Pain; Cough; Crystal								
Arthropathy; Diarrhoea;								
Drug Ineffective; Drug								
Intolerance; Erythema;								
Gout; Grip Strength								
Decreased; Infective								
Exacerbation Of								
Bronchiectasis; Ligament								
Sprain; Lung Disorder;								
Middle Lobe Syndrome;								
Nightmare; Oropharyngeal								
Pain; Osteoarthritis; Pain;								
Paraesthesia; Peripheral								
Swelling; Rash;								
Rheumatoid Arthritis;								
Rheumatoid Factor;								
Synovitis; Underweight;								
Upper Respiratory Tract								
Infection								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jan-2020	17301266	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020027058			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury	Azithromycin			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17301389	NON-EXPEDITED			US-PFIZER INC-2020028780			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17302512	NON-EXPEDITED		OT	NVSC2020US015253			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Clostridium Difficile Infection	Azithromycin			S	Unknown	Unk		Novartis	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17303105	NON-EXPEDITED			US-PFIZER INC-2020029247			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Metronidazole			S		Unk		Pfizer	
	Potassium Chloride			S		Unk		Unknown	
	Oxycodone			S		Unk		Not Reported	
	Propoxyphene			S		Unk		Not Reported	
	Sulfanilamide			S		Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17303121	NON-EXPEDITED			US-PFIZER INC-2020029769			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Ear Pain; Expired Product	Zithromax			S		500 Mg, 1x/Day, [Two 250 Mg Tablets Last Night]		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Administered	Zithromax	S			Unk			Pfizer	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17303610	NON-EXPEDITED		HO	NVSC2020US011668			Male	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Malaise	Azithromycin				S	Unknown	250 Mg, Unknown		Novartis
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17303841	EXPEDITED (15-DAY)		OT	CN-CSPC OUYI PHARMACEUTICAL CO., LTD.-2079313		39 YR	Female	CHN
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Chest Discomfort; Hypoaesthesia; Hypoaesthesia; Tachypnoea	Azithromycin				S	Intravenous drip			Cspc Ouyi Pharmaceutical
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17377369	DIRECT	Y	DE, HO			59 YR	Female	USA
Preferred Term	Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Death	Ambrisentan 5mg				S	Oral			Not Reported
	Azithromycin				S				Not Reported
	Bactrim				C				Not Reported
	Cefdinir				C				Not Reported
	Fosamax				C				Not Reported
	Furosemide				C				Not Reported
	Imuran				C				Not Reported
	Ipratropium				C				Not Reported
	Ketoprofen				C				Not Reported
	Mycophenolate				C				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Jan-2020	17378519	DIRECT	Y				35 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension	Endometrin 100mg			S	Vaginal			Ferring
	Follistim Aq 300kiu/0.36ml			S	Subcutaneous			Organon
	Ganirelix			C				Not Reported
	Hcg			C				Not Reported
	Azithromycin			S				Not Reported
	Menopur			C				Not Reported
	Methylprednisolone			C				Not Reported
	Leuprolide			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17275605	EXPEDITED (15-DAY)		OT	ALC2019FR003490			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Conjunctivitis; Dermatitis; Eczema	Tetracaine Hydrochloride			S	Unknown			Not Reported
	Povidone-Iodine			C	Unknown			Not Reported
	Povidone-Iodine			C	Unknown	Unk		Not Reported
	Eylea			S	Intraocular	Unk		Not Reported
	Azyter			S	Unknown	Unk Unk, Tid		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17304881	NON-EXPEDITED			US-PFIZER INC-2020028664		55 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Clindamycin Hcl			S		Unk		Pfizer
	Morphine Sulfate			S		Unk		Unknown
	Chlorhexidine Gluconate			S		Unk		Not Reported
	Aimovig [Erenumab Aooe]			S		Unk		Not Reported
	Iodine			S		Unk		Not Reported
	Nystatin			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Percocet [Oxycodone Hydrochloride;Paracetamol]	S	Unk	Not Reported
Tizanidine	S	Unk	Not Reported
Trimethoprim	S	Unk	Not Reported
Vortioxetine Hydrobromide	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17305386	EXPEDITED (15-DAY)		HO, OT	US-MYLANLABS-2020M1007455		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Treatment Failure	Clindamycin			S	Unknown			Not Reported
	Clindamycin			S	Intravenous (not otherwise specified)	Three Times Daily		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	Loading Dose		Not Reported
	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported
	Quinine			S	Oral	Three Times Daily		Not Reported
	Doxycycline			S	Oral	100 Milligram		Not Reported
	Atovaquone			S	Oral	750 Milligram		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17305808	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1006496		77 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Genital Ulceration; Pharyngeal Ulceration	Azithromycin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17305905	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003454			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lymphoma	Alendronic Acid Tablets	S	Oral	356 Milligram	Aurobindo
	Alendronic Acid Tablets	S			Aurobindo
	Azithromycin	S	Oral	250 Milligram	Aurobindo
	Azithromycin	S			Aurobindo
	Omalizumab	S	Subcutaneous	150 Milligram	Not Reported
	Ventolin	S	Unknown	8 Dosage Form	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Ciclesonide;Formoterol Fumarate	C	Unknown	Unk	Not Reported
	Montelukast	C	Unknown	Unk	Not Reported
	Spiriva	C	Unknown	Unk	Not Reported
	Symbicort Turbuhaler	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17306268	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-234261		84 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis	Amoxicillin			S	Oral	3 Grams,Daily		Sun
	Azithromycin			S	Oral	500 Milligrams, Daily		Sun

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jan-2020	17306900	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-003481			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Arthritis; Drug Hypersensitivity; Gait Disturbance; Inflammation; Musculoskeletal Pain; Pain In Extremity; Thyroid Cancer	Azithromycin			S	Unknown	Unk		Aurobindo
	Cefuroxime			S	Unknown	Unk		Aurobindo
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Tetracycline			S	Unknown	Unk		Not Reported
	Ibuprofen			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil			C		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2020	17307690	EXPEDITED (15-DAY)		HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-234159		58 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Myasthenia Gravis Crisis; Respiratory Failure	Azithromycin			S	Unknown	Unk		Sun		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2020	17307746	EXPEDITED (15-DAY)		OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-234005		25 YR	Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Pneumonia Cryptococcal; Treatment Noncompliance	Azithromycin			S	Unknown	Unk		Sun		
	Amoxicillin/Clavulanate			S	Unknown	Unk		Ranbaxy		
	Ceftriaxone			S	Unknown	Unk		Not Reported		
	Vancomycin Hydrochloride			S	Unknown	Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
23-Jan-2020	17308431	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US- 1171216		53 YR	Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Coeliac Disease; Haematochezia; Vomiting	Azithromycin			S	Unknown			Not Reported		
	Azithromycin			S				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
24-Jan-2020	16318325	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR- APL-2019-027435		39 YR	Female	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Quetiapine Film-Coated Tablet	S	Oral	100 Milligram, Once A Day	Aurobindo
	Quetiapine Film-Coated Tablet	S	Oral	25 Milligram, Two Times A Day	Aurobindo
	Ciprofloxacin Film-Coated Tablets	S	Unknown	Unk	Aurobindo
	Ciprofloxacin Film-Coated Tablets	S	Oral	500 Milligram, Once A Day	Aurobindo
	Azithromycin	S	Unknown	Unk	Aurobindo
	Amoxicillin	C	Unknown	Unk	Not Reported
	Risperidone	C	Unknown	Unk	Not Reported
	Valproate Semisodium	C	Unknown	Unk	Not Reported
	Zyprexa	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	16894605	NON-EXPEDITED			US-PFIZER INC-2019430401			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Cefpodoxime Proxetil			S		Unk		Pfizer
	Hydrocodone			S		Unk		Not Reported
	Levaquin			S		Unk		Not Reported
	Pramipexole Dihydrochloride			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	16950126	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-065183			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Package Associated Injury; Product Packaging Difficult To Open	Azithromycin 250 Mg Tablets Usp			S	Unknown	2 Dosage Form, Daily (First Day)		Aurobindo
	Azithromycin 250 Mg Tablets Usp			S	Unknown	1 Dosage Form, Daily (Each Day)		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17002255	NON-EXPEDITED			PHHY2019US187336		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Mass;	Lamprene			S	Oral	100 Mg, Qd		Novartis	
Abdominal Pain;	Lamprene			S				Novartis	
Abdominal Pain Lower;	Azithromycin			S	Oral	500 Mg, Qd		Not Reported	
Abscess; Granuloma;	Amikacin			S	Intravenous (not otherwise specified)	1200 Mg, (Monday, Wednesday And Friday)		Not Reported	
Muscle Spasms; Muscle Strain; Myalgia; Pruritus; Purulent Discharge; Vulvovaginal Mycotic Infection; Vulvovaginal Mycotic Infection	Primaxin			S	Intravenous (not otherwise specified)	500 Mg, Q12h (Monday, Wednesday And Friday)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17153639	EXPEDITED (15-DAY)		OT	JP-BAUSCH-BL-2019-065100		38 YR	Female	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Corneal Opacity	Mikelan La			S	Ophthalmic	Unknown Dose In Both Eyes		Bausch And Lomb	
	Azimycin			S	Ophthalmic	Unknown Dose In Both Eyes For About 3 Days		Not Reported	
	Chloramphenicol			C	Ophthalmic			Not Reported	
	Flumetholon			C	Ophthalmic			Not Reported	
	Hyalein			C	Ophthalmic			Not Reported	
	Glanatec			C	Ophthalmic			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17313784	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-106226			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration	Azithromycin 250 Mg Tablets			S	Unknown	Unk		Aurobindo	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Error	Usp								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17313797	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2019-070564		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gluten Sensitivity; Muscular Weakness	Azithromycin 250 Mg Tablets			S	Unknown	250 Milligram, Once A Day		Aurobindo	
	Usp								
	Prednisone			S	Unknown	1 Dosage Form		Not Reported	
	Allegra			C	Unknown	Unk		Not Reported	
	Mucinex			C	Unknown	Unk		Not Reported	
	Singular			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17315853	NON-EXPEDITED			US-PFIZER INC- 2020032522		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Malaise	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17315867	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS- 2020M1006920			Unknown	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Genital Ulceration; Pharyngeal Ulceration	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17317274	NON-EXPEDITED			US-PFIZER INC- 2020032509			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dysbiosis	Azithromycin		S			Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17317858	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020027115			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17317859	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020028983		7 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diplopia; Headache; Intracranial Pressure Increased; Papilloedema; Strabismus; Visual Acuity Reduced; Vith Nerve Paralysis	Zithromax			S	Oral	250 Mg, Alternate Day			Pfizer
	Symbicort Turbohaler			S	Respiratory (inhalation)	2 Df, 1x/Day			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17318218	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1007609		57 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection Susceptibility Increased; Lower Respiratory Tract Infection	Azithromycin			S		Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17318309	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2020M1007668		66 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Burning Sensation; Penile Ulceration; Pyrexia	Azithromycin			S	Unknown	1 G			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17318380	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1007743		54 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Blood Pressure Decreased; Diarrhoea; Drug Interaction; Hot Flush	Azithromycin			S		Unk		Not Reported	
	Omeprazole			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2020	17322920	DIRECT		HO			38 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Drug Hypersensitivity; Hypoaesthesia; Hypoaesthesia	Zithromax			S	Oral	Quantity:5 Tablet(S);		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2020	17226462	EXPEDITED (15-DAY)			FR-BAUSCH-BL-2019-066411		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Dermatitis; Drug Hypersensitivity	Tetracaine			S	Ophthalmic			Bausch And Lomb	
	Eylea			S	Other	Intravitreal Route		Not Reported	
	Azyter			S	Ophthalmic			Not Reported	
	Povidone Iodine			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Jan-2020	17400804	DIRECT	Y				75 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Azithromycin (Azithromycin 250mg Cap Pkt,6)			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lisinopril (Lisinopril 20mg Tab)

S

Oral

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	16080688	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-AUROBINDO-AUR-APL-2019-013806		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Pantoprazole			S	Intravenous (not otherwise specified)	8 Milligram, 1 Every 1 Hour(S)		Aurobindo
	Pantoprazole			S	Intravenous (not otherwise specified)	8 Milligram		Aurobindo
	Amiodarone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	10 Milligram, 1 Every 1 Hour(S)		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Milligram, Every Four Hour		Not Reported
	Diltiazem			S	Oral	180 Milligram		Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Milligram, Every Four Hour		Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Milligram, Every Four Hour		Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Milligram, 1 Every 6 Hours		Not Reported
	Adriamycin			S	Intravenous (not otherwise specified)	106 Milligram, 1 Every 14 Day(S)		Not Reported
	Enoxaparin			S	Subcutaneous	40 Milligram, Once A Day		Not Reported
	Furosemide			S	Oral	40 Milligram, Once A Day		Not Reported
	Hydralazine			S	Intravenous (not otherwise specified)	10 Milligram, 1 Every 6 Hours		Not Reported
	Hydralazine			S	Intravenous (not otherwise specified)	10 Milligram, Every Four Hour		Not Reported
Hydromorphone			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)		
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Milligram, Four Times/Day	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Milligram, Four Times/Day	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Milligram, Four Times/Day	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Unk, 1 Every 10 Minute(S)	Not Reported
Morphine	S	Intravenous (not otherwise specified)	1 Dosage Form	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Milligram, 1 Every 14 Day(S)	Not Reported
Pms Azithromycin	S	Intravenous (not otherwise specified)	500 Milligram, Once A Day	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Milligram, 1 Every 14 Days	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Milligram	Not Reported
Diltiazem	S	Oral	180 Milligram	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	0.25 Milligram, 1 Every 4 Hour	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Milligram, 1 Every 4 Hour	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Milligram, Once A Day	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Milligram, 1 Every 2 Weeks	Not Reported
Trastuzumab	S	Unknown	Unk	Not Reported
Ondansetron	C	Oral	8 Gram, Two Times A Day	Not Reported
Dexamethasone	C	Oral	20 Milligram, Once A Day	Not Reported
Metoclopramide	C	Oral	10 Milligram, Four Times/Day	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metoclopramide	C	Oral	10 Milligram	Not Reported
Gabapentin	C	Oral	100 Milligram, 3 Times A Day	Not Reported
Filgrastim	C	Subcutaneous	300 Microgram, Once A Day	Not Reported
Emend	C	Oral	125 Milligram, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	16081392	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012904		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Drug Level Increased; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Azithromycin			S	Oral	Unk		Aurobindo
	Ciprofloxacin			S	Oral	Unk		Aurobindo
	Montelukast			S	Oral	Unk		Aurobindo
	Pantoprazole Injection			S	Unknown	Unk		Aurobindo
	Pantoprazole Injection			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Voriconazole Tablet			S	Oral	Unk		Aurobindo
	Act Azithromycin			S	Unknown	Unk		Not Reported
	Apo Azithromycin			S	Oral	Unk		Not Reported
	Apo Montelukast			S	Oral	Unk		Not Reported
	Apo Mycophenolate			S	Oral	Unk		Not Reported
	Apo Sulfatrim			S	Oral	Unk		Not Reported
	Apo-Voriconazole			S	Oral	Unk		Not Reported
	Candidas			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Candidase			S	Unknown	Unk		Not Reported
	Cipro			S	Oral	Unk, Cyclical		Not Reported
	Mycophenolate Mofetil			S	Oral	Unk		Not Reported
	Nifedipine			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	Unk	Not Reported
Pms Azithromycin	S	Oral	Unk	Not Reported
Pms Azithromycin	S	Unknown	Unk	Not Reported
Pentamidine	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S	Oral	Unk	Not Reported
Sulfadiazine	S	Oral	Unk	Not Reported
Tacrolimus	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	16443899	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-033518		10 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatitis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma; Squamous Cell Carcinoma Of Skin	Ciprofloxacin			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Oral	Unk		Aurobindo
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Pantoprazole			S	Intravenous (not otherwise specified)	Unk		Aurobindo
	Apo Azithromycin			S	Oral	Unk		Not Reported
	Apo Mycophenolate			S	Oral	Unk		Not Reported
	Apo Montelukast			S	Oral	Unk		Not Reported
	Apo Sulfatrim			S	Oral	Unk		Not Reported
	Apo-Voriconazole			S	Oral	Unk		Not Reported
	Candidase			S	Unknown	Unk		Not Reported
	Cancidas			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Nifedipine			S	Oral	Unk		Not Reported
	Prednisone			S	Oral	Unk		Not Reported
	Tacrolimus			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	16843412	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-060957		25 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Mental Impairment; Product Substitution Issue	Pantoprazole			S	Oral	40 Milligram, Daily		Aurobindo
	Toviaz			S	Oral	4 Milligram, Daily		Not Reported
	Aczone			C	Topical	Unk		Not Reported
	Azithromycin			C	Unknown	500 Milligram, Daily		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Daily		Not Reported
	Benzaclin			C	Topical	Unk, Daily		Not Reported
	Nasocort			C	Nasal	55 Microgram, Two Times A Day		Not Reported
	Calcium			C	Oral	500 Milligram, 3 Times A Day		Not Reported
	Cipralex			S	Oral	Unk		Not Reported
	Constella			C	Oral	290 Microgram, Daily		Not Reported
	Omega 3-6-9			C	Oral	Unk		Not Reported
	Diclofenac			C	Unknown	Unk		Not Reported
	Ergocalciferol			C	Oral	2000 International Unit, Daily		Not Reported
	Flovent Hfa			C	Oral	250 Microgram, Two Times A Day		Not Reported
	Genteal			C	Ophthalmic	Unk		Not Reported
	Otrivin			C	Nasal	Unk Unk, Two Times A Day		Not Reported
	Tecta			C	Oral	40 Milligram, Daily		Not Reported
	Tears Plus			C	Ophthalmic	2 Gtt Drops, Cyclical		Not Reported
	Quetiapine Fumarate			C	Oral	25 Milligram, Two Times A Day		Not Reported
	Seroquel			C	Oral	100 Milligram, Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Epival	C	Oral	250 Milligram, 3 Times A Day	Not Reported
Synthroid	C	Oral	150 Microgram, Daily	Not Reported
Toviaz	C	Unknown	Unk	Not Reported
Tylenol	C	Oral	Unk Unk, 3 Times A Day	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Tylenol	C	Unknown	Unk	Not Reported
Zinc Gluconate	C	Unknown	50 Milligram, Daily	Not Reported
Zyloprim	C	Oral	100 Milligram, Daily	Not Reported
Cetaphil	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	16963259	EXPEDITED (15-DAY)		HO, OT	US-009507513-1910USA012296		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Granulomatosis With Polyangiitis; Product Use In Unapproved Indication	Primaxin I.V.			S		Unk		Merck	
	Amikacin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17173886	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2019542356		84 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dizziness; Oxygen Saturation Decreased; Pneumonia; Sedation; Somnolence	Azithromycin			S	Oral	500 Mg, Once Daily The First Day And Then 250 Mg (1 Tablet) Daily Days 2-5		Pfizer	
	Robitussin 12 Hour Cough Relief			C		10 Mg, 2x/Day		Not Reported	
	Robitussin 12 Hour Cough Relief			C				Not Reported	
	Robitussin 12 Hour Cough Relief			C				Not Reported	
	Wal Finate			C		60 Mg, As Needed (1 Tablet Every 4-6 Hours)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Claritin [Loratadine]			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17214144	NON-EXPEDITED			US-PFIZER INC-2019555610			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Detrol			S		Unk		Pfizer	
	Septra			S		Unk		Pfizer	
	Norvasc			S		Unk		Pfizer	
	Amlodipine Besilate			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Hydroxyzine Pamoate			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17323778	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-003777		57 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Blood Thyroid Stimulating Hormone Decreased; Drug Interaction; Dyspnoea; Panic Reaction; Self-Injurious Ideation	Amlodipine			S	Unknown	2.5 Milligram, Two Times A Day		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Micardis			S	Oral	80 Milligram, Once A Day		Not Reported	
	Synthroid			S	Unknown	Unk		Not Reported	
	Hydrochlorothiazide;Spironolactone			C	Unknown	Unk		Not Reported	
	Warfarin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17323840	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2019-073300			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin Tablets 500 Mg			S	Unknown	1 Dosage Form, Once A		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Usp
Azithromycin Tablets 500 Mg
Usp

S

Day

Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17323958	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-003794		21 DAY	Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaemia; Blood Lactic Acid Increased; Foetal Exposure During Pregnancy	Amlodipine Tablets			S	Transplacental	Unk		Aurobindo
	Azithromycin			S	Transplacental	Unk		Aurobindo
	Cefotaxime For Injection			S	Transplacental	Unk		Aurobindo
	Tenofovir			S	Transplacental	300 Milligram, Once A Day		Aurobindo
	Abacavir			S	Transplacental	Unk, Two Times A Day		Not Reported
	Intelence			S	Transplacental	200 Milligram, Two Times A Day		Not Reported
	Monopril			S	Transplacental	Unk		Not Reported
	Prezista			S	Transplacental	600 Milligram, Two Times A Day		Not Reported
	Ritonavir			S	Transplacental	100 Milligram, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17325243	EXPEDITED (15-DAY)		LT	IT-MYLANLABS- 2020M1010388		74 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Vancomycin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Cefepime			S	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17325841	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1008376		78 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Valaciclovir			S	Oral	1 Dosage Form, Qd		Not Reported
	Ramipril			S	Oral	Unk		Not Reported
	Imodium			S	Oral	Unk		Mylan
	Bactrim			S	Oral	3 Dosage Form, Qw		Mylan
	Kardegic			S	Oral	Unk		Mylan
	Tiorfan			S	Oral	Unk		Mylan
	Zithromax			S	Oral	Unk		Mylan
	Oflocet /00731801/			S	Oral	Unk		Mylan
	Retacrit /00928305/			S	Unknown	1 Dosage Form, Qw		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17326695	EXPEDITED (15-DAY)		HO	US-KOWA-20US000160			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Blood Loss Anaemia; Cardiac Failure; Dyspnoea; Hepatocellular Injury; Mental Status Changes; Pneumonia; Renal Impairment	Fenofibrate			S	Intravenous (not otherwise specified)	145 Mg, Qd		H2 Pharma
	Azithromycin			S		500 Mg, Qd		Not Reported
	Ceftriaxone			C		1 G, Qd		Not Reported
	Rosuvastatin			S		5 Mg, Qd		Not Reported
	Aspirin Ec			C		81 Mg, Qd		Not Reported
	Digoxin			C		125 Mg, Qd		Not Reported
	Donepezil			C		10 Mg, Qd		Not Reported
	Memantine			C		10 Mg, Bid		Not Reported
	Fluoxetine			C		40 Mg, Qd		Not Reported
	Latanoprost			C				Not Reported
	Metformin			C		500 Mg, Bid		Not Reported
	Glipizide			C		15 Mg, Bid		Not Reported
	Rivaroxaban			C		15 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cholecalciferol	C		5000 Iu, Qd	Not Reported
Hydrocodone	C	Oral	Unk	Not Reported
Acetaminophen	C	Oral	325 Mg, Qid	Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	4.5 G	Not Reported
Piperacillin & Tazobactam	C		3.375 G, Tid	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	3000 Mg	Not Reported
Vancomycin	C		1500 Mg, Qd	Not Reported
Furosemide	C	Intravenous (not otherwise specified)	40 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17328462	EXPEDITED (15-DAY)		HO	NL-MYLANLABS-2020M1009063		20 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Hypersensitivity; Pharyngeal Swelling; Swollen Tongue	Azithromycin			S	Oral	1e Dag 2 Tegelijk, Daarna 1 Keer Per Dag 1 Tablet		Not Reported
	Microgynon /00022701/			C		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17328945	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1008620		44 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Eosinophilic Pneumonia	Azithromycin			S		Unk		Not Reported
	Amoxicillin/Clavulanic Acid			S		Unk		Not Reported
	Rupatadine			C		Unk		Mylan
	Bromazepam			C		Unk		Mylan
	Venlafaxine			C		Unk		Mylan

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2020	17328980	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1008633		52 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Synovial Sarcoma	Azithromycin			S				Not Reported	
	Meropenem			S				Mylan	
	Ceftriaxone			S				Mylan	
	Rifampicin			S				Mylan	
	Ethambutol			S				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	14262874	EXPEDITED (15-DAY)		OT	CA-APOTEX-2017AP022147		28 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Pneumonia; Vomiting	Azithromycin			S	Unknown	500 Mg, Qd		Apotex	
	Cefprozil			S	Oral	500 Mg, Bid		Apotex	
	Doxycycline			S	Oral	100 Mg, Bid		Apotex	
	Ceftriaxone			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	672 Mg, 1 Every 8 Week		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	10 Mg/Kg, 1 Every 8 Week		Not Reported	
	Pms Azithromycin			S	Unknown	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	15691852	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20181138322			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease;	Benadryl			S	Unknown			Not Reported	
	Simponi			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rheumatoid Arthritis; Treatment Failure	Cimzia	S	Unknown	Not Reported
	Demerol	S	Unknown	Not Reported
	Enbrel	S	Unknown	Not Reported
	Humira	S	Unknown	Not Reported
	Imuran	S	Unknown	Not Reported
	Celebrex	S	Oral	Not Reported
	Methotrexate	S	Unknown	Not Reported
	Plaquenil	S	Unknown	Not Reported
	Pms Azithromycin	S	Unknown	Not Reported
	Procytox	S	Unknown	Not Reported
	Arava	S	Unknown	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Xeljanz	S	Oral	Not Reported
	Levofloxacin	S	Unknown	Not Reported
	Ezetrol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	16443922	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-033231		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation	Azithromycin			S	Oral	250 Milligram		Aurobindo
	Azithromycin			S	Oral	3 Dosage Form		Aurobindo
	Amlodipine Tablets			S	Oral	10 Milligram, Once A Day		Aurobindo
	Amlodipine Tablets			S	Oral	1 Dosage Form, Once A Day		Aurobindo
	Xolair			S	Subcutaneous	225 Milligram		Not Reported
	Advair			C	Unknown	1 Dosage Form, Two Times A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Sputum Discoloured	Asa	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Brilinta	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Hydrochlorothiazide	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Pantoprazole	C	Unknown	Unk	Not Reported
	Singulair	C	Oral	1 Dosage Form, Once A Day	Not Reported
	Spiriva	C	Other	1 Dosage Form, Once A Day	Not Reported
	Ventolin	C	Other	2 Dosage Form	Not Reported
	Mylan Pantoprazole	C	Oral	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17008029	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-226763		60 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Haematochezia; Vomiting	Azithromycin			S	Oral	1 Dosage Form, Daily		Sun	
	Losartan			C	Unknown	()		Not Reported	
	Potassico/Ildroclorotiazide								
	Anastrozole			C	Unknown	()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17286032	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR- APL-2020-002521		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Myasthenia Gravis Crisis	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Flagyl			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17303458	EXPEDITED (15-DAY)		OT	CH-009507513-2001CHE007028		37 YR	Female	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Premenstrual Syndrome	Orgalutran			S	Subcutaneous	0.25 Mg In Total		Merck
	Puregon [Follitropin Beta]			S		Unk		Merck
	Puregon [Follitropin Beta]			S				Merck
	Gonal-F			S	Subcutaneous	30 International Unit In Total		Not Reported
	Gonal-F			S	Subcutaneous	Unk		Not Reported
	Decapeptyl (Triptorelin Acetate)			S	Subcutaneous	0.1 Milligram In Total		Not Reported
	Decapeptyl (Triptorelin Acetate)			S	Subcutaneous	0.1 Milligram In Total		Not Reported
	Azithromycin			S		1 Gram, In Total		Not Reported
	Ethinyl Estradiol (+) Levonorgestrel			S		1 Dosage Form, Ingredient (Ethinylestradiol): 0.02mg; Ingredient (Levonorgestrel): 0.1 Mg		Not Reported
	Menopur			S		Unk		Not Reported
	Merional			S		Unk		Not Reported
	Cetrotide			S		Unk		Not Reported
	Trazodone Hydrochloride			C		Unk		Not Reported
	Trazodone Hydrochloride			C		Unk		Not Reported
	Zoloft			C		Unk		Not Reported
	Dalmadorm			C		Unk		Not Reported
	Imovane			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17332237	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1176106		70 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Pressure Systolic Increased; Cough; Dizziness; Drug Ineffective; Dyspnoea; Epistaxis; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Headache; Lung Disorder; Malaise; Nasopharyngitis; Oxygen Saturation Decreased; Sputum Discoloured	Amlodipine Besilate	S	Oral	1 Dosage Forms Daily;	Barr
	Azithromycin	S	Oral	3 Dosage Form	Pliva
	Omalizumab	S	Subcutaneous		Not Reported
	Omalizumab	S	Subcutaneous		Not Reported
	Brilinta	C	Oral	1 Dosage Forms Daily;	Not Reported
	Advair	C	Oral		Not Reported
	Asa	C	Oral	1 Dosage Forms Daily;	Not Reported
	Hydrochlorothiazide	C	Oral	1 Dosage Forms Daily;	Not Reported
	Pantoprazole	C	Oral	1 Dosage Forms Daily;	Not Reported
	Pantoprazole	C	Oral	1 Dosage Forms Daily;	Not Reported
	Singulair	C	Oral	1 Dosage Forms Daily;	Not Reported
	Spiriva	C	Other	1 Dosage Forms Daily;	Not Reported
	Ventolin [Salbutamol]	C	Other		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17333522	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00316		23 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Beta Haemolytic Streptococcal Infection; Exposure During Pregnancy	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram (2 G Q6 X 48 Hours)		Lupin
	Betamethasone			S	Unknown	Unk		Not Reported
	Magnesium Sulfate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ampicillin			S	Intravenous (not otherwise specified)	2 Gram (2 G Q6 X 48 Hours)		Not Reported
	Ampicillin			S	Oral	Unk		Not Reported
	Erythromycin			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17334094	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS,I		60 YR	Male	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

NC./RIDGEFIELD-2020-
BI-00

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Parainfluenzae Virus Infection; Pneumonia	Combivent			S	Unknown			Boehringer Ingelheim
	Spiriva			S	Unknown			Boehringer Ingelheim
	Asa			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Daxas			S	Unknown			Not Reported
	Mepolizumab			S	Subcutaneous			Not Reported
	Mepolizumab Symbicort Turbuhaler			S	Unknown	Powder		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17334420	EXPEDITED (15-DAY)		CA, DE, HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00387			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Septal Defect; Escherichia Sepsis; Foetal Exposure During Pregnancy; Group B Streptococcus Neonatal Sepsis; Low Birth Weight Baby; Patent Ductus Arteriosus; Pneumonia Escherichia; Premature Baby; Pulmonary Hypertension; Respiratory Distress	Azithromycin			S	Transplacental	500 Milligram (2 G Q6 X 48 Hours)		Lupin
	Betamethasone			S	Transplacental	Unk		Not Reported
	Magnesium Sulfate			S	Transplacental	Unk		Not Reported
	Ampicillin			S	Transplacental	2 Gram (2 G Q6 X 48 Hours)		Not Reported
	Ampicillin			S	Transplacental	Unk		Not Reported
	Erythromycin			S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jan-2020	17338707	DIRECT	Y					Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Cefdinir 300mg			S			10 DAY	Not Reported
	Azithromycin 500mg			S		500mg, Day 1 Then 250 Mg Days 2-5		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	8339787	EXPEDITED (15-DAY)		HO, OT	PHHY2012PT002059		78 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
C-Reactive Protein Increased; Condition Aggravated; Epidermal Necrosis; Hyperplasia; Neutrophil Function Disorder; Papule; Rash Erythematous; Red Blood Cell Sedimentation Rate Increased; Skin Burning Sensation; Skin Erosion; Skin Exfoliation; Skin Oedema; Toxic Skin Eruption; Vulvovaginal Candidiasis	Fluorouracil			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Cyclophosphamide			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	15425208	EXPEDITED (15-DAY)		CA, DS, HO, OT	PHHY2018LV103112			Female	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anal Atresia; Duodenal Atresia; Female Genital Tract Fistula; Foetal Exposure During Pregnancy; Oesophageal Atresia; Respiratory Distress; Spine Malformation	Azithromycin			S	Transplacental	Maternal Dose: 500mg Qd		Novartis
	Cefuroxime			S	Transplacental	Maternal Dose: 1500 Mg, Bid		Not Reported
	Paracetamol			S	Transplacental	500 Mg, Bid		Not Reported
	Iron			S	Transplacental	Unk		Not Reported
	Penicillin G Benzathine			S	Transplacental	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ferinject	S	Transplacental	Maternal Dose: 50mg/MI	Not Reported
	Venofer	S	Transplacental	Maternal Dose: 100mg	Not Reported
	Maltofer (Ferric Hydroxide Polymaltose Complex)	S	Transplacental		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	16215930	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2019-CA-1039373		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Azithromycin			S	Unknown			Not Reported
	Quetiapine Fumarate			S	Oral	50 Milligram Daily;		Teva
	Quetiapine Fumarate			S		100 Milligram Daily;		Teva
	Ciprofloxacin			S	Oral	500 Milligram Daily;		Not Reported
	Ciprofloxacin			S				Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Amoxicillin			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported
	Valproate Semisodium			C	Unknown			Not Reported
	Zyprexa			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17163662	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2019543047		58 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; General Physical Health Deterioration; Pyrexia	Azithromycin			S		Unk		Pfizer
	Furadantine			S		Unk		Not Reported
	Tavanic			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17257157	EXPEDITED (15-DAY)			US-INSMED, INC.-US-INS-19-03591			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Infection; Cough; Headache; Oral Mucosal Blistering; Sputum Decreased	Arikayce			S	Respiratory (inhalation)			Insmed
	Arikayce			S	Respiratory (inhalation)			Insmed
	Lamira Nebulizer System			S				Insmed
	Ethambutol			S				Not Reported
	Rifabutin			S				Not Reported
	Azithromycin			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17336274	EXPEDITED (15-DAY)		DE, HO, LT, OT	DE-MYLANLABS-2020M1010441			Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Autoimmune Hepatitis; Brain Abscess; Iris Adhesions; Multiple Allergies; Pancytopenia; Pneumonia; Rash; Sepsis; Toxic Epidermal Necrolysis	Levetiracetam			S	Unknown	1000 Df, Qd (1000 Absent, Qd)		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Nivolumab			S	Intravenous (not otherwise specified)	1 Mg/Kg, Q3cycles		Mylan
	Novalgine /06276704/			S	Unknown	Unk		Mylan
	Ipilimumab			S	Intravenous (not otherwise specified)	3 Mg/Kg (Q3cycles)		Mylan
	Ranitidine			C	Unknown	300 Mg, Qd		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17337155	EXPEDITED (15-DAY)		HO, OT	NVSC2020PT004039		72 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatosis; Erythema; Malaise; Pharyngeal Enanthema; Pruritus; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Novartis

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17337261	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2020-004147		62 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Eye Swelling; Impaired Healing; Knee Operation; Lip Swelling; Urticaria	Metformin			S	Oral	500.0 Milligram, Two Times A Day		Aurobindo	
	Pms Azithromycin			S	Oral	250.0 Milligram		Not Reported	
	Rabeprazole			S	Oral	20 Milligram		Not Reported	
	Supeudol			S	Oral	5 Milligram		Not Reported	
	Supeudol			S	Unknown	Unk		Not Reported	
	Tamsulosin Hydrochloride			S	Oral	0.4 Milligram		Not Reported	
	Tobramycin			S	Unknown	0.3 Percent		Not Reported	
	Aerius			C	Unknown	Unk		Not Reported	
	Amlodipine			C	Unknown	Unk		Not Reported	
	Camphor;Cinchocaine Hydrochloride;Diphenhydramine; Enoxolone;Levomenol			C	Unknown	Unk		Not Reported	
	Cozaar			C	Unknown	Unk		Not Reported	
	Hydroxyzine Hydrochloride			C	Unknown	Unk		Not Reported	
	Tylenol			C	Unknown	Unk		Not Reported	
	Zantac			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17339538	NON-EXPEDITED			US-APOTEX-2019AP011809			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Dyspnoea; Heart Rate Increased; Rash	Paxil			S	Unknown	Unk		Apotex	
	Azithromycin			S	Unknown	Unk		Apotex	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17339742	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2020036071		3 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypothermia	Zithromax			S	Oral	1 Df, Daily (1 X 3 Days Child)		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17343685	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020033276		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Ceftriaxone Sodium			S				Pfizer	
	Ceftriaxone Sodium			S				Pfizer	
	Ceftriaxone Sodium			S				Pfizer	
	Vancomycin Hcl			S	Intravenous (not otherwise specified)	Unk		Unknown	
	Vancomycin Hcl			S				Unknown	
	Vancomycin Hcl			S				Unknown	
	Vancomycin Hcl			S				Unknown	
	Oxygen			S	Nasal	5 L, Unk		Not Reported	
	Oxygen			S	Nasal	Unk Supplemental Oxygen By Nasal Cannula)		Not Reported	
	Oxygen			S				Not Reported	
	Oxygen			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17344023	EXPEDITED (15-DAY)		HO	NVSC2020DE018647			Female	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Cardiovascular Disorder; Chills; Dehydration; Diarrhoea; Nausea	Azithromycin 500 - 1 A Pharma			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Jan-2020	17345866	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC- 2020036019		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Ibuprofen			S	Oral	600 Mg, 4x/Day (Every 6 Hours) (1-1-1-1)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17347211	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2020-004017		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Pneumonia; Hypoxia; Metabolic Alkalosis; Procalcitonin Increased; Respiratory Alkalosis	Azithromycin			S	Unknown	Unk		Aurobindo	
	Prednisone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17350369	EXPEDITED (15-DAY)		OT	NL-AMNEAL PHARMACEUTICALS- 2020-AMRX-00280		7 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Marrow Failure; Hepatotoxicity;	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Milligram/Kilogram, Daily In 2 Doses		Amneal	
Hypertriglyceridaemia; Nausea; Toxic Skin Eruption; Vomiting	Tigecycline			S	Topical	5 Mg/ML, 3 Drops Tid		Amneal	
	Azithromycin			S	Oral	10 Milligram/Kilogram, Qd		Amneal	
	Azithromycin			S				Amneal	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imipenem And Cilastatin	S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2 To 4 Doses	Not Reported
Imipenem And Cilastatin	S	Topical	5/5 Mg/ML; 3 Drops Tid	Not Reported
Clofazimine	C	Oral	Unk	Not Reported
Clofazimine	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17351002	EXPEDITED (15-DAY)		DS, OT	CA-TEVA-2020-CA-1176469		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Azithromycin			S	Unknown			Not Reported
	Ciprofloxacin			S	Unknown			Not Reported
	Ciprofloxacin			S	Oral	500 Milligram Daily;		Not Reported
	Quetiapine Fumarate			S	Oral	50 Milligram Daily;		Teva
	Amoxicillin			C	Unknown			Not Reported
	Risperidone			C	Unknown			Not Reported
	Valproate Semisodium			C	Unknown			Not Reported
	Zyprexa			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17351088	EXPEDITED (15-DAY)		OT	HR-TEVA-2020-HR-1177115		31 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Localised Oedema; Swollen Tongue; Urticaria	Sumamed			S	Unknown			Not Reported
	Klavocin			S	Unknown			Teva

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17351262	EXPEDITED (15-DAY)		OT	US-ZYDUS-046894		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Overgrowth Fungal	Azithromycin	S	Unknown	Zydus Pharm
	Prednisone	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17351964	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-00		52 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Chest Discomfort; Cough; Dyspnoea; Malaise; Oropharyngeal Pain; Therapeutic Product Effect Incomplete	Spiriva			S	Respiratory (inhalation)			Boehringer Ingelheim
	Azithromycin			S	Unknown			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Symbicort Turbuhaler			S	Respiratory (inhalation)	Dosage Form: Powder		Not Reported
	Zenhale			S	Unknown	Dosage Form: Aerosol, Metered Dose		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2020	17352025	NON-EXPEDITED		OT	US-AMNEAL PHARMACEUTICALS- 2019-AMRX-03345			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Reaction; Dyspnoea	Azithromycin			S	Unknown	Unk		Amneal

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2020	16694465	EXPEDITED (15-DAY)		CA, HO, OT	US-VIIV HEALTHCARE LIMITED- BW2019GSK146248			Unknown	BWA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Exomphalos; Foetal Exposure During Pregnancy; Premature Baby	Dolutegravir			S	Transplacental	Unk		Viiv
	Viread			S	Transplacental	Unk		Glaxosmithkline
	Iron Sulphate			S	Transplacental	Unk		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Folate	S	Transplacental	Unk		Glaxosmithkline
	Ceftriaxone	S	Transplacental	Unk Unk, Single		Glaxosmithkline
	Azithromycin	S	Transplacental	Unk Unk, Single		Glaxosmithkline
	Metronidazole	S	Transplacental	Unk Unk, Single		Glaxosmithkline
	Emtriva	S	Transplacental	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2020	17262359	NON-EXPEDITED			US-PFIZER INC-2020013249		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Novocain			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2020	17352462	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-235035		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Ibuprofeno (1769a)			S	Oral	1-1-1-1		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2020	17356070	EXPEDITED (15-DAY)		HO, OT	US-GLAXOSMITHKLINE-B0477588A			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Dermatitis Bullous; Dermatitis Bullous;	Zanamivir			S	Unknown			Glaxosmithkline	
Dysphagia; Erythema;	Rimantadine			S	Unknown			Not Reported	
Erythema Of Eyelid; Eyelid Oedema; Genital Erosion;	Azithromycin			S	Unknown			Glaxosmithkline	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Linear Iga Disease; Mouth Swelling; Odynophagia; Oral Mucosa Erosion; Rash Papular; Respiratory Disorder

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2020	17356632	EXPEDITED (15-DAY)		HO	CA-ASTRAZENECA-2020SE15572		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma	Ciclesonide			S	Respiratory (inhalation)	400.0ug Unknown		Not Reported	
	Symbicort Turbuhaler			S	Respiratory (inhalation)	4 Df Unknown Unknown		Astrazeneca	
	Zithromax			S	Unknown	Unknown		Not Reported	
	Atrovent			S	Unknown			Not Reported	
	Rupatadine Fumarate			S	Unknown	Unknown		Not Reported	
	Salbutamol			S	Respiratory (inhalation)	100.0ug Unknown		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unknown		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2020	17358419	EXPEDITED (15-DAY)		OT	US-EMCURE PHARMACEUTICALS LTD-2020-EPL-0098		57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	Single Dose Of 4 Mg Iv		Emcure	
	Tacrolimus			S				Heritage	
	Sulfamethoxazole, Trimethoprim			S				Heritage	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2020	17358584	EXPEDITED (15-DAY)		OT	US-EMCURE PHARMACEUTICALS		38 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

LTD-2020-EPL-0101

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged	Ondansetron			S	Intravenous (not otherwise specified)	4 Milligram, Single Dose Of 4 Mg Iv		Emcure
	Tacrolimus			S		Unk		Heritage
	Sulfamethoxazole, Trimethoprim			S		Unk		Heritage
	Prochlorperazine Edisylate			S		Unk		Emcure
	Azithromycin			S		Unk		Not Reported
	Levalbuterol /01419301/			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2020	17359049	EXPEDITED (15-DAY)		OT	LV-TEVA-2020-LV- 1177316		29 YR	Female	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Paraesthesia Oral; Rash; Rash Pruritic	Sumamed 500 Mg Apvalkotas Tabletes			S	Oral	500 Mg		Not Reported
	Pulmicort 0,5 Mg/MI Suspensija Izsmidzinasanai			C	Respiratory (inhalation)			Not Reported
	Xyzal 5 Mg Apvalkotas Tabletes			C	Oral	5 Mg		Not Reported
	Xyzal 5 Mg Apvalkotas Tabletes			C				Not Reported
	Ventolin 5 Mg/MI Skidums Izsmidzinasanai			C	Respiratory (inhalation)			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	6461815	EXPEDITED (15-DAY)		OT	GB-RANBAXY-2007RR- 10189			Unknown	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Arthropathy; Blood Creatinine Increased;	Anadin (Ibuprofen)			S	Unknown	Unk		Not Reported
	Anadin (Ibuprofen)			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Blood Urea Increased; Creatinine Renal Clearance Decreased;	Tobramycine Rpg 25mg/2.5ml Solution Injectable	S	Intravenous (not otherwise specified)	8 Mg/Kg, Qd	Sun
Drug Interaction;	Tobramycine Rpg 25mg/2.5ml Solution Injectable	S			Sun
Dyspepsia; Hypophagia; Influenza Like Illness; Off Label Use; Polyarthritis; Vomiting; Weight Decreased	Azithromycine Ranbaxy 250 Mg Comprime Pellicule	S		Unk	Sun
	Colomycin (Colistimethate Sodium)	S	Intravenous (not otherwise specified)	2 Miu, Tid	Not Reported
	Colomycin (Colistimethate Sodium)	S			Not Reported
	Colomycin (Colistimethate Sodium)	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2020	17360515	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2020AMR016587			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Localised Infection	Benlysta			S		Unk (Dose Used: 550)		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2020	17362239	EXPEDITED (15-DAY)		OT	CH-FERRINGPH- 2020FE00442		37 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Influenza Like Illness; Premenstrual Syndrome; Product Use In Unapproved Indication	Decapeptyl (Triptorelin Acetate)			S	Subcutaneous	0.1 Mg, Once/Single		Not Reported	
	Decapeptyl (Triptorelin Acetate)			S	Subcutaneous	0.1 Mg, Once/Single		Not Reported	
	Menopur			S	Unknown	225 Iu		Ferring	
	Gonal-F			S	Subcutaneous	225 Iu		Not Reported	
	Gonal-F			S	Subcutaneous	10 Injections Of 30 Iu		Not Reported	
	Orgalutran			S	Subcutaneous	5 Injections Of 0.25 Mg		Not Reported	
	Azithromycine			S	Unknown	1 G		Not Reported	
	Levonorgestrel + Etinilestradiol			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Puregon [Follitropin Beta]	S	Unknown	225 Iu	Not Reported
Merional	S	Unknown	225 Iu For 10 Days	Not Reported
Cetrotide [Cetrorelix]	S	Unknown	Unk	Not Reported
Trazodone	C		Unk	Not Reported
Trazodone	C		Unk	Not Reported
Zoloft	C		Unk	Not Reported
Dalmadorm	C		Unk	Not Reported
Imovane	C		Unk	Not Reported
Gabapentine	C		Unk	Not Reported
Gabapentine	C			Not Reported
Vitex Agnus-Castus	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2020	17363170	NON-EXPEDITED			NVSC2020US027241			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Incorrect Dose Administered	Azithromycin 250 Mg			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2020	17367806	DIRECT					41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Diarrhoea;	Azithromycin 250mg Tablets			S	Oral	Quantity:6 Tablet(S);Other		Not Reported
Gastrooesophageal Reflux Disease; Nausea; Pruritus; Tachycardia	Labetalol			C		Frequency:2x Day 1;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	13570920	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2017-34280		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain; Biopsy	Cefixime	S	Unknown	Unk, Single Course	Aurobindo
Colon Abnormal; Blood	Ciprofloxacin	S	Oral	Unk	Aurobindo
Pressure Decreased; C-Reactive Protein	Moxifloxacin	S	Unknown	Unk	Aurobindo
Increased; Diarrhoea;	Azithromycin	S	Unknown	Unk, Single Course	Aurobindo
Dysbiosis; Enteritis;	Azithromycin	S	Unknown	Unk	Aurobindo
Frequent Bowel	Pms Azithromycin	S	Unknown	Unk	Not Reported
Movements;	Pms Azithromycin	S			Not Reported
Gastroenteritis	Pms Azithromycin	S			Not Reported
Staphylococcal;		S			Not Reported
Gastrointestinal Mucosa					
Hyperaemia;					
Haematochezia; Heart					
Rate Increased; Nausea;					
Purulence; Staphylococcal					
Infection; Weight					
Decreased					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	14032210	NON-EXPEDITED			US-PFIZER INC-2017424076		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	16177694	EXPEDITED (15-DAY)		HO, OT	DE-AUROBINDO-AUR-APL-2019-017226		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Transitional Cell Carcinoma	Fluconazole Puren Capsules			S	Unknown	Unk		Aurobindo	
	Hard			S	Unknown	Unk		Aurobindo	
	Valsartan-Comp Puren Film-Coated Tablet			S	Unknown	Unk		Aurobindo	
	Valsartan+Hydrochlorothiazide Film-Coated Tablet			S	Unknown	Unk		Aurobindo	
	Cefpodoxime Film-Coated Tablets			S	Unknown	Unk		Aurobindo	
	Lercanidipine Film-Coated			S	Unknown	Unk		Not Reported	

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Pantoprazole	S	Unknown	Unk	Aurobindo
Moronal	S	Unknown	Unk	Not Reported
Ibu 1a Pharma	S	Unknown	Unk	Not Reported
Ciprofloxacin Al	S	Unknown	Unk	Not Reported
Azithromycin 1a Pharma	S	Unknown	Unk	Not Reported
Roxithromycin	S	Unknown	Unk	Not Reported
Ibuflam [Ibuprofen]	S	Unknown	Unk	Not Reported
Linola H Fett N	S	Unknown	Unk	Not Reported
Lercanidipin Omniapharm	S	Unknown	Unk	Not Reported
Decortin H	S	Unknown	Unk	Not Reported
L-Thyrox Hexal	S	Unknown	Unk	Not Reported
Doxagamma	S	Unknown	Unk	Not Reported
Ampicillin Ratiopharm	S	Unknown	Unk	Not Reported
Valsartan Ratiopharm Comp	S	Unknown	Unk	Not Reported
Spironolacton Aristo	S	Unknown	Unk	Not Reported
Eferox	S	Unknown	Unk	Not Reported
Ciprofloxacin Aristo	S	Unknown	Unk	Not Reported
Euthyrox	S	Unknown	Unk	Not Reported
Ampho Moronal	S	Unknown	Unk	Not Reported
Alfason Crelo	S	Unknown	Unk	Not Reported
Mometahexal	S	Nasal	Unk	Not Reported
Pantoprazol Pensa	S	Unknown	Unk	Not Reported
Hct Hexal	S	Unknown	Unk	Not Reported
Cotrimoxazol Al	S	Unknown	Unk	Not Reported
Clindamycin Al	S	Unknown	Unk	Not Reported
Valsacor Comp	S	Unknown	Unk	Not Reported
Novaminsulfon	S	Unknown	Unk	Not Reported
Hygroton	S	Unknown	Unk	Not Reported
Flumetasone/Clioquinol	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefpo	S	Unknown	Unk	Not Reported
Cefpo	S	Unknown	Unk	Not Reported
Clindasol [Clindamycin Hydrochloride]	S	Unknown	Unk	Not Reported
Cefpodoxim Hexal	S	Unknown	Unk	Not Reported
Cefpodoxim Hexal	S	Unknown	Unk	Not Reported
Valsartan Hexal Comp	S	Unknown	Unk	Not Reported
Clinda-Saar	S	Unknown	Unk	Not Reported
Valsartan 1a Pharma Plus	S	Unknown	Unk	Not Reported
Doxazosin-1 A Pharma	S	Unknown	Unk	Not Reported
Codeintropfen Ct	S	Unknown	Unk	Not Reported
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Not Reported
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Not Reported
Nebivolol Actavis	S	Unknown	Unk	Not Reported
Monuril	S	Unknown	Unk	Not Reported
Doxycyclin 1a Pharma	S	Unknown	Unk	Not Reported
Cotrim Forte	S	Unknown	Unk	Not Reported
Lonolox	S	Unknown	Unk	Not Reported
Valsartan Hexal	S	Unknown	Unk	Not Reported
Valsartan Hexal	S	Unknown	Unk	Not Reported
Dolgit	S	Unknown	Unk	Not Reported
Rasilez	S	Unknown	Unk	Not Reported
Rasilez	S			Not Reported
ClindaHexal	S	Unknown	Unk	Not Reported
Cipro	S	Unknown	Unk	Not Reported
Locacorten Vioform	S	Unknown	Unk	Not Reported
Eutirox	S	Unknown	Unk	Not Reported
Cefpodoxime Proxetil	S	Unknown	Unk	Not Reported
Ciprofloxacin	S	Unknown	Unk	Not Reported
Cotrimox Forte	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clioquinol;Flumetasone	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	S	Unknown	Unk	Not Reported
Levothyroxine	S	Unknown	Unk	Not Reported
Lercanidipine Ratiopharm	S	Unknown	Unk	Not Reported
Valsartan Comp	S	Unknown	Unk	Not Reported
Clindamycin Hydrochloride	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	16924017	EXPEDITED (15-DAY)		LT, OT	PHHY2019BR191050			Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Miflasone			S	Unknown	200 Ug, Unk (60 Cs) (1-3		Not Reported
Agitation; Allergy To						Times A Day)		
Chemicals; Anxiety;	Miflasone			S	Unknown	400 Ug, Bid (60 Cs)		Not Reported
Asthma; Asthmatic Crisis;	Miflasone			S	Unknown	50 Ug		Not Reported
Blood Pressure Increased;	Miflonide			S	Unknown	Unk		Novartis
Bronchitis; Cardiovascular	Beclomethasone Dipropionate			S	Unknown	Unk		Not Reported
Disorder; Collateral	Clenil Pulvinal			S	Unknown	Unk		Not Reported
Circulation; Constipation;	Fluticasone			S	Unknown	Unk		Not Reported
Cough; Depression; Drug	Aerocort			S	Unknown	Unk		Not Reported
Hypersensitivity; Drug	Alenia (Budesonide\Formoterol			S	Unknown	Unk		Not Reported
Intolerance; Dysphagia;	Fumarate)							
Extrapyrimaldal Disorder;	Flixotide			S	Endocervical	50 Ug		Not Reported
Fatigue; Feeling	Flixotide			S	Endocervical	200 Unk		Not Reported
Abnormal; Food	Plasil			S	Unknown	Unk		Not Reported
Poisoning; Gastric	Rilan [Cromoglicate Sodium]			S	Unknown	Unk		Not Reported
Disorder; Headache;	Azithromycin			S	Unknown	Unk		Not Reported
Hypersensitivity	Clenil			S	Unknown	Unk		Not Reported
Pneumonitis; Influenza;								
Lung Disorder; Malaise;								
Muscle Disorder; Muscle								
Spasms; Muscular								
Weakness;								
Musculoskeletal								
Discomfort;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Myalgia; Nervous System Disorder; Oropharyngeal Discomfort;	Fostair	C	Unknown	Unk	Not Reported
Oropharyngeal Pain; Pain; Pneumonitis; Reflux	Aspirin	C	Unknown		Not Reported
Gastritis; Renal Disorder; Sinusitis; Tinnitus; Urinary Tract Infection; Weight Increased; Wheezing	Beclometasone Propionate	C	Unknown		Not Reported
	Seretide	C	Unknown	Unk	Not Reported
	Atrovent	C	Unknown	Unk	Not Reported
	Alvesco	C	Unknown	Unk (10 Years Ago)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	16929994	EXPEDITED (15-DAY)			CA-PFIZER INC- 2019448940		6 DAY	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyperbilirubinaemia Neonatal; Incorrect Route Of Product Administration	Zithromax			S	Intravenous (not otherwise specified)	6.4 Mg, 1x/Day		Pfizer
	Dopamine Hcl			C		Unk		Not Reported
	Fluconazole			C		Unk		Not Reported
	Hydrocortisone			C		Unk		Not Reported
	Ibuprofen			C		Unk		Not Reported
	Insulin			C		Unk		Not Reported
	Linezolid			C		Unk		Not Reported
	Morphine			C		Unk		Not Reported
	Piperacillin / Tazobactam			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	16953136	EXPEDITED (15-DAY)		OT	NL-PFIZER INC- 2019453422		9 YR	Female	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthropathy; Fatigue; Hepatotoxicity; Nausea; Off Label Use; Product Use In Unapproved	Azithromycin			S	Oral	10 Mg/Kg, Daily		Pfizer
	Azithromycin			S				Pfizer
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg, Daily (In 2 Doses)		Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Indication; Vomiting	Tigecycline	S	Intravenous (not otherwise specified)	Unk, Daily (60/60 Mg/Kg/Day In 2-4 Doses)	Pfizer
	Imipenem/Cilastatin	S			Not Reported
	Imipenem/Cilastatin	S	Topical	Unk, 3x/Day (5/5 Mg/ML; Three Drops)	Not Reported
	Imipenem/Cilastatin	S			Not Reported
	Imipenem/Cilastatin	S	Topical	Unk, 3x/Day (Three Drops)	Not Reported
	Tigecycline	S			Not Reported
	Tigecycline	S	Oral	Unk, 1x/Day (50mg Once Daily; If Weight >40kg, Then 100mg Once Daily)	Not Reported
	Clofazimine	S			Not Reported
	Clofazimine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	16957123	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2019447286		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Hepatotoxicity; Hypertriglyceridaemia; Nausea; Vomiting	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg, Daily In 2 Doses		Pfizer
	Azithromycin			S	Oral	10 Mg/Kg, 1x/Day		Pfizer
	Imipenem/Cilastatin			S	Topical	5/5 Mg/ML; Three Drops Three Times Daily		Not Reported
	Imipenem/Cilastatin			S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses		Not Reported
	Tigecycline			S	Topical	5 Mg/ML; Three Drops Three Times Daily		Not Reported
	Clofazimine			S	Oral	50mg Once Daily; If Weight >40kg, Then 100mg Once Daily)		Not Reported
	Minocycline			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17225892	EXPEDITED (15-DAY)		HO, LT, OT	GB-TAKEDA-2019TEU016041		97 YR	Female	GBR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Interaction; Erythema; Eye Irritation; Eye Pain; Eye Swelling; Genital Burning Sensation; Hypersensitivity; Inappropriate Schedule Of Product Administration; Incorrect Product Administration Duration; Ocular Hyperaemia; Peripheral Swelling; Product Use In Unapproved Indication; Rash; Sudden Visual Loss; Systemic Lupus Erythematosus	Lansoprazole			S	Oral	Unk		Takeda
	Azyter			S	Ophthalmic	Unk		Not Reported
	Azyter			S	Ophthalmic	Unk		Not Reported
	Azyter			S	Ophthalmic	Unk		Not Reported
	Digoxin			C	Unknown	Unk		Not Reported
	Eliquis			C	Unknown	Unk		Not Reported
	Pradaxa			C	Unknown	Unk		Not Reported
	Furosemide			C	Unknown	100 Milligram, Qd		Not Reported
	Colchicine			C	Unknown	Unk		Not Reported
	Torsemide			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17242959	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2020M1001340		56 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17364556	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020-BI-00		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal; Blood Pressure Increased; Body Temperature Increased; Cataract; Cough; Drug Dependence;	Spiriva			S	Unknown			Boehringer Ingelheim
	Advair			S	Unknown			Not Reported
	Azithromycin			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Heart Rate Increased;	Prednisone	S	Oral		Not Reported
Lung Diffusion Test	Salbutamol	S	Unknown		Not Reported
Decreased; Nasal	Zenhale	S	Unknown	Dosage Form: Aerosol, Metered Dose	Not Reported
Disorder; Nasopharyngitis; Obstructive Airways	Cetirizine	C	Unknown		Not Reported
Disorder; Pyrexia;	Pariet	C	Unknown	Tablet (Enteric Coated)	Not Reported
Restrictive Pulmonary	Rosuvastatin	C	Unknown		Not Reported
Disease; Therapeutic					
Response Decreased;					
Type 2 Diabetes Mellitus					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17364927	EXPEDITED (15-DAY)		OT	FR- GLAXOSMITHKLINE- FR2020015663		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis;	Pantoprazole			S	Oral	Unk		Glaxosmithkline	
Hepatocellular Injury	Zelitrex			S	Oral	1000 Mg, Qd		Glaxosmithkline	
	Zithromax			S	Oral	Unk		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
	Zelitrex			C	Oral	Unk		Glaxosmithkline	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17364952	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA- 1178468		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oesophageal Ulcer;	Ciprofloxacin			S	Oral	1000 Milligram Daily;		Not Reported	
Oesophagitis; Rash;	Azithromycin			S	Unknown			Not Reported	
Stevens-Johnson	Fluticasone			C				Not Reported	
Syndrome	Ipratropium			C				Not Reported	
	Quetiapine			C				Not Reported	
	Risedronate Sodium			C				Not Reported	
	Salbutamol			C				Not Reported	
	Tiotropium Bromide			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17365227	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1180916		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral			Teva	
	Zithromax			S	Oral	Unspecified		Not Reported	
	Zelitrex			S	Oral	1000 Mg Per Day		Not Reported	
	Bactrim			S	Oral	Unspecified		Not Reported	
	Zelitrex			C	Oral	Unspecified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17365623	EXPEDITED (15-DAY)		OT	CA-SA-2020SA023865			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Plaquenil			S				Sanofi	
	Arava			S				Sanofi	
	Diphenhydramine Hydrochloride			S				Sanofi	
	Celecoxib			S	Oral			Not Reported	
	Demerol			S				Sanofi	
	Levofloxacin			S				Not Reported	
	Methotrexate			S				Not Reported	
	Azithromycin			S		250 Mg, Qd		Not Reported	
	Cyclophosphamide			S		2000 Unk		Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Enbrel			S				Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Imuran [Azathioprine]			S				Not Reported	
	Simponi			S	Subcutaneous			Not Reported	
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported	
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported	
	Xeljanz			S	Oral	5 Mg, 2 Every 1 Days		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

	Xeljanz		S	Oral	5 Mg, 2 Every 1 Days		Not Reported		
	Ezetrol		C				Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17367133	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1012055		52 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypotension	Aciclovir			S	Intravenous (not otherwise specified)	10 Milligram/Kilogram, Q8h		Not Reported	
	Metformine Arrow			S	Oral	3 Dosage Form, Qd		Mylan	
	Malocide /00112501/			S		50 Milligram, Qd		Mylan	
	Zithromax			S	Oral	1 Dosage Form, Qd		Mylan	
	Seretide			C		Unk		Mylan	
	Pantoprazole			C		Unk		Mylan	
	Novorapid			C		Unk		Mylan	
	Atorvastatine /01326101/			C		Unk		Mylan	
	Moxonidine			C				Mylan	
	Lantus			C		Unk		Mylan	
	Nebivolol			C		Unk		Mylan	
	Galvus			C		Unk		Mylan	
	Furosemide			C		Unk		Mylan	
	Tarka			C				Mylan	
Montelukast			C		Unk		Mylan		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2020	17369671	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-004941		76 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphopenia; Neutropenia; Purpura; Rash Pruritic; Thrombocytopenia	Azithromycin Arrow Film-Coated Tablets 250mg			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Metoclopramide Hydrochloride			C	Intravenous drip	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spasfon	C	Intravenous drip	Unk	Not Reported
Hydrochlorothiazide	C	Unknown	12.5 Milligram, Once A Day	Not Reported
Ringer Lactate Fresenius	C	Intravenous drip	Unk	Not Reported
Spasfon Lyoc	C	Sublingual	240 Milligram, Once A Day	Not Reported
Lercanidipine Hydrochloride	C	Oral	10 Milligram, Once A Day	Not Reported
Metoclopramide	C	Rectal	3 Dosage Form, Once A Day	Not Reported
Lovenox	C	Subcutaneous	Unk	Not Reported
Doliprane	C	Oral	Unk	Not Reported
Tiorfan	C	Oral	3 Dosage Form, Once A Day	Not Reported
Terbutaline Sulfate	C	Respiratory (inhalation)	Unk	Not Reported
Cetirizine Dihydrochloride	C	Oral	Unk	Not Reported
Symbicort Turbuhaler	C	Respiratory (inhalation)	Unk	Not Reported
Candesartan Cilexetil	C	Unknown	8 Milligram, Once A Day	Not Reported
Nebivolol	C	Oral	5 Milligram, Once A Day	Not Reported
Diffu K	C	Oral	1800 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	16740836	EXPEDITED (15-DAY)	CA, OT		US-VIIV HEALTHCARE LIMITED-BW2019GSK146253			Unknown	BWA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Live Birth; Talipes	Dolutegravir			S	Transplacental	Unk		Viiv
	Vitamin C			S	Transplacental	Unk		Glaxosmithkline
	Ceftriaxone			S	Transplacental	Unk Unk, Single		Glaxosmithkline
	Azithromycin			S	Transplacental	Unk Unk, Single		Glaxosmithkline
	Metronidazole			S	Transplacental	Unk Unk, Single		Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Metronidazole	S	Transplacental	Unk	Glaxosmithkline
Erythromycin	S	Transplacental	Unk	Glaxosmithkline
Methyldopa	S	Transplacental	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	16957178	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2019454054		7 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bone Marrow Failure; Dermatitis; Hepatotoxicity; Hypertriglyceridaemia; Nausea; Vomiting	Azithromycin			S	Oral	10 Mg/Kg, Daily		Pfizer	
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg, Daily (2.4 Mg/Kg/Day In 2 Doses)		Pfizer	
	Clofazimine			S	Oral	Unk, 1x/Day(50mg Once Daily; If Weight >40kg, Then 100mg Once Daily)		Not Reported	
	Imipenem/Cilastatin			S	Intravenous (not otherwise specified)	Unk, Daily (60/60 Mg/Kg/Day In 2-4 Doses)		Not Reported	
	Imipenem/Cilastatin			S	Topical	Unk, 3x/Day (5/5 Mg/ML; Three Drops Three Times Daily)		Not Reported	
	Tigecycline			S	Topical	5 Mg/ML, 3x/Day (5 Mg/ML; Three Drops Three Times Daily)		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17369952	EXPEDITED (15-DAY)		HO	DE-TEVA-2020-DE-1181571		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Cardiovascular Disorder; Chills; Dehydration; Diarrhoea; Nausea	Azithromycin 500 Mg			S	Oral	500 Mg, 1 Tablet Taken		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17369959	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-00		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal;	Spiriva			S	Unknown			Boehringer Ingelheim	
Blood Pressure Increased;	Advair			S	Unknown			Not Reported	
Body Temperature	Azithromycin			S	Oral			Not Reported	
Increased; Cataract;	Prednisone			S	Oral			Not Reported	
Cough; Drug Dependence;	Salbutamol			S	Unknown			Not Reported	
Heart Rate Increased;	Zenhale			S	Unknown	Dosage Form: Aerosol, Metered Dose		Not Reported	
Lung Diffusion Test	Cetirizine			C	Unknown			Not Reported	
Decreased; Nasal	Pariet			C	Unknown	Tablet (Enteric Coated)		Not Reported	
Disorder; Nasopharyngitis;	Rosuvastatin			C	Unknown			Not Reported	
Obstructive Airways									
Disorder; Pyrexia;									
Restrictive Pulmonary									
Disease; Therapeutic									
Response Decreased;									
Type 2 Diabetes Mellitus									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17370298	EXPEDITED (15-DAY)		HO	NO-PFIZER INC- 2020047309		55 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Oesophagitis;	Azitromax			S	Oral	250 Mg, 1x/Day		Pfizer	
Gastroenteritis	Rifampicin			S	Oral	600 Mg, 1x/Day		Not Reported	
Eosinophilic; Off Label	Myambutol			S	Oral	900 Mg, 1x/Day		Not Reported	
Use; Product Use Issue	Klacid Od			S	Oral	Unk		Not Reported	
	Seretide Discus			C	Respiratory (inhalation)	1 Df, 2x/Day (Every 12 Hours)		Not Reported	
	Singulair			C	Oral	10 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17370872	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020052304		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk		Pfizer	
	Zithromax			S	Oral	Unk		Pfizer	
	Zelitrex			S	Oral	1000 Milligram, Qd		Not Reported	
	Bactrim			S	Oral	Unk		Not Reported	
	Zelitrex			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17371138	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020044893		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Drug Interaction; Oral Fungal Infection; Renal Impairment; Vomiting	Novatrex			S		4 Df, Weekly		Pfizer	
	Bactrim Forte			S	Oral	2 Df, 1x/Day		Not Reported	
	Enalapril Maleate			C		Unk		Not Reported	
	Tenstaten			C		Unk		Not Reported	
	Lercanidipine Hcl			C		Unk		Not Reported	
	Speciafoldine			C		2 Df, Weekly		Not Reported	
	Crestor			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17372233	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1179208			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pancreatitis Acute	5-Asa			S	Unknown			Actavis	
	Azathioprine			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Mercaptopurine	S	Unknown	Teva
	Asacol	S	Unknown	Not Reported
	Infliximab	S	Unknown	Not Reported
	Levonorgestrel	S	Unknown	Not Reported
	Mezavant Also Known As Mesalamine	S	Unknown	Not Reported
	Para-Aminosalicylic Acid	S	Unknown	Not Reported
	Prednisone	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17372435	EXPEDITED (15-DAY)		OT	NL-MYLANLABS- 2020M1013021		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Dermatitis; Hepatotoxicity; Leukopenia; Rash; Thrombocytopenia; Urticaria	Azithromycin			S	Oral	10 Milligram, Qd		Not Reported
	Azithromycin			S				Not Reported
	Imipenem And Cilastatin			S	Intravenous (not otherwise specified)	Imipenem/Cilastatin 60/60 Mg/Kg/Day In 2 To 4 Doses		Mylan
	Imipenem And Cilastatin			S				Mylan
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Mylan
	Tigecycline			S				Mylan
	Clofazimine			S	Oral	50mg Once Daily		Mylan
	Clofazimine			S				Mylan
	Dexamethasone			C	Unknown			Mylan
	Dexamethasone			C				Mylan
	Sodium Chloride			C	Intravenous (not otherwise specified)			Mylan
	Imipenem And Cilastatin			C	Topical	5/5 Mg/MI; Three Drops Three Times Daily		Mylan
	Imipenem And Cilastatin			C				Mylan
	Tigecycline			C	Topical	5 Mg/ MI; Three Drops Three Times Daily		Mylan
	Tigecycline			C				Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Granisetron	C	Unknown	Mylan
Granisetron	C		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17372765	EXPEDITED (15-DAY)		DE, HO	JP-CELGENEUS-JPN-20180109152		70 YR	Female	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cytomegalovirus Infection;	Pomalyst			S	Oral	Unknown		Not Reported
Diarrhoea; Hypokalaemia;	Revlimid			S	Oral	25 Milligram		Celgene
Neutrophil Count	Revlimid			S	Oral	25 Milligram		Celgene
Decreased; Neutrophil	Revlimid			S	Oral	25 Milligram		Celgene
Count Decreased;	Revlimid			S	Oral	25 Milligram		Celgene
Oedema; Plasma Cell	Revlimid			S	Oral	25 Milligram		Celgene
Myeloma; Pneumocystis	Revlimid			S	Oral	25 Milligram		Celgene
Jirovecii Pneumonia;	Revlimid			S	Oral	25 Milligram		Celgene
Pneumonia Bacterial;	Revlimid			S	Oral	25 Milligram		Celgene
Pulmonary Artery	Revlimid			S	Oral	20 Milligram		Celgene
Thrombosis; Rash; Rash;	Revlimid			S	Oral	25 Milligram		Celgene
Renal Disorder	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	25 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	15 Milligram		Celgene
	Revlimid			S	Oral	5 Milligram		Celgene
	Revlimid			S	Oral	15 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene
	Revlimid			S	Oral	10 Milligram		Celgene

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lenadex	S	Oral	20 Milligram	Not Reported
Lenadex	S	Oral	12 Milligram	Not Reported
Lenadex	S	Oral		Not Reported
Lenadex	S	Oral		Not Reported
Lenadex	S	Oral		Not Reported
Lenadex	S	Oral		Not Reported
Lenadex	S	Oral		Not Reported
Lenadex	S	Oral	Unknown	Not Reported
Velcade	S	Unknown	Unknown	Not Reported
Loxoprofen	S	Oral	Unknown	Not Reported
Bactramin	S	Intravenous drip	Unknown	Not Reported
Bactramin	S			Not Reported
Luprac	S	Oral	Unknown	Not Reported
Finibax	S	Intravenous drip	Unknown	Not Reported
Finibax	S			Not Reported
Zithromac	S	Intravenous drip	Unknown	Not Reported
Zithromac	S			Not Reported
Empliciti	S	Unknown	Unknown	Not Reported
Kyprolis	S	Unknown	Unknown	Not Reported
Brotizolam	C	Oral	Unknown	Not Reported
Olmotec	C	Oral	Unknown	Not Reported
Atelec	C	Oral	Unknown	Not Reported
Amlodin	C	Oral	Unknown	Not Reported
Bayaspirin	C	Oral	Unknown	Not Reported
Rebamipide	C	Oral	Unknown	Not Reported
Dexart	C	Intravenous drip	6.6 Milligram	Not Reported
Dexart	C	Intravenous drip	6.6 Milligram	Not Reported
Dexart	C	Intravenous drip	6.6 Milligram	Not Reported
Astric	C	Oral	Unknown	Not Reported
Calonal	C	Oral	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Restamin	C	Topical	Unknown	Not Reported
Furosemid	C	Oral	Unknown	Not Reported
Spironolactone	C	Unknown	Unknown	Not Reported
Dermovate	C	Topical	Unknown	Not Reported
Predonine	C	Oral	Unknown	Not Reported
Nexium	C	Oral	Unknown	Not Reported
Baktar	C	Oral	Unknown	Not Reported
Cyclophosphamide	C	Unknown	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2020	17374313	NON-EXPEDITED			US-PFIZER INC-2020046645		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	16138695	EXPEDITED (15-DAY)		OT	CA-009507513-1903CAN012848		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal; Blood Pressure Increased; Body Temperature Increased; Cataract; Cough; Drug Dependence; Heart Rate Increased; Lung Diffusion Test Decreased; Nasal Disorder; Nasopharyngitis; Obstructive Airways Disorder; Pyrexia; Restrictive Pulmonary Disease; Therapeutic Response Decreased; Type 2 Diabetes Mellitus	Zenhale			S	Unknown	2 Dosage Forms, 2 Every 1 Day, Dosage Form: Aerosol Metered Dose		Merck
	Zenhale			S	Unknown	1 Dosage Form, 2 Every 1 Day		Merck
	Albuterol Sulfate			S	Unknown	Unk		Merck
	Advair			S	Unknown	1 Dosage Form, 2 Every 1 Day		Not Reported
	Azithromycin			S	Oral	250 Milligram, 1 Every 1 Day		Not Reported
	Azithromycin			S	Oral	250 Milligram		Not Reported
	Prednisone			S	Oral	8.0 Milligram, 1 Every 1		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	Day 8 Milligram, 1 Every 24 Hours	Not Reported
Spiriva	S	Unknown	18 Microgram, 1 Every 1 Day	Not Reported
Spiriva	S	Unknown	18 Microgram, 1 Every 24 Hours	Not Reported
Albuterol	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	C	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	C	Unknown	20 Milligram, 1 Every 1 Day	Not Reported
Cetirizine Hydrochloride	C	Unknown	20 Milligram, 1 Every 24 Hrs	Not Reported
Pariet	C	Unknown	Dosage Form: Tablet (Enteric Coated)	Not Reported
Rosuvastatin Calcium	C	Unknown	Unk	Not Reported
Rosuvastatin Calcium	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	16742128	NON-EXPEDITED			US-PFIZER INC-2019362506			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	16903512	EXPEDITED (15-DAY)		HO, LT, OT	PT-MYLANLABS-2019M1095086		73 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Respiratory Distress Syndrome; Pneumonia;	Pantoprazole			S	Unknown	Unk		Not Reported
Toxic Epidermal Necrolysis	Acetylsalicylic Acid			S	Unknown	Unk		Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bisoprolol	S	Unknown	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Not Reported
Simvastatin	S	Unknown	Unk	Not Reported
Losartan	S	Unknown	Unk Unk, Unknown Freq.	Not Reported
Cardio [Meprobamate\Neostigmine Bromide\Quinidine Sulfate]	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17267331	EXPEDITED (15-DAY)		HO, OT	NVSC2020PT005026		77 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Drug Ineffective; Erythema; Genital Ulceration; Pemphigoid; Pharyngeal Ulceration	Azithromycin			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17360283	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR016637			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Dyspnoea; Loss Of Personal Independence In Daily Activities; Sleep Disorder Due To A General Medical Condition; Therapeutic Product Effect Incomplete	Salbutamol Sulphate			S	Respiratory (inhalation)	100 Ug, Bid(1-2 Puffs)		Glaxosmithkline
	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline
	Azitromycin			S		Unk, 250 Mg		Glaxosmithkline
	Symbicort			S	Respiratory (inhalation)	4 Puff(S), Bid		Not Reported
	Spiriva			S	Respiratory (inhalation)	2 Puff(S), Qd(2.5 Ug)		Not Reported
	Oseltamivir			S		30 Mg, Qd		Not Reported
	Lipitor			S		20 Mg		Not Reported
	Teva-Trazodone			S		150 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azopt	S	2 Df, Qd	Not Reported
Alendronato	S	Unk	Not Reported
Restorolax	S	Unk	Not Reported
Prednisone	S	Respiratory (inhalation) 50 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17374115	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1181593		74 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual	Azithromycin			S	Oral	1500 Mg		Not Reported	
	Flecainide Acetate			C				Not Reported	
	Losartan			C				Not Reported	
	Salbutamol			C				Not Reported	
	Symbicort			C				Not Reported	
	Apixaban			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17375478	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-005643		74 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual	Azithromycin			S	Oral	1500 Milligram, Every Week		Aurobindo	
	Flecainide Acetate			C	Unknown	Unk		Not Reported	
	Losartan			C	Unknown	Unk		Not Reported	
	Salbutamol			C	Unknown	Unk		Not Reported	
	Symbicort			C	Unknown	Unk		Not Reported	
	Apixaban			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17375562	EXPEDITED (15-DAY)		HO	SI-TEVA-2020-SI-1181892		22 YR	Male	SVN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatic Enzyme Increased	Sumamed 500 Mg			S	Oral	500 Milligram		Not Reported
	Lekadol 1000 Mg			S	Oral	1000 Milligram		Not Reported
	Lekadol 1000 Mg			S	Oral			Not Reported
	Lekadol 1000 Mg			S	Oral			Not Reported
	Lekadol 1000 Mg			S	Oral			Not Reported
	Zaldiar 37,5 Mg / 325 Mg			S	Oral	37,5 Mg/325 Mg		Not Reported
	Zaldiar 37,5 Mg / 325 Mg			S		37,5 Mg/325 Mg		Not Reported
	Neodolpasse 75 Mg/30 Mg			C		75mg/30mg, 1-2 Dose 2x/Day As Necessary		Not Reported
	Amoksiklav 1,2 G			C		On 6 January 2020 Only One Dose In The Morning		Not Reported
	Pansemyl 20 Mg			C				Not Reported
	Tazocin 4 G / 0.5 G			C	Intravenous (not otherwise specified)			Not Reported
	Fraxiparin 0,4			C				Not Reported
	Tazocin 4 G / 0,5 G			C	Intravenous (not otherwise specified)	4.5 Gram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17375826	EXPEDITED (15-DAY)		OT	AU-ASTRAZENECA- 2019SF64022		56 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Autoimmune Disorder; Candida Infection; Disease Progression; Dry Mouth; Dry Skin; Foot Fracture; Glossodynia; Hot Flush; Lower Respiratory Tract Infection; Paraesthesia Oral	Fasenra			S	Subcutaneous	30mg/ML Every Eight Weeks		Astrazeneca
	Fasenra			S	Subcutaneous	30mg/ML Every Eight Weeks		Astrazeneca
	Azithromycin			S	Oral	Half Tablet 3 Times A Week		Not Reported
	Ventolin			C		2-3 Times Per Day, Started 30 Years Ago		Not Reported
	Symbicort			C		2-3 Times Per Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrovent			C		2-3 Times Per Day			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17375940	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1181974		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Anaemia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported	
	Coumadine 2 Mg, Comprimé			S	Oral	1 Dosage Form		Not Reported	
	Sécable								
	Seretide			C				Not Reported	
	Amiodarone			C				Not Reported	
	Bronchodual			C				Not Reported	
	Spiriva			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17375968	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-005702		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Anaemia	Azithromycin			S	Oral	250 Milligram, Every Other Day		Aurobindo	
	Coumadine			S	Oral	1 Dosage Form, Once A Day		Not Reported	
	Seretide			C	Unknown	Unk		Not Reported	
	Amiodarone			C	Unknown	Unk		Not Reported	
	Bronchodual			C	Unknown	Unk		Not Reported	
	Spiriva			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17376302	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2018GSK046121			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Therapeutic	Salbutamol Sulphate			S		Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Effect Incomplete	Nucala	S	100 Mg, Z (Monthly)	Glaxosmithkline
	Singulair	S	10 Mg, Qd	Glaxosmithkline
	Azithromycin	S	3 Df, We	Glaxosmithkline
	Zenhale	S	200 Ug, Bid	Not Reported
	Nasonex	S	Unk Unk, Prn	Not Reported
	Pulmicort	S	Unk Unk, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17376625	EXPEDITED (15-DAY)		OT	NVSC2019GB009615		57 YR	Male	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Infection Susceptibility Increased; Lower Respiratory Tract Infection	Prednisolone			S	Unknown	Unk		Not Reported
	Paracetamol			S	Unknown	Unk		Novartis
	Azithromycin			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Hydrocortisone			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17376795	EXPEDITED (15-DAY)		OT	NVSC2020FR028237		78 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agranulocytosis; Thrombocytopenia	Valaciclovir			S	Oral	1 Ot, Qd		Novartis
	Ramipril			S	Oral	Unk		Not Reported
	Inipomp			S	Oral	Unk		Not Reported
	Imodium			S	Oral	Unk		Not Reported
	Bactrim			S	Oral	3 Ot, Qw		Not Reported
	Kardegic			S	Oral	Unk		Not Reported
	Tiorfan			S	Oral	Unk		Not Reported
	Zithromax			S	Oral	Unk		Not Reported
	Oflozet			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Retacrit			S		Unknown		1 Ot, Qw		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
06-Feb-2020	17377594	EXPEDITED (15-DAY)		OT	PT-MYLANLABS-2020M1013177		45 YR	Female	PRT	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Encephalomyelitis; Neuropathy Peripheral	Azithromycin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
06-Feb-2020	17377849	EXPEDITED (15-DAY)		OT	AU-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2020-BI-00		20 YR	Female	AUS	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Lower Respiratory Tract Infection; Malaise; Nasopharyngitis	Spiriva			S	Unknown				Boehringer Ingelheim	
	Asmol [Salbutamol Sulfate]			S	Unknown				Not Reported	
	Azithromycin			S	Unknown				Not Reported	
	Colistimethate Sodium			S	Unknown				Not Reported	
	Hypertonic Saline Solution			S	Other	Nebulizer Route			Not Reported	
	Lexam			S	Unknown				Not Reported	
	Nucala			S	Subcutaneous				Not Reported	
	Omeprazole			S	Unknown				Not Reported	
	Ondansetron			S	Unknown				Not Reported	
	Prednisone			S	Unknown				Not Reported	
	Seretide			S	Unknown	250/25 Milligram			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
06-Feb-2020	17378182	EXPEDITED (15-DAY)		DE, LT, OT	US-FRESENIUS KABI-FK202001207			Male	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Exposure During Pregnancy; Pneumonia Escherichia; Pulmonary Hypertension; Respiratory Distress; Sepsis	Azithromycin (Manufacturer Unknown)	S	Transplacental		Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)	S			Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)	S			Fresenius Medical Care
	Ampicillin	S	Transplacental		Not Reported
	Ampicillin	S			Not Reported
	Ampicillin	S			Not Reported
	Ampicillin	S	Transplacental	Unknown	Not Reported
	Ampicillin	S			Not Reported
	Ampicillin	S			Not Reported
	Erythromycin	S	Transplacental	Unknown	Not Reported
	Erythromycin	S			Not Reported
	Erythromycin	S			Not Reported
	Betamethasone	C	Transplacental	Unknown	Not Reported
	Magnesium Sulfate	C	Transplacental	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17378674	NON-EXPEDITED			US-ABBVIE-19K-163-2671183-00			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Humira			S	Subcutaneous			Not Reported
	Mesalamine			S	Unknown			Not Reported
	Aza (Azithromycin Dihydrate)			S	Unknown			Not Reported
	Remicade			S	Unknown			Not Reported
	Entyvio			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17381278	NON-EXPEDITED			US-ABBVIE-19K-163-2791346-00			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Intolerance	Humira			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lyrica	S	Unknown	Not Reported
Medrol Dosepak	S	Unknown	Not Reported
Zithromax	S	Unknown	Not Reported
Effexor	S	Unknown	Not Reported
Neurontin	S	Unknown	Not Reported
Skelaxin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384757	NON-EXPEDITED			US-EPIC PHARMA LLC-2019EPC00345			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Ineffective; Expired Product Administered; Product Dispensing Error; Pyrexia	Azithromycin			S	Oral	4 MI, 3x/Week (M, W, F) At Night		Epic Pharm
	Albuterol Inhaler (Non Company Product)			C				Not Reported
	Ranitidine			C		Unk, 1x/Day		Not Reported
	Unknown Medication For Acid Reflux?Stomach Upset			C				Not Reported
	Unknown Medication For Acid Reflux?Stomach Upset			C				Not Reported
	Advair Inhaler			C				Not Reported
	Ibuprofen			C		Cycled With Acetaminophen Every 3 Hours As Needed		Not Reported
	Acetaminophen			C		Cycled With Ibuprofen Every 3 Hours As Needed		Not Reported
	Sodium Chloride 3% Nebulizer Solution			C		Unk, 2x/Day		Not Reported
	Albuterol Nebulizer Solution			C		Every 4 Hours As Needed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384761	NON-EXPEDITED			US-EPIC PHARMA LLC-2019EPC00331		4 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Exposure To Allergen;	Azithromycin	S	Oral	5 MI, Once	Epic Pharm
Product Dispensing Error;	Azithromycin	S			Epic Pharm
Pruritus; Urticaria	Xyzal	C		Unk	Not Reported
	Flovent	C		2 Dosage Units, 2x/Day	Not Reported
	Albuterol	C			Not Reported
	Mucinex Dm	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384765	NON-EXPEDITED			US-EPIC PHARMA LLC-2019EPC00346			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Malaise	Azithromycin			S		4 MI, 1x/Day		Epic Pharm	
	Azithromycin			S		2.5 MI, 1x/Day (Days 2-5)		Epic Pharm	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384768	NON-EXPEDITED			US-EPIC PHARMA LLC-2019EPC00358		3 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Taste Abnormal; Throat Irritation; Vomiting	Azithromycin			S	Oral	7.5 MI, Once		Epic Pharm	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384771	NON-EXPEDITED			US-EPIC PHARMA LLC-2019EPC00360		3 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Taste Abnormal; Throat Irritation; Vomiting	Azithromycin			S	Oral	7.5 MI, Once		Epic Pharm	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384970	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019040179		11 DAY	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diarrhoea Neonatal; Off Label Use; Product Use Issue		Zithromax		S	Intravenous drip	0.17 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17384988	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2019470108		21 DAY	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea Neonatal; Off Label Use; Product Use Issue	Zithromax			S	Intravenous drip	0.049 G, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17386704	NON-EXPEDITED			US-PFIZER INC-2020050404			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune System Disorder	Zithromax			S		500 Mg, 1x/Day [Taking 2 A Day For 20 Days]		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17386856	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020049337		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Altered State Of Consciousness; Bone Marrow Failure; Diarrhoea; Fall; Haemorrhage; Hepatocellular Injury; Hyperbilirubinaemia; Mucosal Inflammation; Neutropenic Colitis; Oral Candidiasis; Pyrexia; Renal Impairment; Septic Shock	Novatrex			S	Oral	5 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2020	17450430	DIRECT		DS, HO, LT, OT			31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lip Swelling; Rash; Skin Discolouration; Stevens-Johnson Syndrome	Gabapentin			S				Not Reported	
	Hydrochlorothiazide			S				Not Reported	
	Fluconazole			C				Not Reported	
	Loratadine			C				Not Reported	
	Nystatin			C				Not Reported	
	Sulfamethoxazole And Trimethoprim			S				Not Reported	
	Atorvastatin			S				Not Reported	
	Metformin			S				Not Reported	
	Flucanazole			S				Not Reported	
	Hydroxyzine			S				Not Reported	
	Dapsone			S				Not Reported	
	Zaditor			S				Not Reported	
	Hydrocortisone			S				Not Reported	
	Azithromax			S				Not Reported	
	Biktarvy			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2020	13263706	NON-EXPEDITED			US-PFIZER INC-2017068456			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
	Aspirin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2020	17345661	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1175341		58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Myasthenia Gravis	Azithromycin			S	Unknown			Teva	
	Ceftriaxone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Flagyl			S		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2020	17389425	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1014726			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Azithromycin			S	Unknown	1 Gram, Total		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2020	17389936	EXPEDITED (15-DAY)		HO, OT	NVSC2020PT031953		44 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eosinophilic Pneumonia	Azithromycin			S	Unknown	Unk		Novartis	
	Amoxicillin,Clavulanic Acid			S	Unknown	Unk		Not Reported	
	Rupatadine			C	Unknown	Unk		Not Reported	
	Bromazepam			C	Unknown	Unk		Not Reported	
	Venlafaxine			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2020	17389948	EXPEDITED (15-DAY)		HO, OT	NVSC2020PT031942		52 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Synovial Sarcoma	Azithromycin			S	Unknown			Novartis	
	Ceftriaxone			S	Unknown			Not Reported	
	Meropenem			S	Unknown	Unk		Not Reported	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2020	17390790	EXPEDITED (15-DAY)		HO, LT, OT	CZ-AUROBINDO-AUR-APL-2020-005790		62 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Diarrhoea; Haematuria; Oliguria; Proteinuria; Renal Tubular Necrosis; Vomiting	Azithromycin			S	Unknown	Unk		Aurobindo	
	Cefepime			S	Unknown	Unk		Not Reported	
	Heparin			C	Unknown	Unk		Not Reported	
	Imunoglobulin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2020	17373657	EXPEDITED (15-DAY)		HO, OT	NVSC2020PT005029		72 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Stevens- Johnson Syndrome; Transaminases Increased	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2020	17393612	EXPEDITED (15-DAY)		HO	NVSC2020DE028898		55 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperhidrosis; Respiratory Disorder; Skin Irritation; Swelling; Urticaria	Azithromycin 1 A Pharma 500 Mg Filmtabletta			S	Oral	500 Mg, Qd (1x1)		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2020	17393677	EXPEDITED (15-DAY)		OT	NVSC2020TR032235			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Exposure During Pregnancy; Premature Baby	Betamethasone	S	Transplacental	12 Mg, Qd 9every 24 Hours) (Maternal Dose)	Novartis
	Ampicillin	S	Transplacental	1 G, Qd (4x1) (Maternal Dose)	Not Reported
	Azithromycin	S	Transplacental	500 Mg, Qd (1x1 For First 3 Days) (Maternal Dose)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	15932180	NON-EXPEDITED			US-PFIZER INC-2019042266		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17092766	EXPEDITED (15-DAY)		HO, OT	BR-GLAXOSMITHKLINE-BR2019GSK098082			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension;	Nucala			S		100 Mg, Z Monthly		Glaxosmithkline	
Asthma; Asthmatic Crisis;	Relvar Ellipta			S		Unk Unk, Qd		Glaxosmithkline	
Bronchitis; Drug	Aerolin			S		4 Df (Jets)		Glaxosmithkline	
Ineffective; Dyspnoea;	Azithromycin			S		Unk		Glaxosmithkline	
Fatigue; Feeling	Symbicort			S		Unk Unk, Bid		Not Reported	
Abnormal; Gastric									
Disorder; Intentional Dose									
Omission; Malaise;									
Product Availability Issue;									
Secretion Discharge									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17178836	NON-EXPEDITED			US-PFIZER INC-2019543725		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Off	Azithromycin			S		250 Mg, 1x/Day		Pfizer	
Label Use; Product Use In	Azithromycin			S				Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17180494	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2019M1124069		24 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
Anaesthesia; Dysentery;	Coumadin			S	Oral	5 Mg, Prn (As Necessary)		Mylan	
Nausea	Paracetamol			C	Oral	1 Gram		Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17272637	NON-EXPEDITED			US-PFIZER INC-2020014897		55 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Iron	Zithromax			S		Unk		Pfizer	
Decreased; Diarrhoea;	Orenitram			S	Oral	0.25 Mg, Unk		Not Reported	
Fatigue; Haemoglobin	Orenitram			S	Oral	0.125 Mg, Unk		Not Reported	
Decreased; Malaise;	Orenitram			S	Oral	2.5 Mg, Unk		Not Reported	
Product Dose Omission;	Orenitram			S	Oral	Unk		Not Reported	
Rhinorrhoea	Orenitram			S	Oral	3.125 Mg, 3x/Day (Q (Every) 8h)		Not Reported	
	Orenitram			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17329736	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1009068		10 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Off Label Use	Azithromycin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17393874	EXPEDITED (15-DAY)		HO, OT	CA-B.I.		54 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

PHARMACEUTICALS,I
NC./RIDGEFIELD-2020-
BI-00

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Cough; Dyspnoea; Gastroesophageal Reflux Disease; Therapeutic Product Effect Incomplete	Spiriva			S	Unknown			Boehringer Ingelheim
	Azithromycin			S	Unknown			Not Reported
	Montelukast			S	Unknown			Not Reported
	Pulmicort			S	Unknown			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported
	Symbicort Turbuhaler			S	Unknown	Powder		Not Reported
	Erythromycin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17395376	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2020AMR020775			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Drug Hypersensitivity; Gait Disturbance; Inflammation; Musculoskeletal Pain; Pain In Extremity; Thyroid Cancer	Cefuroxime Axetil			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Humira			S	Subcutaneous	Unk		Not Reported
	Methotrexate			S		Unk		Not Reported
	Tetracycline			S		Unk		Not Reported
	Ibuprofen			C		Unk		Glaxosmithkline
	Plaquenil			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17395397	EXPEDITED (15-DAY)		HO	FR-ZYDUS-047389		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Wall	Warfarin	S	Oral	Not Reported
Haematoma; Anaemia	Azithromycin	S	Oral	Zydus Pharm
	Fluticasone	C		Not Reported
	Propionate/Salmeterol Xinafoate			
	Amiodarone	C		Not Reported
	Tiotropium	C		Not Reported
	Fenoterol	C		Not Reported
	Hydrobromide\lpratropium			
	Bromide			

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17396534	NON-EXPEDITED			US-PFIZER INC-2020053662			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ocular Discomfort; Off Label Use; Pain; Product Use In Unapproved Indication	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17396747	NON-EXPEDITED			US-PFIZER INC-2020054538			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Diclofenac Epolamine			S		Unk		Unknown
	Methotrexate Sodium			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2020	17397919	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2080039		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain	Azithromycin			S	Oral			Wockhardt
	Nifedipine			C				Not Reported
	Carvedilol			C				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Soliris

C

Intravenous (not
otherwise specified)

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	13341413	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2016GSK122625			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Asthma; Chest Discomfort; Cough; Depressed Mood; Dyspnoea; Insomnia; Intentional Dose Omission; Laboratory Test Abnormal; Lower Respiratory Tract Infection; Productive Cough; Productive Cough; Respiratory Tract Congestion; Sputum Discoloured; Treatment Noncompliance; Wheezing	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z		Glaxosmithkline
	Ventolin			S		Unk		Glaxosmithkline
	Azithromycin			S		Unk		Glaxosmithkline
	Montelukast			S		Unk		Glaxosmithkline
	Theophylline			S		600 Mg, Unk		Glaxosmithkline
	Pulmicort			S		2 Df, Bid		Not Reported
	Prednisone			S		10 Mg, Qd		Not Reported
	Prednisone			S		50 Mg, Unk		Not Reported
	Atrovent			S		Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	16216320	EXPEDITED (15-DAY)		DS, OT	CA-AUROBINDO-AUR-APL-2019-020596		39 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Diarrhoea; Flank Pain; Haematocrit Decreased; Haemoglobin Decreased; Hypertension; Infection; Nausea; Obesity; Renal Disorder; Renal Impairment	Azithromycin			S	Unknown	Unk		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Oral	25 Milligram, Two Times A Day		Aurobindo	
	Quetiapine Film-Coated Tablet			S	Oral	100 Milligram, Once A Day		Aurobindo	
	Cipro			S	Oral	500 Milligram, Once A Day		Not Reported	
	Cipro			S				Not Reported	
	Amoxicillin			C	Unknown	Unk		Not Reported	
	Risperidone			C	Unknown	Unk		Not Reported	
	Valproate Semisodium			C	Unknown	Unk		Not Reported	
	Zyprexa			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17242061	EXPEDITED (15-DAY)		OT	NVSC2020BR001633			Male	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Azithromycin			S	Transplacental	Unk (Maternal Dose: Single Dose 1 Gram, Until Labor)		Novartis	
	Ampicillin			S	Transplacental	Maternal Dose: Until Labor)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17284429	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2020VAL000044			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Demerol			S	Unknown	Unk		Validus	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Plaquenil /00072603/	S	Unknown	Unk	Not Reported
	Arava	S	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
	Celecoxib	S	Oral	Unk	Not Reported
	Levofloxacin	S	Unknown	Unk	Not Reported
	Methotrexate	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	250 Mg, Qd	Not Reported
	Cyclophosphamide	S	Unknown	2000, Unk	Not Reported
	Cimzia	S	Subcutaneous	Unk	Not Reported
	Enbrel	S	Unknown	Unk	Not Reported
	Humira	S	Subcutaneous	Unk	Not Reported
	Imuran /00001501/	S	Unknown	Unk	Not Reported
	Simponi	S	Subcutaneous	Unk	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Xeljanz	S	Oral	5 Mg, 2 Every 1 Days	Not Reported
	Ezetrol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17313834	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-003457		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Bronchiectasis; Cardiac Failure Congestive; Chronic Obstructive Pulmonary Disease; Constipation; Diastolic Dysfunction; Dyspnoea; Ejection Fraction Abnormal;	Amlodipine Tablets			S	Unknown	5 Milligram, Once A Day		Aurobindo
	Atorvastatin Tablets			S	Unknown	20 Milligram, Once A Day		Not Reported
	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo
	Citalopram			S	Unknown	20 Milligram		Aurobindo
	Risedronate Tablet			S	Unknown	35 Milligram		Aurobindo
	Bisoprolol			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Emphysema; Lung	Calcium Carbonate	S	Unknown	Unk Unk, Once A Day	Not Reported
Hyperinflation; Obstructive	Docusate	S	Unknown	100 Milligram	Not Reported
Airways Disorder;	Furosemide	S	Unknown	20 Milligram, Once A Day	Not Reported
Oedema Peripheral;	Hydromorphone	S	Unknown	1 Milligram	Not Reported
Oxygen Saturation	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
Abnormal; Productive	Salbutamol Sulfate	S	Unknown	Unk Unk, Every Other Day	Not Reported
Cough; Pulmonary	Tiotropium	S	Unknown	2 Dosage Form, Once A Day	Not Reported
Embolism; Respiratory	Xarelto	S	Unknown	20 Milligram, Once A Day	Not Reported
Failure; Sputum	Zenhale	S	Unknown	2 Dosage Form, Two Times A Day	Not Reported
Discoloured; Therapeutic	Lasix	C	Unknown	Unk	Not Reported
Product Effect Incomplete;					
Ventricular Dysfunction;					
Ventricular Hypokinesia;					
Wheezing					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17400114	EXPEDITED (15-DAY)		OT	AT-ACCORD-172067			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; C-Reactive Protein	Tigecycline			S				Not Reported	
Increased; Candida	Azithromycin			S				Not Reported	
Infection; Drug Ineffective;	Colistin			S				Not Reported	
Infection	Cubicin			S				Not Reported	
	Rifoldin			S	Intravenous (not otherwise specified)			Not Reported	
	Sulbactam			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17401654	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1014367		74 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual	Azithromycin			S	Oral	1500 Milligram, Qw		Not Reported	
	Flecainide Acetate			C		Unk		Mylan	
	Losartan			C		Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Salbutamol		C		Unk				Mylan
	Symbicort		C		Unk				Mylan
	Apixaban		C		Unk				Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17401782	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1014657		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk			Not Reported
	Zelitrex			S	Oral	Non Renseignée			Mylan
	Zelitrex			S	Oral	1000 Milligram, Qd			Mylan
	Zithromax			S	Oral	Non Renseignée			Mylan
	Bactrim			S	Oral	Non Renseignée			Mylan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17402121	NON-EXPEDITED			US-PFIZER INC-2020058295			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk			Pfizer
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17403020	EXPEDITED (15-DAY)		HO	DE-PFIZER INC-2020059653		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Cardiovascular Disorder; Chills; Dehydration; Diarrhoea; Nausea	Azithromycin			S	Oral	500 Mg, Single (1 Tablet Taken)			Pfizer

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17403149	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020057607		46 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Face Oedema	Zitromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17403214	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020056147		78 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arteriosclerosis	Azithromycin			S		Unk		Pfizer	
Coronary Artery; Back Pain; Bradycardia;	Ceftriaxone Sodium			S		Unk		Pfizer	
Bronchitis; Cardiac Failure	Amoxicillin Trihydrate			S		Unk		Not Reported	
Congestive; Chronic	Fluticasone			S		Unk		Not Reported	
Obstructive Pulmonary Disease; Coronary Artery Disease; Cough;	Furoate/Umeclidinium Bromide/Vilanterol Trifenatate								
Diarrhoea; Dyslipidaemia;	Shingrix			S		Unk		Not Reported	
Dyspnoea Exertional;	Zostavax			S		Unk		Not Reported	
Epigastric Discomfort;									
Faeces Discoloured;									
Haemoglobin Decreased;									
Hip Arthroplasty;									
Hypercholesterolaemia;									
Hypertension;									
Intervertebral Disc Degeneration; Lung Disorder; Macule;									
Melaena; Oedema									
Peripheral; Osteoarthritis;									
Pneumonia; Pulmonary Fibrosis; Pulmonary Mass;									
Pulmonary Oedema;									
Rotator Cuff Syndrome;									
Senile Dementia;									
Wheezing									

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2020	17403423	EXPEDITED (15-DAY)		HO	US-MYLANLABS-2020M1015675		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Azithromycin			S	Unknown			Not Reported	
	Ibuprofen			S	Unknown			Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	
	Vancomycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	16126785	EXPEDITED (15-DAY)		OT	AT-AXELLIA-002325			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; C-Reactive Protein Increased; Candida Infection; Drug Ineffective; Infection	Colistin			S				Not Reported	
	Tigecycline			S				Not Reported	
	Sulbactam			S				Not Reported	
	Cubicin			S				Not Reported	
	Azithromycin			S				Not Reported	
	Rifoldin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17405064	NON-EXPEDITED		HO, OT	PHHY2018US003016		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Count Abnormal; Device Related Infection; Diarrhoea; Fatigue; Pneumonia	Jakafi			S	Unknown	15 Mg, Bid		Not Reported	
	Jakafi			S	Oral	5 Mg, Bid		Not Reported	
	Jakafi			S	Oral	10 Mg Qam, 5 Mg Qpm		Not Reported	
	Azithromycin			S	Unknown	Unk		Novartis	
	Fish Oil			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin B12	C	Unknown		Not Reported
Vitamin D	C	Unknown	Unk	Not Reported
Myrbetriq	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17406846	EXPEDITED (15-DAY)		OT	NL-TEVA-2020-NL-1182968		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Cortisol Deficiency; Dermatitis; Hepatotoxicity; Hypertriglyceridaemia; Leukopenia; Nausea; Rash; Thrombocytopenia; Urticaria; Vomiting; Weight Increased	Azithromycin			S	Oral	10 Milligram Daily;		Not Reported
	Azithromycin			S				Not Reported
	Dexamethasone			S	Unknown			Actavis
	Dexamethasone			S				Actavis
	Imipenem-Cilastatin			S	Intravenous (not otherwise specified)	Imipenem/Cilastatin 60/60 Mg/Kg/Day In 2 To 4 Doses		Not Reported
	Imipenem-Cilastatin			S	Topical	5/5 Mg/MI; Three Drops Three Times Daily		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Not Reported
	Tigecycline			S	Topical	5 Mg/ MI; Three Drops Three Times Daily		Not Reported
	Clofazimine			S	Oral	50mg Once Daily; If Weight Is >40 Kg, Then 100 Mg Once Daily		Not Reported
	Clofazimine Sodium Chloride			S C	Intravenous (not otherwise specified)			Not Reported Not Reported
	Granisetron			C	Unknown			Not Reported
	Granisetron			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17408826	EXPEDITED (15-DAY)		OT	US-FRESENIUS KABI-FK202001405		11 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Linear Iga Disease	Azithromycin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care
	Acyclovir Sodium (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Vancomycin (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Nafcillin			S	Intravenous (not otherwise specified)			Not Reported
	Fluconazole			S	Intravenous (not otherwise specified)			Not Reported
	Ibuprofen			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17409986	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020057657		66 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eosinophilic Fasciitis; Lichenoid Keratosis	Zithromax			S	Oral	Unk		Pfizer
	Darzalex			S	Intravenous (not otherwise specified)	1232 Mg, Unk		Not Reported
	Privigen			S	Intravenous (not otherwise specified)	10 G, Unk		Not Reported
	Privigen			S	Intravenous (not otherwise specified)	20 G, Unk		Not Reported
	Augmentin [Amoxicillin;Clavulanate Potassium]			S	Oral	Unk		Not Reported
	Rocephine			S		Unk		Not Reported
	Bactrim Forte			S	Oral	3 Df, Weekly		Not Reported
	Inexium [Esomeprazole Sodium]			C		Unk		Not Reported
	Topalgic			C		Unk		Not Reported
	Valaciclovir			C		Unk		Not Reported
	Solupred [Prednisolone]			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	C	Unk	Not Reported
Lyrica	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17409996	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020060462		74 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hallucination, Visual	Azithromycin			S	Oral	1500 Mg, Weekly		Pfizer	
	Apixaban			C		Unk		Not Reported	
	Flecainide Acetate			C		Unk		Not Reported	
	Losartan			C		Unk		Not Reported	
	Salbutamol			C		Unk		Not Reported	
	Symbicort			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17410177	EXPEDITED (15-DAY)		HO, OT	DE-BAUSCH-BL-2020-004212		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Transitional Cell Carcinoma	Locoid (Hydrocortisone Butyrate)			S	Unknown			Not Reported	
	Moronal			S	Unknown			Not Reported	
	Ibu 1a Pharma			S	Unknown			Not Reported	
	Ciprofloxacin Al			S	Unknown			Not Reported	
	Valsartan Comp Puren			S	Unknown			Not Reported	
	Azithromycin 1a Pharma			S	Unknown			Not Reported	
	Roxithromycin Heumann			S	Unknown			Not Reported	
	Ibuflam Lichtenstein			S	Unknown			Not Reported	
	Linola H Fett N			S	Unknown			Not Reported	
	Lercanidipin Ratiopharm			S	Unknown			Not Reported	
	Decortin H			S	Unknown			Not Reported	
	L-Zhyrox Hexal (Levothyroxine)			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxagamma	S	Unknown	Not Reported
Ampicillin Ratiopharm	S	Unknown	Not Reported
Valsartan Ratiopharm Comp	S	Unknown	Not Reported
Spironolacton Aristo	S	Unknown	Not Reported
Eferox	S	Unknown	Not Reported
Ciprofloxacin Aristo	S	Unknown	Not Reported
Euthyrox	S	Unknown	Not Reported
Ampho Moronal	S	Unknown	Not Reported
Mometahexal	S	Unknown	Not Reported
Pantoprazol Pensa	S	Unknown	Not Reported
Hct Hexal	S	Unknown	Not Reported
Cotrimoxazol Al Forte	S	Unknown	Not Reported
Cotrimoxazol Al Forte	S	Unknown	Not Reported
Clindamycin Al	S	Unknown	Not Reported
Valsacor Comp	S	Unknown	Not Reported
Novaminsulfon	S	Unknown	Not Reported
Hygroton	S	Unknown	Not Reported
Locacorten Vioform	S	Unknown	Not Reported
Cefpo Basics	S	Unknown	Not Reported
Cefpo Basics	S	Unknown	Not Reported
Clindasol (Clindamycin Hydrochloride)	S	Unknown	Not Reported
Cefpodoxim Hexal	S	Unknown	Not Reported
Valsartan Hexal	S	Unknown	Not Reported
Valsartan Hexal	S	Unknown	Not Reported
Fluconazol Puren	S	Unknown	Not Reported
Clinda-Saar	S	Unknown	Not Reported
Valsartan 1a Pharma Plus	S	Unknown	Not Reported
Doxazosin 2 Cor 1a Pharma	S	Unknown	Not Reported
Codeintropfen Ct	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefpodoxim 1 A Pharma	S	Unknown	Not Reported
Nebivolol Actavis	S	Unknown	Not Reported
Monuril	S	Unknown	Not Reported
Doxycyclin 1a Pharma	S	Unknown	Not Reported
Cotrim Forte Ratiopharm	S	Unknown	Not Reported
Lonolox	S	Unknown	Not Reported
Dolgit 600	S	Unknown	Not Reported
Rasilez	S	Unknown	Not Reported
Rasilez	S		Not Reported
Clindahexal	S	Unknown	Not Reported
Levothyroxine	S	Unknown	Not Reported
L-Thyrox Hexal	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Cotrimox Forte	S	Unknown	Not Reported
Valsartan/Hct	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17410762	NON-EXPEDITED			NVSC2020US038213			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pain; Swelling	Azithromycin 600 Mg			S	Unknown	Unk		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17410818	NON-EXPEDITED			US-PFIZER INC-2020061194			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Methylprednisolone Acetate			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17410879	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-BAXTER-2020BAX002741		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Procytox (Cyclophosphamide) 2000mg/Vial			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Baxter	
	Adriamycin			S	Intravenous (not otherwise specified)			Not Reported	
	Amiodarone			S	Unknown	Dosage Form Not Specified		Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	
	Diltiazem Cd			S	Oral	Capsule Controlled-Delivery		Not Reported	
	Dimenhydrinate			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	
	Enoxaparin			S	Subcutaneous			Not Reported	
	Furosemide			S	Oral	Dosage Form Not Specified		Not Reported	
	Hydralazine			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	
	Hydromorphone			S	Intravenous (not otherwise specified)	Dosage Form Tablets		Not Reported	
	Methylprednisolone Nos			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	
	Metoprolol			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	
	Metoprolol			S	Intravenous (not otherwise specified)	Dosage Form Not Specified		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine Sulfate	S	Intravenous (not otherwise specified)	Injection Usp; Dosage Form Liquid Intramuscular	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	Injection; Dosage Form Liquid Intravenous	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	Dosage Form Not Specified	Not Reported
Pms-Azithromycin	S	Intravenous (not otherwise specified)	Dosage Form Not Specified	Not Reported
Trastuzumab	S	Unknown		Not Reported
Dexamethasone	C	Unknown	Dosage Form Not Specified	Not Reported
Emend	C	Unknown		Not Reported
Filgrastim	C	Unknown		Not Reported
Gabapentin	C	Unknown	Dosage Form Not Specified	Not Reported
Metoclopramide	C	Unknown	Dosage Form Not Specified	Not Reported
Ondansetron	C	Unknown	Dosage Form Tablets	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2020	17411468	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-236514		57 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Hepatocellular Injury	Pantoprazole			S	Oral	Unk		Sun	
	Zithromax			S	Oral	Non Renseigneur ()		Not Reported	
	Zelitrex			S	Oral	1000 Milligram, Daily		Not Reported	
	Bactrim			S	Oral	Non Renseigneur ()		Not Reported	
	Zelitrex			C	Oral	Non Renseigneur ()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	13304987	EXPEDITED (15-DAY)		HO	US-PFIZER INC- 2017090861		78 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Circumstance Or Information Capable Of Leading To Medication Error; Musculoskeletal Chest Pain; Nasopharyngitis; Product Availability Issue; Vomiting	Zithromax			S		Unk		Pfizer	
	Xtandi			S	Oral	160 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	16454242	NON-EXPEDITED			PHEH2019US025247			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Hypoacusis	Azithromycin			S	Unknown	Unk		Novartis	
	Metformin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	16462003	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-034305		25 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Azithromycin			S	Unknown	Unk		Aurobindo	
	Levofloxacin			S	Unknown	Unk		Aurobindo	
	Diphenhydramine Hydrochloride			S	Unknown	Unk		Not Reported	
	Diphenhydramine Hydrochloride			S				Not Reported	
	Diphenhydramine Hydrochloride			S				Not Reported	
	Diphenhydramine Hydrochloride			S				Not Reported	
	Omalizumab			S	Unknown	Unk		Not Reported	
	Omalizumab			S	Unknown	300 Milligram,1 Every 2 Week		Not Reported	
	Omalizumab			S	Unknown	150 Milligram		Not Reported	
	Reactine (Cetirizine Hydrochloride)			S	Unknown	20 Milligram, Every Other Day		Not Reported	
	Reactine (Cetirizine			S	Unknown	10 Milligram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrochloride) Xolair	S	Subcutaneous	300 Milligram, 1 Every 2 Week	Not Reported
Xolair	S	Subcutaneous	150 Milligram	Not Reported
Rifadin	S	Unknown	Unk	Not Reported
Rifampin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	16719230	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2019-052999		67 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use In Unapproved Indication; Product Use Issue	Atorvastatin Tablets			S	Oral	20 Milligram		Not Reported
	Atorvastatin			S	Unknown	20 Milligram		Not Reported
	Azithromycin			S	Oral	250 Milligram, 3 Times A Day		Aurobindo
	Azithromycin			S	Oral	250 Milligram, Two Times A Day		Aurobindo
	Apo Azithromycin			S	Oral	250 Milligram, Two Times A Day		Not Reported
	Seebri Breezhaler			S	Unknown	50 Milligram, Daily		Not Reported
	Glycopyrronium Bromide;Indacaterol			S		1 Dosage Form		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Dexilant			C	Unknown	Unk		Not Reported
	Fosamax			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Pulmicort			C	Unknown	Unk		Not Reported
	Qvar			C	Unknown	Unk		Not Reported
	Remicade			C	Unknown	Unk		Not Reported
	Salbutamol			C	Unknown	Unk		Not Reported
	Alendronate Sodium			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Montelukast	C	Unknown	Unk	Not Reported
Pulmicort	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17411528	EXPEDITED (15-DAY)		DE, HO, LT	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-236141			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance; Escherichia Sepsis; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pneumonia Escherichia	Azithromycin			S	Transplacental	500 Mg Q 6 X 48 Hours		Sun
	Azithromycin			S				Sun
	Ampicillin			S	Transplacental	2 G Q 6 X 48 Hours		Not Reported
	Ampicillin			S				Not Reported
	Ampicillin			S	Transplacental	Unk		Not Reported
	Ampicillin			S				Not Reported
	Erythromycin			S	Transplacental	Unk		Not Reported
	Erythromycin			S				Not Reported
	Gentamycin			S	Transplacental	Unk		Not Reported
	Penicillin			S	Transplacental	Unk		Not Reported
	Betamethasone			C	Unknown	Unk		Not Reported
	Magnesium Sulfate			C	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17412216	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1183494		35 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypoxia; Maternal Exposure During Pregnancy; Ventilation Perfusion Mismatch	Omeprazole			S		40 Milligram Daily;		Teva
	Fluticasone			S	Unknown			Teva
	Salbutamol			S	Respiratory (inhalation)			Actavis
	Tobramycin			S	Respiratory (inhalation)			Teva

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bupivacaine Hydrochloride	S	Unknown		Not Reported
Fentanyl	S	Unknown		Not Reported
Levothyroxine Sodium	S	Unknown	125 Microgram Daily;	Not Reported
Morphine Sulfate	S	Unknown		Not Reported
Ondansetron	S	Intravenous (not otherwise specified)		Not Reported
Oxytocin	S	Intravenous (not otherwise specified)		Not Reported
Phenylephrine Hcl	S	Intravenous (not otherwise specified)		Not Reported
Pms Azithromycin	S	Respiratory (inhalation)		Not Reported
Serevent	S	Respiratory (inhalation)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17412365	EXPEDITED (15-DAY)		OT	BE-TEVA-2020-BE-1185179		35 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Swelling	Azithromycin 500 Mg			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17412426	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-006869		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Dyspnoea; Increased Upper Airway Secretion; Loss Of Personal Independence In Daily Activities;	Azithromycin			S	Unknown	Unk		Aurobindo	
Polymyositis; Sleep Apnoea Syndrome; Sleep	Alvesco			S	Unknown	2 Dosage Form, Once A Day		Not Reported	
	Nucala			S	Intravenous (not otherwise specified)	100 Milligram		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder Due To A General Medical Condition; Therapeutic Product Effect Incomplete; Thyroid Disorder; Wheezing	Tiotropium	S	Unknown	2 Dosage Form, Once A Day	Not Reported
	Zenhale	S	Unknown	2 Dosage Form, Two Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17412455	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2020-006949		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	Unk		Aurobindo
	Advair			S	Unknown	Unk		Not Reported
	Atrovent			S	Unknown	Unk		Not Reported
	Nucala			S	Intravenous (not otherwise specified)	100 Milligram		Not Reported
	Prednisone			S	Unknown	10 Milligram		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17412880	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020-BI-00		58 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Oesophageal Carcinoma; Wheezing	Spiriva			S	Unknown			Boehringer Ingelheim
	Alvesco			S	Unknown	Dosage Form-Aerosol, Metered Dose		Not Reported
	Salbutamol			S	Unknown			Not Reported
	Zenhale			S	Unknown	Dosage Form-Aerosol Metered Dose		Not Reported
	Zithromax			S	Unknown			Not Reported
	Prednisone			C	Unknown	Dosage Form-Not Specified		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17413034	NON-EXPEDITED			NVSC2020US038069			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Gene Mutation	Azithromycin			S	Unknown	1 G		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17413597	EXPEDITED (15-DAY)		HO	NVSC2020NL034521		20 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea;	Azithromycin			S	Oral	1e Dag 2 Tegelijk, Daarna		Novartis	
Hypersensitivity;						1 Keer Per Dag 1 Tablet			
Pharyngeal Swelling;	Microgynon			C	Unknown			Not Reported	
Swollen Tongue	Methylfenidaat Hcl			C	Unknown	Ochtend 1, Middag Een Halve Tablet		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17413662	DIRECT		OT			28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction;	Azithromycin Tablets 250 Mg			S	Oral	Quantity:1 Tablet(S);		Greenstone	
Hypersensitivity; Nausea;	Sudafed			C				Not Reported	
Product Substitution Issue;	Tylenol			C				Not Reported	
Rash Macular; Swollen Tongue									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17413936	EXPEDITED (15-DAY)		OT	CA-BAXTER-2020BAX002879			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity;	Procytox (Cyclophosphamide)			S	Intravenous (not otherwise specified)	Dosage Form- Not Specified		Baxter	
Drug Ineffective; Drug	2000mg/Vial								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Arava	S	Unknown	Dosage Form- Tablets	Not Reported
	Azithromycin	S	Unknown	Dosage Form- Not Specified	Not Reported
	Azithromycin	S	Unknown	Dosage Form- Not Specified	Not Reported
	Benadryl	S	Unknown	Dosage Form- Not Specified	Not Reported
	Celebrex	S	Oral		Not Reported
	Cimzia	S	Subcutaneous	Dosage Form- Solution Subcutaneous Single-Use Prefilled Syringe	Not Reported
	Demerol	S	Unknown	Dosage Form- Not Specified	Not Reported
	Enbrel	S	Unknown		Not Reported
	Humira	S	Subcutaneous	Dosage Form- Solution Subcutaneous	Not Reported
	Imuran	S	Unknown	Dosage Form- Not Specified	Not Reported
	Levofloxacin	S	Unknown	Dosage Form- Not Specified	Not Reported
	Methotrexate	S	Unknown		Not Reported
	Methotrexate	S	Unknown	Dosage Form Not Specified	Not Reported
	Plaquenil	S	Unknown	Dosage Form- Tablets	Not Reported
	Simponi	S	Subcutaneous	Dosage Form- Solution Subcutaneous	Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Xeljanz	S	Oral		Not Reported
	Ezetrol	C	Unknown	Dosage Form- Tablets	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17413996	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1016518		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Salbutamol			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Prednisone			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Mycophenolate Mofetil			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17414198	EXPEDITED (15-DAY)		HO, OT	GR-MYLANLABS-2020M1003349		79 YR	Female	GRC
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumocystis Jirovecii Pneumonia	Methotrexate			S	Oral	15 Mg, Weekly, 15 Mg Per Os Once A Week		Not Reported	
	Tofacitinib Citrate			S	Oral	5 Mg,2x/Day		Mylan	
	Prednisolone			S	Oral	5 Mg,Daily, (5 Mg/Day Per Os)		Mylan	
	Prednisolone			S	Oral	1 Mg/Kg (Milligram Per Kilogram) (1 Mg/Kg/Day)		Mylan	
	Prednisolone			S		5 Mg, Qd (5 Mg/Day Per Os)		Mylan	
	Trimethoprim Sulfamethoxazole			S		Unk, 15mg Tmp/Kg/Day `		Mylan	
	Tofacitinib			S		5 Mg, Bid Rheumatoid Arthritis		Mylan	
	Tofacitinib			S		5 Mg, Bid (5 Mg Per Os Twice A Day)		Mylan	
	Moxifloxacin			S		Unk		Mylan	
	Azithromycin			S		Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Oseltamivir	S	Mylan
Cefixime	S	Mylan
Meropenem	S	Mylan
Levofloxacin	S	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17414902	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020059630		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Wall Haematoma; Anaemia	Azithromycin			S	Oral	250 Mg, Alternate Day		Pfizer
	Coumadine			S	Oral	1 Df, 1x/Day		Not Reported
	Seretide			C		Unk		Not Reported
	Amiodarone			C		Unk		Not Reported
	Bronchodual			C		Unk		Not Reported
	Spiriva			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17415223	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020057069		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis Ulcerative; Crohn'S Disease; Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S	Oral	Unk		Pfizer
	Codeine			C	Unknown	Unk For 10 Days		Not Reported
	Pregabalin			C	Oral	Unk		Not Reported
	Salbutamol			C	Respiratory (inhalation)	Unk		Not Reported
	Flovent			C	Respiratory (inhalation)	Unk		Not Reported
	Accutane			C	Oral	Unk		Not Reported
	Calcium			C	Oral	Unk		Not Reported
	Apo-Venlafaxine Xr			C	Oral	150 Mg, Unk		Not Reported
	Pantoprazole			C	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Naproxen	C	Oral	Unk	Not Reported
D-Tabs	C	Oral	Unk	Not Reported
Candesartan	C	Oral	Unk	Not Reported
Co-Carbonate	C	Oral	Unk	Not Reported
Tylenol	C	Oral	Unk	Not Reported
Vitamin D	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17415310	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020063172		30 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact; Pruritus; Rash; Rash Erythematous	Zithromax			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17415984	EXPEDITED (15-DAY)		HO, LT	GB-MYLANLABS-2020M1015853		52 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Drug-Induced Liver Injury; Faeces Pale; Hepatitis Cholestatic; Jaundice	Azithromycin			S		1500 Milligram, Qw		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2020	17416152	NON-EXPEDITED			US-TEVA-2020-US-1184343			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Anxiety; Crying; Emotional Disorder; Irritability; Urticaria	Azithromycin			S	Oral	Form Strength: 200 Mg Per 5 MI		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	16117604	EXPEDITED (15-DAY)		OT	AT-TEVA-2019-AT-1028157			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; C-Reactive Protein Increased; Candida Infection; Drug Ineffective; Infection	Azithromycin			S	Unknown			Not Reported	
	Colistin Sulfate			S	Unknown			Not Reported	
	Sulbactam			S	Unknown			Not Reported	
	Cubicin			S	Unknown			Not Reported	
	Tigecycline			S	Unknown			Not Reported	
	Rifoldin			S	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	16186814	EXPEDITED (15-DAY)		HO, OT	DE-ALLERGAN-1915887US			Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Transitional Cell Carcinoma	Fosfomycin Tromethamine - Bp			S		Unk		Allergan	
	Moronal			S	Unknown	Unk		Not Reported	
	Ibu 1a Pharma			S	Unknown	Unk		Not Reported	
	Ciprofloxacin Al			S	Unknown	Unk		Not Reported	
	Valsartan Hct			S	Unknown	Unk		Not Reported	
	Azithromycin 1 A Pharma			S	Unknown	Unk		Not Reported	
	Roxithromycin			S	Unknown	Unk		Not Reported	
	Ibuflam (Ibuprofen)			S	Unknown	Unk		Not Reported	
	Linola H Fett N			S	Unknown	Unk		Not Reported	
	Lercanidipina Ratiopharm			S	Unknown	Unk		Not Reported	
	Decortin H			S	Unknown	Unk		Not Reported	
	L-Thyrox			S	Unknown	Unk		Not Reported	
	Doxagamma			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ampicillin Ratiopharm	S	Unknown	Unk	Not Reported
Valsartan Ratiopharm Comp	S	Unknown	Unk	Not Reported
Spironolacton Aristo	S	Unknown	Unk	Not Reported
Eferox	S	Unknown	Unk	Not Reported
Ciprofloxacin	S	Unknown	Unk	Not Reported
Ciprofloxacin	S		Unk	Not Reported
Euthyrox	S	Unknown	Unk	Not Reported
Ampho Moronal	S	Unknown	Unk	Not Reported
Alfason Crelo	S	Unknown	Unk	Not Reported
Mometahexal	S	Nasal	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Hct Hexal	S	Unknown	Unk	Not Reported
Cotrim Forte	S	Unknown	Unk	Not Reported
Clindamycin Al	S	Unknown	Unk	Not Reported
Valsacor	S	Unknown	Unk	Not Reported
Novaminsulfon	S	Unknown	Unk	Not Reported
Hygroton	S	Unknown	Unk	Not Reported
Locacorten Vioform	S	Unknown	Unk	Not Reported
Cefpodoxim	S	Unknown	Unk	Not Reported
Cefpodoxim	S		Unk	Not Reported
Clindasol (Clindamycin Hydrochloride)	S	Unknown	Unk	Not Reported
Cefpodoxim Hexal	S	Unknown	Unk	Not Reported
Fluconazole	S	Unknown	Unk	Not Reported
Clinda-Saar	S	Unknown	Unk	Not Reported
Valsartan 1a Pharma Plus	S	Unknown	Unk	Not Reported
Doxazosin 1 A Pharma	S	Unknown	Unk	Not Reported
Codeintropfen Ct	S	Unknown	Unk	Not Reported
Nebivolol Actavis	S	Unknown	Unk	Not Reported
Nebivolol Actavis	S			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxycyclin 1a Pharma	S	Unknown	Unk	Not Reported
Sulfamethoxazole	S	Unknown	Unk	Not Reported
W/Trimethoprim	S	Unknown	Unk	Not Reported
Trimethoprim	S	Unknown	Unk	Not Reported
Lonolox	S	Unknown	Unk	Not Reported
Valsartan Hexal	S	Unknown	Unk	Not Reported
Dolgit	S	Unknown	Unk	Not Reported
Rasilez	S	Unknown	Unk	Not Reported
Rasilez	S	Unknown	Unk	Not Reported
Clindahexal	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	16740365	EXPEDITED (15-DAY)	OT		CA-BAYER-2019-149923		57 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Discomfort; Diverticulum Intestinal; Female Genital Tract Fistula; Haemorrhoids; Large Intestinal Ulcer; Lithotripsy; Loss Of Personal Independence In Daily Activities; Nausea; Nephrolithiasis; Pain; Stent Placement; Vaginal Discharge; Vaginal Flatulence; Vaginal Haemorrhage	Cipro 500 Mg			S		500 Mg, Bid		Bayer
	Inflectra [Infliximab Dyyb]			S	Intravenous (not otherwise specified)	5 Mg/Kg At 0, 2, 6 Weeks, Then Every 8 Weeks		Not Reported
	Vitamin B12 Nos			S		1000 Mcg/MI Vial		Not Reported
	Vancomycin			S		Unk Unk, Bid		Not Reported
	Azithromycin			S		Unk		Not Reported
	Methotrexate			S	Oral	2.5 Mg 8 Tablets Weekly On Saturdays		Not Reported
	Folic Acid			C		5mg 6 Times Per Week		Not Reported
	Flagyl [Metronidazole Benzoate]			C	Oral	500mg Po Bid - Loe		Not Reported
	Oxycodone			C		Unk		Not Reported
	Cyanocobalamin			C		1000 Mcg/MI Vial		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	16755836	EXPEDITED (15-DAY)	CA, DS, HO, OT		LV-AMERICAN REGENT INC-20181739			Unknown	LVA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Anal Atresia; Duodenal Atresia; Female Genital Tract Fistula; Foetal Exposure During Pregnancy; Oesophageal Atresia; Respiratory Distress; Spine Malformation	Ferinject (Ferric Carboxymaltose - Vifor) (Fer-Vifor-02)	S	Transplacental	50 Milligram Per Millilitre	American Regent
	Venofer (Iron Sucrose Injection-Vifor)	S	Transplacental	100 Mg	American Regent
	Azithromycinum	S	Transplacental	500 Mg (500 Mg, 1 In 1 D)	Not Reported
	Cefuroxime	S	Transplacental	1500 Mg (750 Mg, 2 In 1 D)	Not Reported
	Cefuroxime	S	Transplacental	3000 Mg (1500 Mg, 2 In 1 D)	Not Reported
	Penicillin G Benzathine	S	Transplacental	4 Gm (1 Gm, 4 In 1 D)	Not Reported
	Paracetamol	S	Transplacental	1000 Mg (500 Mg, 2 In 1 D)	Not Reported
	Maltofer (Iron Iii Hydroxide Polymaltose Complex) Ferrum	S	Transplacental	Unknown	Not Reported
		S	Transplacental	100 Mg Three Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	16780407	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019386353		63 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Failure	Levofloxacin			S	Unknown	Unk		Pfizer
	Levofloxacin			S				Pfizer
	Levofloxacin			S				Pfizer
	Levofloxacin			S				Pfizer
	Levofloxacin			S				Pfizer
	Levofloxacin			S				Pfizer
	Rifabutin			S	Unknown	Unk		Pfizer
	Rifabutin			S				Pfizer
	Rifabutin			S				Pfizer
	Rifabutin			S				Pfizer
	Rifabutin			S				Pfizer
	Rifabutin			S				Pfizer
	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer
	Azithromycin			S				Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Azithromycin	S			Pfizer
Isoniazid	S	Unknown	Unk	Not Reported
Isoniazid	S			Not Reported
Isoniazid	S			Not Reported
Isoniazid	S			Not Reported
Isoniazid	S			Not Reported
Isoniazid	S			Not Reported
Pyrazinamide	S	Unknown	Unk	Not Reported
Pyrazinamide	S			Not Reported
Pyrazinamide	S			Not Reported
Tacrolimus	C		Unk	Not Reported
Mycophenolate Mofetil	C		Unk	Not Reported
Thymoglobulin	C		Unk (4-6 Mg/Kg)	Not Reported
Prednisone	C		Unk	Not Reported
Valganciclovir	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17007129	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2019-070251		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bone Marrow Failure; Nausea; Toxicity To Various Agents; Transaminases Increased; Vomiting	Azithromycin			S	Oral	10 Milligram/Kilogram, Once A Day		Aurobindo
	Azithromycin			S	Intravenous (not otherwise specified)	60 Milligram/Kilogram, Once A Day (60/60 Mg/Kg/Day In 2-4 Doses, Dilution Of Powder Formulations)		Aurobindo
	Cilastatin;Imipenem			S				Not Reported
	Cilastatin;Imipenem			S	Intravenous (not otherwise specified)	2.4 Milligram/Kilogram, Once A Day (In 2 Doses, Dilution Of Powder Formulations)		Not Reported
	Tigecycline			S				Not Reported
	Tigecycline			S	Oral	Unk, Once A Day		Not Reported
	Clofazimine			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Clofazimine		S						Not Reported
	Tigecycline		S		Topical		3 Gtt Drops, 3 Times A Day (Three Drops Three Times Daily)		Not Reported
	Tigecycline		S						Not Reported
	Cilastatin;Imipenem		S		Topical		3 Gtt Drops, 3 Times A Day (Three Drops Three Times Daily)		Not Reported
	Cilastatin;Imipenem		S						Not Reported
	Sodium Chloride 0.9%		C		Unknown		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17417006	EXPEDITED (15-DAY)		HO, OT	US-APOTEX-2020AP007573		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Azithromycin			S	Unknown	Unk			Apotex
	Ibuprofen			S	Unknown	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17418038	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-236581		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Anaemia	Azithromycin			S	Oral	250 Milligram, 1dose/2days			Sun
	Coumadine 2 Mg, Comprime			S	Oral	1 Dosage Form, Daily			Not Reported
	Secable								
	Seretide			C	Unknown	Unk			Not Reported
	Amiodarone			C	Unknown	Unk			Not Reported
	Bronchodual			C	Unknown	Unk			Not Reported
	Spiriva			C	Unknown	Unk			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17418483	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-00282		68 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin Tablets, 250 Mg			S	Unknown	2 Dosage Form, Single		Lupin	
	Azithromycin Tablets, 250 Mg			S	Unknown	250 Milligram, Qd		Lupin	
	Esomeprazole Magnesium			C	Unknown	Unk (Tapered Dose)		Not Reported	
	Prednisone			C	Unknown	Unk (Tapered Dose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17419038	EXPEDITED (15-DAY)		DE, OT	CA-TEVA-2020-CA- 1184748		81 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Acute	Risedronate Sodium			S	Unknown			Teva	
Kidney Injury; Adjustment	Codeine			S	Unknown			Not Reported	
Disorder; Anaemia;	Aclasta			S	Intravenous drip			Not Reported	
Angina Pectoris; Atrophy;	Amoxil			S	Unknown			Not Reported	
Back Pain; Bundle Branch	Zithromax			S	Unknown			Not Reported	
Block Left; Drug	Esomeprazole Sodium			C	Unknown			Not Reported	
Hypersensitivity; Drug	Dilaudid			C	Unknown			Not Reported	
Intolerance; Hepatic	Propranolol Hydrochloride			C	Unknown			Not Reported	
Steatosis;									
Hypercalcaemia;									
Hypertension; Monoclonal									
Gammopathy;									
Musculoskeletal Pain;									
Osteoarthritis; Palmar									
Erythema; Plasma Cell									
Myeloma; Sacroiliitis;									
Spinal Disorder; Toxicity									
To Various Agents									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17419542	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1183560			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Acetaminophene			S	Unknown			Not Reported
	Alprazolam			S	Unknown			Actavis
	Amoxicillin			S	Unknown			Teva
	Atorvastatin			S	Unknown			Teva
	Azithromycin Dihydrate			S	Unknown			Not Reported
	Betamethasone			S	Unknown			Actavis
	Betamethasone Dipropionate			S	Unknown			Actavis
	Calcium Carbonate			S	Unknown			Not Reported
	Calcium Carbonate/Vitamin D3			S	Unknown			Not Reported
	Calcium Carbonate/Vitamin D3			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Actavis
	Diphenhydramine			S	Unknown			Barr
	Magnesium Sulfate			S	Unknown			Not Reported
	Morphine Sulfate			S	Unknown			Not Reported
	Nicotine			S	Unknown			Actavis
	Nicotine Polacrilex			S	Unknown			Actavis
	Pantoprazole			S	Unknown			Teva
	Prednisone			S	Unknown			Actavis
	Pregabalin			S	Unknown			Actavis
	Sulfamethoxazole And Trimethoprim			S	Unknown			Actavis
	Glycerine			S	Oral			Not Reported
	Zinc Oxide			S	Unknown			Teva
	Apo Hydro			S	Endocervical			Not Reported
	Atropine Sulfate/Diphenoxylate Hydrochloride			S	Oral			Not Reported
	Avamys			S	Unknown			Not Reported
	Biaxin XL			S	Unknown			Not Reported
	Bisacodyl			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cetirizine	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Cupric Oxide	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
DI-Alpha Tocopheryl Acetate	S	Unknown	Not Reported
Entocort	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Jackson'S Mineral Salts Sodium Chloride [Homeopathic]	S	Nasal	Not Reported
Kenalog	S	Intra-articular	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride/So	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported
Ms Ir	S	Unknown	Not Reported
Mupirocin	S	Unknown	Not Reported
Mupirocin	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sinus Rinse	S	Nasal	Not Reported
Vitamin D3	S	Unknown	Not Reported
Xantofyl Palmitate	S	Unknown	Not Reported
Zeaxanthin	S	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Valsartan			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17420060	NON-EXPEDITED			US-PFIZER INC-2020062618			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17420908	EXPEDITED (15-DAY)		HO	IT-MYLANLABS-2020M1015898		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Diarrhoea; Jaundice; Liver Disorder	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Augmentin /00852501/			S	Oral	2 Gram, Qd		Mylan	
	Fidato			S	Intramuscular	1 Dosage Form, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2020	17422244	NON-EXPEDITED			NVSC2020US039732		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Novartis	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Albuterol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2020	17422582	EXPEDITED (15-DAY)		OT	BE-AUROBINDO-AUR-APL-2020-007315		35 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Swelling	Azithromycin 500 Mg			S	Oral	Unk		Aurobindo	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2020	17422658	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007465			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Alendronic Acid			S	Oral	35 Milligram		Aurobindo
	Alendronic Acid			S				Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Alendronic Acid Tablets			S				Aurobindo
	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Oral	25 Milligram		Aurobindo
	Salbutamol			S	Unknown	8 Dosage Form		Not Reported
	Xolair			S	Subcutaneous	150 Milligram		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Ciclesonide			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Symbicort			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2020	17422793	EXPEDITED (15-DAY)		DE	US-ZYDUS-047558			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Neonatal Infection	Azithromycin			S	Unknown			Zydus Pharm
	Ampicillin			S	Intravenous (not otherwise specified)			Not Reported
	Erythromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2020	17422812	EXPEDITED (15-DAY)		DE, OT	NVSC2020CA040475		84 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Decreased	Afinitor			S	Unknown	5 Mg, Qd		Novartis
Appetite; Drug Ineffective;	Azithromycin			S	Unknown	Unk		Not Reported
Fatigue; Malignant	Ciprofloxacin Hydrochloride			S	Unknown	Unk		Not Reported
Neoplasm Progression;	Sandostatin Lar			S	Unknown	60 Mg		Not Reported
Pancreatic	Octreotide			S	Unknown			Not Reported
Neuroendocrine Tumour;	Trimethoprim			S	Unknown			Not Reported
Platelet Count Decreased;								
Rash; Weight Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2020	17422814	EXPEDITED (15-DAY)		DE, OT	NVSC2020CA039183		84 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Death;	Afinitor			S	Oral	5 Mg, Qd		Novartis
Decreased Appetite; Drug	Azithromycin			S	Unknown	Unk		Not Reported
Ineffective; Fatigue;	Ciprofloxacin			S	Unknown	Unk		Not Reported
Malignant Neoplasm	Sandostatin Lar			S	Unknown	60 Mg		Not Reported
Progression; Pancreatic	Octreotide			S	Subcutaneous	Unk		Not Reported
Neuroendocrine Tumour;	Trimethoprim			S	Unknown			Not Reported
Platelet Count Decreased;								
Rash; Somnolence;								
Weight Decreased								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2020	17352034	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1175469		33 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Candida Pneumonia;	Azithromycin			S	Unknown			Not Reported
Hypoxia;	Prednisone			S	Unknown			Actavis
Lymphadenopathy								
Mediastinal; Metabolic								
Alkalosis; Respiratory								
Alkalosis								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	15566391	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2018GSK196467		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Off Label Use; Product Use Issue; Serum Sickness; Therapeutic Product Effect Incomplete	Fluticasone Furoate + Vilanterol Trifenatate			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Ventolin			S		Unk		Glaxosmithkline	
	Singulair			S		10 Mg, Qd		Glaxosmithkline	
	Arnuity Ellipta			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Flovent Diskus			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Azithromycin			S	Respiratory (inhalation)	Unk		Glaxosmithkline	
	Omalizumab			S		Unk		Not Reported	
	Prednisone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17269341	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1003479		60 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Haematochezia; Vomiting	Azithromycin			S	Oral	1 Dosage Form, Qd		Not Reported	
	Losartan Potasico			C	Unknown	Unk		Mylan	
	Hidroclorotiazida			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17369940	EXPEDITED (15-DAY)		HO	FR-BEH-2020112585		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Fasciitis;	Esomeprazole Sodium			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Lichenoid Keratosis	Zithromax	S	Oral	Non Renseignée	Not Reported
	Rocephine	S		Unk	Not Reported
	Darzalex	S	Intravenous (not otherwise specified)		Not Reported
	Tramadol Hydrochloride	C			Not Reported
	Valaciclovir	C			Not Reported
	Solupred [Prednisolone Metasulfobenzoate Sodium]	C			Not Reported
	Furosemide	C			Not Reported
	Privigen	S	Intravenous (not otherwise specified)	10 Gram	Csl Behring
	Privigen	S	Intravenous (not otherwise specified)	20 Gram	Csl Behring
	Bactrim	S	Oral		Not Reported
	Lyrica	C			Not Reported
	Augmentin Sr	S	Oral	Non Renseignée	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17396633	NON-EXPEDITED			PHHY2019US194994		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Skin Discolouration; Weight Decreased	Lamprene (Clofazimine)			S	Oral	100 Mg, Qd		Novartis
	Lamprene (Clofazimine)			S	Oral	100 Mg, Qod		Novartis
	Azithro (Azithromycin)			S	Unknown	Unk Unk, Qod		Not Reported
	Etham (Ethambutol Dihydrochloride)			S	Unknown	Unk Unk, Qod		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17423728	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-007445		66 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea;	Atorvastatin Tablets			S	Oral	20 Milligram		Not Reported
	Azithromycin			S	Oral	250 Milligram, 3 Times A		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use In Unapproved Indication	Glycopyrronium Bromide;Indacaterol Maleate Seebri Breezhaler	S		Day	Not Reported
		S		1 Dosage Form	Not Reported
		S		50 Microgram, Once A Day	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Montelukast	C	Unknown	Unk	Not Reported
	Pulmicort	C	Unknown	Unk	Not Reported
	Qvar	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported
	Salbutamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17424746	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-007471		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Exercise Tolerance Decreased; Lymphoma; Quality Of Life Decreased	Azithromycin			S	Oral	1 Dosage Form		Aurobindo
	Azithromycin			S		Unk		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Alendronic Acid Tablets			S				Aurobindo
	Alendronic Acid			S	Oral	1 Dosage Form		Aurobindo
	Alendronic Acid			S				Aurobindo
	Omalizumab			S	Subcutaneous	150 Milligram		Not Reported
	Alvesco			C		2 Dosage Form, Two Times A Day		Not Reported
	Calcium			C	Oral	1 Dosage Form, Two Times A Day		Not Reported
	Calcium Singulair			C C	Oral	1 Dosage Form, Once A Day		Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spiriva	C	1 Dosage Form, Once A Day	Not Reported
Symbicort	C	2 Dosage Form, Two Times A Day	Not Reported
Ventolin	C	8 Dosage Form	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17425147	EXPEDITED (15-DAY)	HO		CN-ROCHE-2549045		7 YR	Male	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
White Blood Cell Count Decreased	Rocephin			S	Intravenous drip			Not Reported
	Oseltamivir			S	Oral			Not Reported
	Azithromycin			S	Intravenous drip			Not Reported
	Sterile Water			C	Intravenous drip			Not Reported
	Glucose And Sodium Chloride			C	Intravenous drip			Not Reported
	Glucose			C	Intravenous drip	Solvent For Azithromycin For Injection		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2020	17428952	NON-EXPEDITED			NVSC2020US016774			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchitis; No Adverse Event	Cosentyx			S	Subcutaneous	300 Mg, Qmo		Novartis
	Cosentyx			S	Subcutaneous			Novartis
	Azithromycin			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	16983283	EXPEDITED (15-DAY)	OT		NL-009507513-1910NLD014597		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol	Imipenem (+) Cilastatin Sodium			S	Intravenous (not	60/60 Mg/Kg/Day In 2-4		Merck

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Hepatotoxicity; Hypertriglyceridaemia	Imipenem (+) Cilastatin Sodium Tigecycline	S S	otherwise specified)	Doses		Merck Not Reported
	Tigecycline	S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	Reduced Dosage		Not Reported
	Azithromycin	S	Oral	10 Mg/Kg Once Daily		Not Reported
	Clofazimine	S	Oral	50mg Once Daily; If Weight More Than 40kg, Then 100mg Once Daily		Not Reported
	Clofazimine	S				Not Reported
	Cilastatin Sodium (+) Imipenem	S	Topical	5/5 Mg/MI; Three Drops Three Times Daily		Not Reported
	Cilastatin Sodium (+) Imipenem Tigecycline	S S	Topical	5 Mg/MI; Three Drops Three Times Daily		Not Reported
	Tigecycline Granisetron	S C		Unk		Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17215653	NON-EXPEDITED			US-PFIZER INC- 2019560212		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17333736	EXPEDITED (15-DAY)		HO	PL-TEVA-2020-PL- 1175844		32 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abdominal Pain Upper; Abdominal Pain Upper; Diarrhoea; Pancreatic	Sumamed			S	Oral	500 Milligram Daily; The Patient Took Only 1 Dose		Not Reported	
	Cipronex			C		2 X 500 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disorder; Vomiting		Metronidazole		C		3 X 500 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17409297	NON-EXPEDITED			US-PFIZER INC-2020062983		72 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17420774	NON-EXPEDITED			US-PFIZER INC-2020066541			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17426851	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1186419			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pathogen Resistance	Azithromycin			S	Unknown	Single Dose			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17427465	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2020-BI-00		78 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anaemia; Aspiration; Asthenia; Asthma; Blood Calcium Increased; Blood Creatinine Increased; Blood Test Abnormal;	Spiriva			S	Unknown			Boehringer Ingelheim	
	Atrovent			S	Unknown			Boehringer Ingelheim	
	Mepolizumab			S	Intravenous (not otherwise specified)	Intravenous (Nototherwisespecified)		Not Reported	
	Mepolizumab			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bronchiectasis;	Montelukast	S	Oral	Not Reported
Bronchopulmonary	Morphine	S	Unknown	Not Reported
Aspergillosis Allergic;	Nasonex	S	Unknown	Not Reported
Constipation; Cough; Drug	Nitroglycerin	S	Unknown	Not Reported
Hypersensitivity; Drug	Pantoloc [Pantoprazole]	S	Unknown	Not Reported
Ineffective; Dyspnoea;	Pramipexole	S	Oral	Not Reported
Fatigue;	Pramipexole	S	Oral	Not Reported
Gastroesophageal Reflux	Pregabalin	S	Oral	Not Reported
Disease; Haemoptysis;	Prevnar	S	Unknown	Not Reported
Headache; Hypoxia; Liver	Quetiapine	S	Unknown	Not Reported
Function Test Increased;	Acetaminophen	S	Unknown	Not Reported
Lower Respiratory Tract	Azithromycin	S	Unknown	Not Reported
Infection; Lung Opacity;	Budesonide	S	Unknown	Not Reported
Musculoskeletal Stiffness;	Candesartan	S	Oral	Not Reported
Obstructive Airways	Dexilant	S	Unknown	Not Reported
Disorder; Oedema	Domperidone	S	Unknown	Not Reported
Peripheral; Pain; Pleural	Efinaconazole	S	Unknown	Not Reported
Effusion; Pneumonia;	Fluvaccin	S	Unknown	Not Reported
Pulmonary Fibrosis;	Lansoprazole	S	Unknown	Not Reported
Pyrexia; Rales; Sputum	Levothyroxine Sodium	S	Unknown	Not Reported
Discoloured; Total Lung	Ranitidine	S	Unknown	Not Reported
Capacity Decreased;	Risedronate	S	Unknown	Not Reported
Transaminases Increased;	Rosuvastatin Calcium	S	Unknown	Not Reported
Tremor; Upper Respiratory	Sennosides	S	Unknown	Not Reported
Tract Infection; Wheezing	Senokot	S	Unknown	Not Reported
	Singulair	S	Unknown	Not Reported
	Statex [Morphine Sulfate]	S	Oral	Not Reported
	Symbicort	S	Unknown	Not Reported
	Synthroid	S	Unknown	Not Reported

Capsule, Delayed Release

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Trazodone	S	Unknown	Not Reported
	Trazodone	S	Unknown	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Not Reported
	Vitamin D Nos	S	Oral	Not Reported
	Xolair	S	Unknown	Not Reported
	Zopiclone	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17429341	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020057735			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Premature Baby; Transient Tachypnoea Of The Newborn	Azithromycin			S	Transplacental	Unk		Pfizer	
	Methylprednisolone Sodium Succinate			S	Transplacental	Unk (2-Day Course)		Pfizer	
	Dexamethasone			S	Transplacental	Unk		Not Reported	
	Oseltamivir			S	Transplacental	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17429476	EXPEDITED (15-DAY)		HO	NVSC2020US038444			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Dermatitis Bullous; Linear Iga Disease; Lymphadenopathy; Mouth Ulceration; Pharyngeal Erythema; Pyrexia; Rash	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Novartis	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Aciclovir			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Nafcillin			C	Unknown	Unk		Not Reported	
	Diflucan			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17430072	NON-EXPEDITED			US-SHIRE- US202006193			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection	Hyqvia			S	Subcutaneous	30 Gram, Every 4 Wk		Shire	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Diphenhydramine			C		Unk		Not Reported	
	Ibuprofen			C		Unk		Not Reported	
	Normal Saline			C		Unk		Not Reported	
	Epinephrine			C		Unk		Not Reported	
	Nexium [Esomeprazole Sodium]			C		Unk		Not Reported	
	Ketorolac			C		Unk		Not Reported	
	Vicodin			C		Unk		Not Reported	
	Brimonidine			C		Unk		Not Reported	
	Detrol			C		Unk		Not Reported	
	Spiriva			C		Unk		Not Reported	
	Bisoprolol			C		Unk		Not Reported	
	Celebrex			C		Unk		Not Reported	
	Montelukast			C		Unk		Not Reported	
	Diovan			C		Unk		Not Reported	
	Lorazepam			C		Unk		Not Reported	
	Aspirin [Acetylsalicylic Acid]			C		Unk		Not Reported	
	Ventolin [Salbutamol Sulfate]			C		Unk		Not Reported	
	Levothyroxine			C		Unk		Not Reported	
	Fluticasone			C		Unk		Not Reported	
	Simvastatin			C		Unk		Not Reported	
	Qvar			C		Unk		Not Reported	
	Gabapentin			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17430076	NON-EXPEDITED			US-PFIZER INC-2020067945		28 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glossodynia; Lip Pain; Nausea; Off Label Use; Product Use In Unapproved Indication; Rash Macular; Swollen Tongue	Azithromycin			S	Oral	250 Mg, 2x/Day (Two By Mouth The First Day)		Pfizer	
	Sudafed [Pseudoephedrine Hydrochloride]			C		Unk Unk, As Needed		Not Reported	
	Tylenol [Paracetamol]			C		500 Mg, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17430337	NON-EXPEDITED			US-PFIZER INC-2020071592		56 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lyrica			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Aleve			S		Unk		Not Reported	
	Ambien			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17430824	EXPEDITED (15-DAY)		HO, OT	US-ROCHE-1993207		31 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Blindness; Dyspnoea; Multiple Sclerosis; Multiple Sclerosis; Pneumonia; Product Administration Error; Sepsis; Underdose; Visual Impairment; White Blood Cell Count Decreased	Ocrevus			S	Intravenous (not otherwise specified)	Subsequent Dose; 13/Feb/2019, 05/Aug/2019, 06/Feb/2020		Not Reported	
	Z-Pak			S	Unknown			Not Reported	
	Z-Pak			S				Not Reported	
	Cefepime			S	Unknown			Not Reported	
	Cefepime			S				Not Reported	
	Solumedrol			C	Intravenous (not	3 Doses One Received On		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Solumedrol	C	otherwise specified)	29, 30, And 31 August	
		Intravenous (not otherwise specified)	One Time Pre-Medication Dose	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	C	Intravenous (not otherwise specified)		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17430916	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020065820		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Bronchiectasis; Cardiac Failure	Atorvastatin Calcium			S	Unknown	20 Mg, 1x/Day		Pfizer
Congestive; Chronic Obstructive Pulmonary Disease; Constipation; Diastolic Dysfunction; Dyspnoea; Ejection Fraction Abnormal; Emphysema; Lung Hyperinflation; Obstructive Airways Disorder; Oedema Peripheral; Oxygen Saturation Abnormal; Productive Cough; Pulmonary Embolism; Respiratory Failure; Sputum Discoloured; Therapeutic Product Effect Incomplete; Ventricular Dysfunction; Ventricular Hypokinesia; Wheezing	Azithromycin			S	Unknown	250 Mg, 1x/Day		Pfizer
	Calcium Carbonate			S	Unknown	Unk, 1x/Day		Pfizer
	Furosemide			S	Unknown	20 Mg, 1x/Day		Unknown
	Hydromorphone Hydrochloride			S	Unknown	1 Mg, Unk		Unknown
	Amlodipine Besilate			S	Unknown	5 Mg, 1x/Day		Pfizer
	Bisoprolol			S	Unknown	Unk		Not Reported
	Citalopram			S	Unknown	20 Mg, Unk		Not Reported
	Docusate			S	Unknown	100 Mg, Unk		Not Reported
	Risedronate			S	Unknown	35 Mg, Unk		Not Reported
	Salbutamol			S	Unknown	Unk [1 Every 2 Days]		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Tiotropium			S	Unknown	2 Df, 1x/Day		Not Reported
	Xarelto			S	Unknown	20 Mg, 1x/Day		Not Reported
	Zenhale			S	Unknown	2 Df, 2x/Day		Not Reported
	Lasix			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17431940	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1186481		11 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Linear Iga Disease	Azithromycin	S	Unknown	Not Reported
	Ibuprofen	S	Unknown	Actavis
	Vancomycin	S	Intravenous (not otherwise specified)	Not Reported
	Vancomycin	S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17431988	NON-EXPEDITED			US-AKRON, INC.-2080632			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vision Blurred	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17432005	NON-EXPEDITED			US-AKRON, INC.-2080634			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypersensitivity; Migraine	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2020	17472855	DIRECT	N				23 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain	Azithromycin 250mg Tab Lupi			S	Oral	Other Dose:250;		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	14836834	EXPEDITED (15-DAY)		HO, OT	US-INCYTE CORPORATION-2018IN004082			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal; Device Related Infection; Diarrhoea; Fatigue; Pneumonia	Jakafi			S	Unknown	15 Mg, Bid		Incyte
	Jakafi			S	Oral	5 Mg, Bid		Incyte
	Jakafi			S	Oral	10mg Qam, 5mg Qpm		Incyte

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown		Not Reported
Fish Oil	C	Unknown	Unk	Not Reported
Vitamin D3	C	Unknown	Unk	Not Reported
Vitamin B12 /00056201/	C	Unknown	Unk	Not Reported
Vitamin D [Vitamin D Nos]	C	Unknown		Not Reported
Myrbetriq	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	16449296	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-034298		44 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthma; Blood Count Abnormal; Chills; Choking; Cough; Diarrhoea; Dysphagia; Dyspnoea; Dyspnoea Exertional; Ill-Defined Disorder; Obstruction; Oral Candidiasis; Pyrexia; Rhinitis Allergic; Sinusitis; Therapeutic Product Effect Incomplete; Weight Fluctuation; Wheezing	Azithromycin			S	Unknown	500 Milligram		Aurobindo
	Prednisone			S	Unknown	Unk		Not Reported
	Pulmicort			S		200 Microgram, 3 Times A Day		Not Reported
	Salbutamol			S	Unknown	3 Dosage Form		Not Reported
	Zenhale			S		200 Microgram, Two Times A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17408074	EXPEDITED (15-DAY)		HO	PT-MYLANLABS- 2020M1015175		83 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Abdomen; Drug Ineffective; Incarcerated Hernia; Pneumonia	Azithromycin			S	Unknown	Unk		Not Reported
	Amoxicillin/Clavulanic Acid			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17433916	EXPEDITED (15-DAY)		OT	SI-TEVA-2020-SI- 1187736		61 YR	Female	SVN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury	Sumamed 500 Mg			S	Intravenous (not otherwise specified)	500 Mg		Not Reported
	Berodual			C		2ml, 2ml+2ml Saline Solution		Not Reported
	Medrol 32 Mg			C		32 Mg		Not Reported
	Lekadol 500 Mg			C		1500mg, Up To 3x1/Day As Necessary		Not Reported
	Solu Cortef 100 Mg			C	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Lyrica 75 Mg			C	Oral	75 Milligram Daily; 75mg, 1 Caps In The Mornings		Not Reported
	Aspirin Protect 100mg			C	Oral	100 Milligram Daily; 100mg, 1 Tbl At Noon		Not Reported
	Amoksiklav 1000 Mg			C	Oral	1000 Mg		Not Reported
	Acipan 40 Mg			C	Oral	40 Milligram Daily; 1 Tbl In The Mornings		Not Reported
	Amoksiklav			C	Intravenous (not otherwise specified)	0.6 Gm		Not Reported
	Amoksiklav			C	Intravenous (not otherwise specified)			Not Reported
	Solu Cortef			C	Intravenous (not otherwise specified)	50 Mg		Not Reported
	Fragmin 5000 Ie			C		5000 Iu		Not Reported
	Irumed 10 Mg			C		15mg, 1tbl In The Mornings And 1/2 Tbl In The Evenings		Not Reported
	Daktarin			C	Oral	3 Dosage Forms		Not Reported
	Hydrocortisone 10 Mg			C	Oral	10mg, 2+1+1		Not Reported
	Foster 100 Mikrogramm/6 Mikrogramm			C		4 Dosage Forms, 100/6mcg/Inhalation, 2x2		Not Reported
	Dulcolax			C	Rectal	1 Dosage Form		Not Reported
	Spiriva 18 Microgram			C		18 Mcg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Portalac		C	Oral	2 Tablespoons			Not Reported	
	Tamiflu 75 Mg		C	Oral	75 Mg			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17435220	EXPEDITED (15-DAY)		HO	US-AMNEAL PHARMACEUTICALS- 2020-AMRX-00514		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis Bacterial; Linear Iga Disease	Ibuprofen			S	Unknown	Unk		Amneal	
	Ibuprofen			S				Amneal	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17435627	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1017887		77 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Dermatitis; Drug Hypersensitivity	Azithromycin			S	Ophthalmic	Unk		Not Reported	
	Tetracaine			S	Ophthalmic	Eye Drops		Mylan	
	Eylea			S	Intraocular	Unk		Mylan	
	Povidone Iodine			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17436793	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2020M1018103		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Amoxicillin			S	Oral	3 Gram, Qd		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17436840	NON-EXPEDITED		DE	NVSC2020US045572		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Unk		Novartis	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
	Ibrutinib			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437016	NON-EXPEDITED			US-AKRON, INC.- 2080670			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ocular Hyperaemia	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437059	NON-EXPEDITED			US-AKRON, INC.- 2080672			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dry Skin; Eye Pain	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437072	NON-EXPEDITED			US-AKRON, INC.- 2080673			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437075	EXPEDITED (15-DAY)		DE, HO	US-TEVA-2020-US- 1186402			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Bradycardia; Drug Ineffective; Escherichia Infection; Foetal Exposure During Pregnancy; Neonatal Respiratory Distress Syndrome; Pathogen Resistance; Pneumonia; Pulmonary Congestion; Pulmonary Haemorrhage; Respiratory Acidosis; Sepsis Neonatal	Norepinephrine Ampicillin Ampicillin Azithromycin Azithromycin Erythromycin Erythromycin Betamethasone Magnesium Sulfate Dopamine Dobutamine	S S S S S S S S S S S S	Unknown Transplacental Transplacental Transplacental Transplacental Transplacental Transplacental Transplacental Transplacental Unknown Unknown	Every 6 X 48 Hours Every 6x 48 Hours	Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437090	NON-EXPEDITED			US-AKRON, INC.-2080674			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437108	NON-EXPEDITED			US-AKRON, INC.-2080675			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437157	EXPEDITED (15-DAY)		OT	NVSC2020US044972			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Neonatal Tachypnoea	Azithromycin			S	Transplacental	Maternal Dose: Unknown		Novartis

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17437158	NON-EXPEDITED			US-AKRON, INC.- 2080676			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17437174	NON-EXPEDITED			US-AKRON, INC.- 2080677			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17437193	NON-EXPEDITED			US-AKRON, INC.- 2080678			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation; Vision Blurred	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17437221	NON-EXPEDITED			US-AKRON, INC.- 2080679			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Corneal Abrasion; Dry Eye; Eye Irritation; Eye Irritation; Foreign Body Sensation In Eyes; Ocular Hyperaemia; Rhinorrhoea	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
19-Feb-2020	17437226	NON-EXPEDITED			US-AKRON, INC.- 2080680			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Ineffective; Instillation Site Pustules		Azasite		S		Akorn			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437275	NON-EXPEDITED			US-AKRON, INC.- 2080682			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Ocular Hyperaemia	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437302	NON-EXPEDITED			US-AKRON, INC.- 2080683			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Of Eyelid; Eye Irritation; Eye Irritation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437530	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2080691			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Hypoaesthesia; Hypoaesthesia	Azithromycin			S	Oral			Wockhardt	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2020	17437547	EXPEDITED (15-DAY)		HO	HT-AKRON, INC.- 2080692		11 YR	Male	HTI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Azasite			S	Intravenous (not otherwise specified)			Akorn	
	Ibuprofen			S				Not Reported	
	Vancmoycin Hcl Capsules, Usp			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	16075455	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-012918			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Alendronic Acid Tablets			S	Oral	35 Milligram		Aurobindo
	Alendronic Acid Tablets			S	Unknown	Unk		Aurobindo
	Azithromycin			S	Oral	250 Milligram		Aurobindo
	Azithromycin			S				Aurobindo
	Ventolin			S	Unknown	8 Dosage Form		Not Reported
	Xolair			S	Subcutaneous	150 Milligram		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Symbicort			C	Unknown	Unk		Not Reported
	Ciclesonide;Formoterol Fumarate			C	Unknown	Unk		Not Reported
	Ciclesonide			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	16387113	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-030100		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Exercise Tolerance Decreased; Lymphoma; Quality Of Life Decreased	Alendronic Acid Tablets			S	Oral	1 Dosage Form, Unk		Aurobindo
	Alendronic Acid Tablets			S				Aurobindo
	Azithromycin			S	Oral	1 Dosage Form, Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Omalizumab			S	Subcutaneous	150 Milligram, Unk		Not Reported
	Omalizumab			S	Subcutaneous	150 Milligram, Unk		Not Reported
	Alvesco			C		2 Dosage Form, Two Times A Day		Not Reported
	Calcium			C	Oral	1 Dosage Form, Two		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Calcium Singulair	C		Times A Day	Not Reported
		C	Oral	1 Dosage Form, Once A Day	Not Reported
	Spiriva	C		1 Dosage Form, Once A Day	Not Reported
	Symbicort	C		2 Dosage Form, Two Times A Day	Not Reported
	Ventolin	C		8 Dosage Form, Unk	Not Reported
	Alendronate Sodium	S	Oral	1 Dosage Form	Not Reported
	Alendronate Sodium	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17336351	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00389		83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Activated Partial Thromboplastin Time Prolonged; Alanine Aminotransferase Increased; Aspartate Aminotransferase Increased; Blood Lactate Dehydrogenase Increased; Hepatocellular Injury; International Normalised Ratio Increased	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Qd		Lupin
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Qd		Not Reported
	Rosuvastatin			C	Unknown	5 Milligram, Qd (At Bedtime)		Not Reported
	Fenofibrate			C	Unknown	145 Milligram, Qd (At Bedtime)		Not Reported
	Rivaroxaban			C	Unknown	15 Milligram, Qd		Not Reported
	Aspirin (E.C.)			C	Unknown	81 Milligram, Qd (Enteric-Coated)		Not Reported
	Digoxin			C	Unknown	125 Microgram, Qd		Not Reported
	Donepezil			C	Unknown	10 Milligram, Qd (At Bedtime)		Not Reported
	Memantine			C	Unknown	10 Milligram, Bid		Not Reported
	Fluoxetine			C	Unknown	40 Milligram, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Latanoprost	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	500 Milligram, Qd	Not Reported
Glipizide	C	Unknown	15 Milligram, Bid (Before Meals)	Not Reported
Cholecalciferol	C	Unknown	5000 International Unit, Qd	Not Reported
Hydrocodone	C	Unknown	5 Milligram	Not Reported
Acetaminophen	C	Oral	325 Milligram, Qid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17425242	EXPEDITED (15-DAY)		HO, LT, OT	US-STRIDES ARCOLAB LIMITED-2020SP001361		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Linear Iga Disease; Neutrophilic Dermatitis	Ibuprofen			S	Unknown	Unk		Unknown	
	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Strides	
	Vancomycin			S				Strides	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Nafcillin			C	Unknown	Unk		Not Reported	
	Aciclovir			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Diflucan			C	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17437988	EXPEDITED (15-DAY)		HO, LT, OT	US-DRREDDYS-USA/USA/20/0119787		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Ibuprofen			S				Not Reported	
	Azithromycin			S				Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17438683	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1188413		86 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram		Not Reported	
	Amoxicillin			S	Intravenous (not otherwise specified)			Not Reported	
	Atorvastatin			C				Not Reported	
	Nicotine			C				Not Reported	
	Clopidogrel			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17438774	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-008805			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Interaction; Maternal Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Aurobindo	
	Isotretinoin			S	Unknown	Unk		Not Reported	
	Mirena			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17438783	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-008807		50 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Therapy Non-Responder	Azithromycin			S	Unknown	250 Milligram, Once A Day		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S	Unknown	Unk		Aurobindo	
	Doxycycline Hyclate			S	Unknown	100 Milligram, Two Times A Day		Not Reported	
	Doxycycline Hyclate			S	Unknown	100 Milligram		Not Reported	
	Doxycycline Hyclate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17438911	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2020-008055		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ibuprofen			S	Unknown	Unk		Aurobindo	
	Vancomycin			S	Intravenous (not otherwise specified)	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439206	EXPEDITED (15-DAY)		OT	UA-TEVA-2020-UA-1186160		5 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Pneumonia; Product Prescribing Error	Sumamed			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439304	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2020-007941			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia; Choking; Cough; Drug Ineffective; Dry Mouth; Finger Deformity; Headache; Malaise; Pain; Rheumatoid Arthritis; Sinusitis; Skin Reaction	Azithromycin			S	Unknown	Unk		Aurobindo	
	Meloxicam			S	Unknown	Unk		Aurobindo	
	Etanercept			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Xeljanz			S	Oral	5 Milligram, Two Times A Day		Not Reported	
	Cetirizine			C	Unknown	Unk		Not Reported	
	Hydroxychloroquine			C	Unknown	Unk		Not Reported	
	Tylenol			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439313	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-008680		40 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Mycobacterium Avium Complex Infection	Azithromycin			S	Unknown	625 Milligram, Once A Day		Aurobindo	
	Ciclosporin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	800 Milligram, Once A Day		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Rifampin			S	Unknown	300 Milligram, Once A Day		Not Reported	
	Insulin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439376	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2020-008802		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Off Label Use; Product Use Issue; Serum Sickness; Therapeutic Product Effect Incomplete	Azithromycin			S		Unk		Aurobindo	
	Arnuity Ellipta			S		Unk		Not Reported	
	Flovent			S		Unk		Not Reported	
	Fluticasone Furoate; Vilanterol Trifenatate			S		Unk		Not Reported	
	Omalizumab			S		Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Salbutamol			S	Unknown	Unk		Not Reported	
	Singulair			S	Unknown	10 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439384	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR- APL-2020-008808		51 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Dyspnoea; Gait Disturbance; Headache; Influenza Like Illness; Malaise; Musculoskeletal Pain; Nasopharyngitis; Neck Pain; Pneumonia; Pyrexia; Seasonal Allergy	Azithromycin	S	Oral	250.0 Milligram	Aurobindo
	Omalizumab	S	Subcutaneous	300.0 Milligram	Not Reported
	Advair	C		1.0 Dosage Form, Two Times A Day	Not Reported
	Atrovent	C	Unknown	1.0 Dosage Form	Not Reported
	Clarithromycin	C	Oral	500.0 Milligram	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Spiriva	C		1.0 Dosage Form, Two Times A Day	Not Reported
	Symbicort Turbuhaler	C		Unk	Not Reported
	Synthroid	C	Unknown	Unk	Not Reported
	Ventolin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439494	EXPEDITED (15-DAY)		HO, OT	US-APTAPHARMA INC.-2080704		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Ibuprofen			S	Unknown			Aptapharma	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439797	EXPEDITED (15-DAY)		OT	US-TARO-2020TAR00284		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Ibuprofen			S	Unknown			Taro	
	Azithromycin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17439986	NON-EXPEDITED			US-PFIZER INC-2020076390		69 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity	Azithromycin	S	Unk	Pfizer
	Duloxetine	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17440121	NON-EXPEDITED			US-TEVA-2020-US-1186508		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17441432	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020072640		29 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea; Hyperhidrosis; Nausea	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2020	17442101	EXPEDITED (15-DAY)		OT	BE-PFIZER INC-2020070855		35 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Pharyngeal Swelling	Azithromycin			S	Oral	Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	13873990	EXPEDITED (15-DAY)		HO, OT	US-JAZZ-2017-US-010383			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity;	Xyrem			S	Oral	3 G, Bid		Jazz
Feeling Abnormal;	Xyrem			S	Oral	3.5 G, Bid		Jazz
Hysterectomy; Migraine;	Xyrem			S	Oral	4.5 G, Bid		Jazz
Nausea; Sleep Apnoea	Xyrem			S	Oral	4.5 G, Bid		Jazz
Syndrome; Somnolence;	Xyrem			S	Oral	4.5 G, Bid		Jazz

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vomiting	Xyrem	S	Oral	4.5 G, Bid	Jazz
	Xyrem	S	Oral	4.25 G, Bid	Jazz
	Topamax	S			Not Reported
	Vancomycin	S			Not Reported
	Azithromycin	S			Not Reported
	Benzylpenicillin	S			Not Reported
	Cephalosporin Nos	S			Not Reported
	Phenergan [Promethazine]	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17352114	NON-EXPEDITED			US-PFIZER INC-2020039400		38 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Back Pain; Hypoaesthesia	Azithromycin			S		500 Mg, 1x/Day		Not Reported
	Azithromycin			S		250 Mg, 1x/Day		Not Reported
	Iron			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17409425	EXPEDITED (15-DAY)		DE, HO, OT	FR-PFIZER INC-2020057655		83 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Colitis; Drug Interaction;	Novatrex			S	Oral	15 Mg, Weekly		Pfizer
Herpes Virus Infection;	Augmentin			S	Oral	Unk		Not Reported
Hyperbilirubinaemia;	[Amoxicillin;Clavulanic Acid]							
Pancytopenia; Respiratory Failure	Prednisone			C	Oral	5 Mg, 1x/Day		Not Reported
	Lercanidipine Hcl			C	Oral	20 Mg, 1x/Day		Not Reported
	Folic Acid			C	Oral	5 Mg, 1x/Day		Not Reported
	Esomeprazole			C	Oral	20 Mg, 1x/Day		Not Reported
	Furosemide			C	Oral	20 Mg, 1x/Day		Not Reported
	Bisoprolol Fumarate			C	Oral	5 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17443179	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2020-008812		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Infection; Malaise; Pneumonia; Product Dose Omission	Azithromycin			S	Unknown	Unk		Aurobindo	
	Advair			S	Unknown	Unk		Not Reported	
	Nucala			S	Intravenous (not otherwise specified)	100 Milligram		Not Reported	
	Prednisone			S	Unknown	10 Milligram		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Spiriva			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17445008	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS- 2020M1018211		83 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diaphragmatic Hernia	Azithromycin			S		Unk		Not Reported	
	Amoxicilina/ Clavulonico			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17445153	NON-EXPEDITED			US-PFIZER INC- 2020077084		94 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown	Unk		Pfizer	
	Amoxicillin			S	Unknown	Unk		Pfizer	
	Septra			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17445206	NON-EXPEDITED			US-PFIZER INC- 2020078372		33 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17445745	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC-2020076270		26 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Erythema Multiforme; Genital Erosion; Lip Erosion; Pruritus; Rash Erythematous; Rash Vesicular	Zithromax			S	Oral	0.5 G, 1x/Day		Pfizer	
	Kai Di Xin			S	Intravenous drip	1.5 G, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17445870	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2020068833		82 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Haemorrhage; Pulmonary Alveolar Haemorrhage; Respiratory Failure	Ceftriaxone Sodium			S		Unk		Pfizer	
	Ceftriaxone Sodium			S				Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Losartan			C		Unk		Not Reported	
	Amlodipine			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17446034	EXPEDITED (15-DAY)		OT	NVSC2020US048429		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Azithromycin			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S	Unknown	Unk		Novartis	
	Prednisone			C	Unknown	20 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ursodiol			C		Unknown		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Feb-2020	17446657	EXPEDITED (15-DAY)		OT	GB-TEVA-2020-GB-1189678		27 YR	Female	GBR	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Pain Upper; Diarrhoea Haemorrhagic; Dizziness	Azithromycin Multivitamin Gaviscon Propranolol			S C C C	Oral	500 Mg			Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Feb-2020	17446668	NON-EXPEDITED			US-AKRON, INC.-2080763			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective; Off Label Use	Azasite			S					Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Feb-2020	17446716	NON-EXPEDITED			US-AKRON, INC.-2080764			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Eye Swelling; Ocular Hyperaemia	Azasite			S					Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Feb-2020	17446790	NON-EXPEDITED			US-AKRON, INC.-2080765			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Eye Burns	Azasite			S					Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
21-Feb-2020	17447716	EXPEDITED (15-DAY)		OT	FR-009507513-2002FRA006988		79 YR	Male	FRA	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State	Invanz			S	Intravenous (not otherwise specified)	1 Gram, Daily (Qd)		Merck	
	Zithromax			S	Oral	250 Milligram, Daily (Qd)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2020	17447814	NON-EXPEDITED			NVSC2020US044959		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	13703530	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2017277510		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Hypersensitivity; Dyspnoea; Heart Rate Increased; Hyperhidrosis; Hypertension; Insomnia; Malaise; Nausea; Palpitations; Tinnitus; Tremor	Azithromycin			S	Oral	250 Mg, Once A Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, 2x/Day (Took Two Pills The Day She Got Home)		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day (Continued To Take The Product One A Day)		Pfizer	
	Zithromax			S	Oral	250 Mg, 2x/Day		Pfizer	
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Synthroid			C	Oral	1 Df, Daily		Not Reported	
	Synthroid			C		25 Mg, Once A Day (In The Morning)		Not Reported	
	Bendroflumethiazide			C		10 Mg, As Needed(10mg, 1 Capsule 4 Times A Day As Needed)		Not Reported	
	Losartan Hctz			C		Unk, 1x/Day (50-12.5 Mg)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zegerid	C		20 Mg, 1x/Day	Not Reported
Biotin	C		Unk	Not Reported
Biotin	C		5000 Ug, 1x/Day	Not Reported
Levothyroxin	C		Unk	Not Reported
Metoprolol Tartrate	C		Unk	Not Reported
Fluconazole	C		Unk	Not Reported
Hyzaar	C	Oral	1 Df, Daily (50-12.5 Mg)	Not Reported
Bentyl	C	Oral	1 Df, 4x/Day (As Needed)	Not Reported
Amoxil	C	Oral	1 Df, 3x/Day	Not Reported
Deltasone	C	Oral	2 Df, Daily	Not Reported
Lopressor	C	Oral	1 Df, 2x/Day	Not Reported
Catapressan	C	Oral	1 Df, 2x/Day	Not Reported
Ergocalciferol	C	Oral	1 Df, Weekly	Not Reported
Valium	C	Oral	0.5 Mg, 3x/Day (As Needed)	Not Reported
Flonase	C	Nasal	1 Df (Spray), Daily	Not Reported
Cranberry Concentrate	C	Oral	Unk, Daily	Not Reported
Zegerid Otc	C	Oral	1 Df, Daily (20-1.1 Mg-Gram)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17189333	NON-EXPEDITED			PHHY2019US145908		77 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Body Temperature Decreased; Burning Sensation; Diarrhoea; Epistaxis; Nausea; Rosacea; Viral Upper Respiratory Tract Infection; Vomiting	Lamprene			S	Oral	100 Mg, Qd		Novartis
	Azithromycin			S	Oral	250 Mg, Unk (Monday To Friday)		Not Reported
	Ethambutol			C	Oral	1 G, Qd		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17368564	EXPEDITED (15-DAY)		HO, LT	NVSC2020DE028597		98 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking Sensation; Dyspnoea; Dyspnoea; Vomiting	Azithromycin 500 - 1 A Pharma			S	Unknown	500 Mg, Qd (3 Tage Lang 1 X Tägl.)		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17414048	NON-EXPEDITED			US-PFIZER INC- 2020062558			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17448962	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-00704		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Dysphagia; Headache; Insomnia; Malaise; Nausea; Pain In Extremity	Oseltamivir Phosphate Capsules Usp, 75 Mg (Base)			S	Oral	Unk Unk, Bid		Lupin	
	Oseltamivir Phosphate Capsules Usp, 75 Mg (Base)			S				Lupin	
	Azithromycin			S	Unknown	250 Milligram, Unk		Not Reported	
	Benzonatate			S	Unknown	Unk		Not Reported	
	Lisinopril			C	Unknown	40 Milligram, Qd		Not Reported	
	Hctz			C	Unknown	Unk Unk, Qd		Not Reported	
	Hydrocodone			C	Unknown	Unk, Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17449114	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1188521			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Macular Degeneration	Prednisone	S	Unknown	Actavis
	Acetaminophene	S	Unknown	Not Reported
	Alprazolam	S	Unknown	Teva
	Amoxicillin	S	Unknown	Not Reported
	Atorvastatin	S	Unknown	Teva
	Azithromycin	S	Unknown	Pliva
	Betamethasone Valerate	S	Unknown	Not Reported
	Betamethasone Valerate	S	Unknown	Not Reported
	Clarithromycin	S	Unknown	Actavis
	Diphenhydramine	S	Unknown	Barr
	Glycerine	S	Unknown	Not Reported
	Pantoprazole	S	Unknown	Actavis
	Pregabalin	S	Unknown	Teva
	Sulfamethoxazole/Trimethoprim	S	Unknown	Actavis
	Apo Hydro	S	Unknown	Not Reported
	Avamys	S	Unknown	Not Reported
	Biaxin XL	S	Unknown	Not Reported
	Bisacodyl	S	Unknown	Not Reported
	Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
	Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
	Cetirizine	S	Unknown	Not Reported
	Clotrimazole	S	Unknown	Not Reported
	Desonide	S	Unknown	Not Reported
	Dilaudid	S	Unknown	Not Reported
	Entocort	S	Unknown	Not Reported
	Ertapenem Sodium	S	Unknown	Not Reported
	Flovent	S	Unknown	Not Reported
	Gramicidin/Neomycin/Polymyxin B Sulfate	S	Unknown	Not Reported
	Habitrol	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humira	S	Subcutaneous		Not Reported
Kenalog	S	Unknown	Suspension Intraarticular	Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride Metronidazole	S	Unknown		Not Reported
Ms Ir	S	Unknown		Not Reported
Mupirocin	S	Unknown		Not Reported
Mupirocin	S	Unknown		Not Reported
Nadolol	S	Unknown		Not Reported
Nicoderm	S	Unknown	Patch	Not Reported
Nicotine Polacrilex	S	Unknown		Not Reported
Pentasa	S	Unknown		Not Reported
Pulmicort	S	Unknown		Not Reported
Refresh Tears	S	Unknown	Drops Ophthalmic	Not Reported
Sinus Rinse	S	Unknown	Solution Nasal	Not Reported
Triamcinolone	S	Unknown	Suspension Intraarticular	Not Reported
Vitamin D3	S	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17450318	EXPEDITED (15-DAY)		OT	US-ZYDUS-047579			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Resistance	Azithromycin			S	Unknown			Zyduz Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17451205	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020074952		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transient Ischaemic Attack		Novatrex	S	Oral	2.5 Mg, Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17451416	NON-EXPEDITED			US-PFIZER INC-2020077795		70 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Ursodeoxycholic Acid			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17451911	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020074993		79 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State	Zithromax			S	Oral	250 Mg, Daily		Pfizer	
	Invanz			S	Intravenous (not otherwise specified)	1 G, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17452006	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020075115		70 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Lampren			S	Oral	100 Mg, 1x/Day		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	1 Df, 1x/Day		Not Reported	
	Noxafil			S	Oral	300 Mg, 1x/Day		Not Reported	
	Cholurso			C				Not Reported	
	Propranolol			C				Not Reported	
	Ethambutol Hydrochloride			C				Not Reported	
	Pantoprazole			C				Not Reported	
	Tramadol			C				Not Reported	
	Aldactone [Spironolactone]			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17452210	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020068824		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatic Cirrhosis; Hepatitis	Ceftriaxone Sodium			S		Unk (One Dose)		Pfizer	
	Azithromycin			S		Unk (5 Day Course)		Pfizer	
	Prednisone			C		20 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17452836	EXPEDITED (15-DAY)		HO	US-EPIC PHARMA LLC-2020EPC00067		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Azithromycin			S	Unknown			Epic Pharm	
	Ibuprofen			S	Unknown			Puracap	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17452837	EXPEDITED (15-DAY)		HO	US-PURACAP PHARMACEUTICAL LLC-2020EPC00080		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Ibuprofen			S	Unknown			Puracap	
	Azithromycin			S	Unknown			Epic Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17452910	NON-EXPEDITED			US-AKRON, INC.-2080834			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dry Eye; Eye Pruritus; Ocular Hyperaemia	Azasite			S				Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2020	17452957	NON-EXPEDITED			US-AKRON, INC.- 2080835			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azasite			S				Akorn	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	15885134	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019GSK013491		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Chest Discomfort; Cough; Dyspnoea; Malaise; Oropharyngeal Pain; Therapeutic Product Effect Incomplete	Salbutamol Sulphate			S		Unk		Glaxosmithkline	
	Azithromycin			S		1 Df Tablet, Qd, 250		Glaxosmithkline	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg, Z,Monthly		Glaxosmithkline	
	Zenhale			S		Unk		Not Reported	
	Spiriva			S	Respiratory (inhalation)	2 Puff(S), Qd		Not Reported	
	Symbicort			S	Respiratory (inhalation)	2 Puff(S), Tid		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	16018042	EXPEDITED (15-DAY)		OT	AT-009507513- 1902AUT010239			Male	AUT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anuria; C-Reactive Protein Increased; Candida Infection; Drug Ineffective; Infection	Cubicin			S	Unknown	Unk		Merck	
	Tigecycline			S	Unknown	Unk		Not Reported	
	Sulbactam			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Rifoldin			S	Intravenous (not otherwise specified)	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Colistin Sulfate

S

Unknown

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	16788978	EXPEDITED (15-DAY)		HO, OT	JP-VIIV HEALTHCARE LIMITED- JP2017JPN098293			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Traumatic;	Dolutegravir			S	Oral	50 Mg, 1d		Viiv
Mycobacterium Avium	Epzicom			S	Oral	1 Df, 1d		Viiv
Complex Infection;	Zithromac			S	Unknown	1200 Mg, Qd		Not Reported
Oesophageal Candidiasis;	Zithromac			S	Unknown	1200 Mg, Qd		Not Reported
Oropharyngeal	Zithromac			S	Unknown	600 Mg, Qd		Not Reported
Candidiasis;	Mycobutin			S	Unknown	300 Mg, Qd		Not Reported
Osteomyelitis; Pain In	Esanbutol			S	Unknown	1000 Mg, Qd		Not Reported
Extremity; Pancytopenia;	Isentress			C		800 Mg, 1d		Not Reported
Seasonal Allergy	Benambax			C		Unk		Not Reported
	Benambax			C		Unk		Not Reported
	Baktar Combination Tablets			C		1 Df, Qd		Not Reported
	Lac-B Granular Powder N			C		Unk		Not Reported
	Loperamide Hydrochloride			C		Unk		Not Reported
	Capsule							
	Influenza Ha Vaccine			C		Unk		Not Reported
	Loxoprofen Sodium Hydrate			C		Unk		Not Reported
	Tablet							
	Rebamipide			C		Unk		Not Reported
	Cefazolin Sodium Injection			C		Unk		Not Reported
	Ms Reishippu			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	16788985	EXPEDITED (15-DAY)		HO, OT	JP- GLAXOSMITHKLINE- JP2017JPN098293			Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Deafness Traumatic; Mycobacterium Avium Complex Infection;	Dolutegravir	S	Oral	50 Mg, 1d	Viiv
Oesophageal Candidiasis; Oropharyngeal Candidiasis;	Epzicom	S	Oral	1 Df, 1d	Viiv
Osteomyelitis; Pain In Extremity; Pancytopenia; Seasonal Allergy	Zithromac	S	Unknown	1200 Mg, Qd	Not Reported
	Zithromac	S	Unknown	1200 Mg, Qd	Not Reported
	Zithromac	S	Unknown	600 Mg, Qd	Not Reported
	Mycobutin	S	Unknown	300 Mg, Qd	Not Reported
	Esanbutol	S	Unknown	1000 Mg, Qd	Not Reported
	Isentress	C		800 Mg, 1d	Not Reported
	Benambax	C		Unk	Not Reported
	Benambax	C		Unk	Not Reported
	Baktar Combination Tablets	C		1 Df, Qd	Not Reported
	Lac-B Granular Powder N	C		Unk	Not Reported
	Loperamide Hydrochloride Capsule	C		Unk	Not Reported
	Influenza Ha Vaccine	C		Unk	Not Reported
	Loxoprofen Sodium Hydrate Tablet	C		Unk	Not Reported
	Rebamipide	C		Unk	Not Reported
	Cefazolin Sodium Injection	C		Unk	Not Reported
	Ms Reishippu	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17219668	NON-EXPEDITED			US-UNITED THERAPEUTICS-UNT- 2019-021595		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Blood Iron Decreased; Diarrhoea;	Orenitram			S	Oral	3.125 Mg, Q8h		Not Reported
Fatigue; Haemoglobin Decreased; Malaise;	Orenitram			S	Oral	Unk		Not Reported
Pneumonia; Product Dose Omission; Productive Cough; Respiratory Tract Infection; Rhinorrhoea	Orenitram			S	Oral	Unk		Not Reported
	Orenitram			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orenitram		S	Oral	Unk	Not Reported				
Z-Pak		S	Unknown	Unk	Not Reported				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17362226	EXPEDITED (15-DAY)		OT	ES-PFIZER INC-2020040841		4 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Dyspnoea; Hypersensitivity; Pruritus; Rash	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17397535	EXPEDITED (15-DAY)		HO	FR-JNJFOC-20200153318		66 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Fasciitis; Lichenoid Keratosis	Darzalex			S	Intravenous (not otherwise specified)				Not Reported
	Zithromax			S	Oral	Non Renseign E			Not Reported
	Rocephine			S	Unknown	Non Renseign E			Not Reported
	Privigen			S	Intravenous (not otherwise specified)				Not Reported
	Privigen			S	Intravenous (not otherwise specified)				Not Reported
	Bactrim			S	Oral				Not Reported
	Augmentin /00852501/			S	Oral				Not Reported
	Inexium /01479302/			C	Unknown				Not Reported
	Topalgic /00599202/			C	Unknown				Not Reported
	Valaciclovir			C	Unknown				Not Reported
	Solupred /00016201/			C	Unknown				Not Reported
	Furosemide			C	Unknown				Not Reported
	Lyrica			C	Unknown				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17456429	NON-EXPEDITED			US-PFIZER INC-2020079998		43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Tinea; Candida Infection; Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17456628	NON-EXPEDITED			US-AKRON, INC.-2080867			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17457555	NON-EXPEDITED			US-AKRON, INC.-2080875			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17457637	EXPEDITED (15-DAY)		DE	JP-PFIZER INC-2020070515		70 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
	Hydrocortisone Sodium Succinate			C		1000 Mg, 1x/Day		Not Reported	
	Prednisolone			C	Oral	40 Mg, 1x/Day		Not Reported	
	Prednisolone			C		7.5 Mg, Daily (Increased From 7.5 Mg To 15 Mg A Day)		Not Reported	
	Prednisolone			C		15 Mg, Daily (Increased From 7.5 Mg To 15 Mg A		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Bicalutamide	C		Day)				Not Reported
		Leuporelin Acetate	C	Subcutaneous	Unk				Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17457878	NON-EXPEDITED			US-AKRON, INC.- 2080882			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Discharge; Eye Pruritus	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17457879	EXPEDITED (15-DAY)		HO	US-ANIPHARMA-2020- US-003216		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Ibuprofen (Non-Specific)			S				Ani	
	Azithromycin			S				Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17457910	NON-EXPEDITED			US-PFIZER INC- 2020080945			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Diazepam			S		Unk		Pfizer	
	Diphenhydramine Hcl			S		Unk		Unknown	
	Pregabalin			S		Unk		Pfizer	
	Duloxetine			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17457965	NON-EXPEDITED			US-AKRON, INC.- 2080884			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458324	NON-EXPEDITED			US-AKRON, INC.- 2080892			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Condition Aggravated; Drug Ineffective	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458834	NON-EXPEDITED			US-AKRON, INC.- 2080905			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Oral Discomfort	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17458931	NON-EXPEDITED			US-AKRON, INC.- 2080907			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Eye Irritation; Eye Pain; Eye Pruritus	Azasite			S				Akorn	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
25-Feb-2020	17459324	NON-EXPEDITED			US-AKRON, INC.- 2080909			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation; Eye Pain;	Azasite			S				Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ocular Hyperaemia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17459993	EXPEDITED (15-DAY)		HO	CA-TEVA-2020-CA-1189647		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Prednisone			S	Unknown			Actavis	
	Azithromycin			S	Unknown			Not Reported	
	Salbutamol Sulfate			S	Unknown			Barr	
	Advair			S	Unknown			Not Reported	
	Atrovent			S	Unknown			Not Reported	
	Nucala			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Feb-2020	17460416	EXPEDITED (15-DAY)		HO	US-BAXTER-2020BAX003744		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Ceftriaxone Injection, Usp (In Dextrose)			S	Unknown			Baxter	
	Azithromycin			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17329002	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020037080		64 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Intentional Product Use Issue; Off Label Use; Product Prescribing Issue; Sinusitis	Zithromax			S	Oral	250 Mg, (Three Times A Day) X 3 Weeks		Pfizer	
	Zithromax			S	Oral	250 Mg, 2x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17429666	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1016460		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; General Physical Condition	Azithromycin			S	Unknown	Unk		Not Reported	
Abnormal; General Physical Health	Tavanic			S	Unknown	Unk		Mylan	
Deterioration; Pyrexia	Furadantine			S	Unknown	Unk		Mylan	
	Nitrofurantoin			S		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17459478	NON-EXPEDITED			US-AKRON, INC.-2080932			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Vision Blurred	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17460581	NON-EXPEDITED			US-PFIZER INC-2020085112		36 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17461050	NON-EXPEDITED			US-CELGENEUS-USA-20200205922		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Upper Respiratory Tract Infection	Otezla			S	Oral	60 Milligram		Celgene	
	Z-Pak			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17462012	EXPEDITED (15-DAY)		OT	US-HETERO- HET2020US00202			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby; Transient Tachypnoea Of The Newborn	Oseltamivir			S	Transplacental	Unk		Hetero	
	Azithromycin			S	Transplacental	Unk		Not Reported	
	Methylprednisolone			S	Intravenous (not otherwise specified)	2 Days Course		Not Reported	
	Dexamethasone			S	Transplacental	2 Days Course		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17462295	EXPEDITED (15-DAY)		HO	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-237756		29 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Hyperhidrosis; Nausea	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17462842	EXPEDITED (15-DAY)		HO	FR-MYLANLABS- 2020M1020529		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
General Physical Health Deterioration; Pyrexia	Azithromycin			S	Unknown	Unspecified Dosage Regimen		Not Reported	
	Tavanic			S	Unknown	Unspecified Dosage Regimen		Mylan	
	Furadantine			S	Unknown	Unspecified Dosage Regimen		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17462926	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR-APL-2020-009237		27 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea Haemorrhagic; Dizziness	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Multivitamin			C	Unknown	Unk		Not Reported	
	Gaviscon			C	Unknown	Unk		Not Reported	
	Propranolol			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17463824	NON-EXPEDITED			US-AKRON, INC.-2080956			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Ocular Hyperaemia	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17463880	NON-EXPEDITED			US-AKRON, INC.-2080958			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eye Irritation; Ocular Hyperaemia; Visual Impairment	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17464037	NON-EXPEDITED			US-AKRON, INC.-2080960			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Ocular Hyperaemia; Vision Blurred	Azasite			S				Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17464102	NON-EXPEDITED			US-AKRON, INC.- 2080961			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Irritation	Azasite			S				Akorn	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17464155	EXPEDITED (15-DAY)		OT	NVSC2020FR047943		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coombs Negative Haemolytic Anaemia	Riamet			S	Oral	3 Df, Qd		Novartis	
	Tiorfan			S	Oral	3 G, Qd		Not Reported	
	Rocephin			S	Intravenous (not otherwise specified)	1 G, Qd		Not Reported	
	Zithromax			S	Oral	250 Mg, Qd		Not Reported	
	Primperan			S	Intravenous (not otherwise specified)			Not Reported	
	Doliprane			C	Oral			Not Reported	
	Phosphoneuros			C	Oral			Not Reported	
	Imovane			C	Oral	3.75 Mg, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17464213	NON-EXPEDITED			US-AKRON, INC.- 2080963			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Swelling Of Eyelid	Azasite			S				Akorn	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Feb-2020	17464718	EXPEDITED (15-DAY)		OT	NVSC2020PT052986		45 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Encephalomyelitis; Neuropathy Peripheral	Azithromycin	S	Unknown	Unk	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	16967782	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-NAPPMUNDI-CAN- 2019-0010358		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Purdue
	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Purdue
	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Purdue
	Morphine Sulfate			S	Intravenous (not otherwise specified)	1 Every 10 Minutes		Purdue
	Amiodarone			S	Unknown	Unk		Not Reported
	Amiodarone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Q24h		Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G, Q24h		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Mg, Q4h		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	0.25 Mg, Unk		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	10 Mg, Q1h		Not Reported
	Digoxin			S	Intravenous (not otherwise specified)	10 Mg, Unk		Not Reported
	Diltiazem			S	Oral	180 Mg, Unk		Not Reported
	Diltiazem			S	Oral	180 Mg, Unk		Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)	50 Mg, Q4h		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Unk	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg Q14days	Not Reported
Doxorubicin	S	Intravenous (not otherwise specified)	106 Mg, Unk	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, Q24h	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, Q24h	Not Reported
Furosemide	S	Oral	40 Mg, Q24h	Not Reported
Furosemide	S	Oral	40 Mg, Q24h	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Q4h	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Qid	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	125 Mg, Q6h	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	2.5 Mg, Q6h	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	5 Mg, Q6h	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk	Not Reported
Pantoprazole Sodium	S	Intravenous (not otherwise specified)	8 Mg, Q1h	Not Reported
Pantoprazole Sodium	S	Intravenous (not otherwise specified)	8 Mg, Unk	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Q24h	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Q24h	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Unk	Not Reported
Trastuzumab	S	Unknown	Unk	Not Reported
Aprepitant	C	Oral	125 Mg, Unk	Not Reported
Dexamethasone	C	Oral	20 Mg, Q24h	Not Reported
Filgrastim	C	Subcutaneous	300 Mcg, Q24h	Not Reported
Gabapentin	C	Oral	100 Mg, Tid	Not Reported
Metoclopramide	C	Oral	10 Mg, Qid	Not Reported
Metoclopramide	C	Oral	10 Mg, Unk	Not Reported
Ondansetron	C	Oral	8 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17391197	EXPEDITED (15-DAY)		DE, HO, LT, OT	IT-AUROBINDO-AUR-APL-2020-005306		74 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Failure; Empyema; Pleural Fistula; Pneumonia Necrotising; Pneumothorax; Pseudomonas Infection; Treatment Failure	Azithromycin			S	Unknown	Unk		Aurobindo	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Cefepime			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17465698	EXPEDITED (15-DAY)		HO, LT, OT	US-JNJFOC-20200225470		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Ibuprofen			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Vancomycin			S	Intravenous (not otherwise specified)			Not Reported	
	Nafcillin			C	Unknown			Not Reported	
	Acyclovir /00587301/			C	Intravenous (not			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diflucan		C		otherwise specified) Unknown		Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17465751	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-2008174US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Refresh Tears			S	Unknown			Allergan	
	Acetaminophen			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Not Reported	
	Amoxicillin Trihydrate			S	Unknown			Not Reported	
	Apo Hydro			S	Unknown			Not Reported	
	Atorvastatin			S	Unknown			Not Reported	
	Avamys			S	Unknown			Not Reported	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
	Bactroban			S	Unknown			Not Reported	
	Betaderm			S	Unknown			Not Reported	
	Betamethasone Dipropionate			S	Unknown			Not Reported	
	Biaxin XI			S	Unknown			Not Reported	
	Bisacodyl			S	Unknown			Not Reported	
	Calcium Carbonate/Magnesium Sulfate/Vitamin D3			S	Unknown			Not Reported	
	Cetirizine			S	Unknown			Not Reported	
	Clarithromycin			S	Unknown			Not Reported	
	Clotrimazole			S	Unknown			Not Reported	
	Desonide			S	Unknown			Not Reported	
	Dilaudid			S	Unknown			Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	Entocort			S	Unknown			Not Reported	
	Ertapenem Sodium			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Flovent	S	Unknown		Not Reported
Glycerin	S	Unknown		Not Reported
Gramicidin W/Neomycin Sulfate/Polymyxin B Sul	S	Unknown		Not Reported
Habitrol	S	Unknown		Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog	S	Intra-articular		Not Reported
Lomotil	S	Oral	Unk	Not Reported
Metronidazole	S	Unknown		Not Reported
Ms Ir	S	Unknown		Not Reported
Mupirocin	S	Topical		Not Reported
Nadolol	S	Unknown		Not Reported
Nicoderm	S	Unknown		Not Reported
Nicotine Polacrilex	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pentasa	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Pregabalin	S	Unknown		Not Reported
Pulmicort	S	Unknown		Not Reported
Salinex [Sodium Chloride]	S	Unknown		Not Reported
Sinus Rinse	S	Unknown		Not Reported
Statex (Morphine Sulfate)	S	Unknown		Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Unknown		Not Reported
Vitamin D3	S	Unknown		Not Reported
Calcium Carbonate/Vitamina D3	C			Not Reported
Valsartan	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17466018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1189922			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Prednisone			S	Unknown			Actavis
	Alprazolam			S	Unknown			Actavis
	Amoxicillin Trihydrate			S	Unknown			Teva
	Azithromycin Dihydrate			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Teva
	Betamethasone Dipropionate			S	Unknown			Actavis
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported
	Paracetamol			S	Unknown			Not Reported
	Calcium W/Cholecalciferol			S	Unknown			Not Reported
	Nicotine			S	Unknown			Actavis
	Pantoprazole			S	Unknown			Teva
	Pregabalin			S	Unknown			Not Reported
	Apo Hydro			S	Unknown			Not Reported
	Atropine Sulphate + Diphenoxylate Hydrochloride			S	Oral			Not Reported
	Avamys			S	Unknown			Not Reported
	Bactrim			S	Unknown			Not Reported
	Bactroban(Mupirocin)			S	Unknown			Not Reported
	Betaderm			S	Unknown			Not Reported
	Biaxin XI			S	Unknown			Not Reported
	Bisacodyl			S	Unknown			Not Reported
	Cetirizine Hydrochloride			S	Unknown			Not Reported
	Clarithromycin			S	Unknown			Not Reported
	Clotrimazole			S	Unknown			Not Reported
	Desonide			S	Unknown			Not Reported
	Dilaudid			S	Unknown			Not Reported
	Entocort			S	Unknown			Not Reported
	Ertapenem Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Glycerine	S	Oral	Not Reported
Gramicidin + Neomycin + Polymyxin B Sulfate	S	Unknown	Not Reported
Habitrol	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Kenalog	S	Intra-articular	Not Reported
Metronidazole	S	Unknown	Not Reported
Ms Ir	S	Unknown	Not Reported
Mupirocin	S	Topical	Not Reported
Nadolol	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sinus Rinse	S	Nasal	Not Reported
Statex (Morphin)	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Vitamin D3	S	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17466038	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1189904		48 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Enterovirus Infection; Transplant Rejection	Mycophenolic Acid			S	Unknown	2 Gram Daily;		Teva
	Prednisone			S	Unknown	15 Milligram Daily;		Actavis
	Valganciclovir			S	Unknown	900 Mg		Actavis
	Abacavir			S	Unknown			Not Reported
	Pms-Azithromycin			S	Unknown			Not Reported
	Sulfamethoxazole			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Tacrolimus		S	Unknown				Not Reported	
	Tivicay		S	Unknown				Not Reported	
	Trimethoprim		S	Unknown				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17466979	EXPEDITED (15-DAY)		OT	US-LUPIN PHARMACEUTICALS INC.-2020-00903		79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Encephalopathy; Multiple Organ Dysfunction Syndrome; Pyrexia	Atovaquone			S	Unknown	Unk		Lupin	
	Azithromycin			S	Unknown	Unk		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17466982	EXPEDITED (15-DAY)		HO, OT	US-LUPIN PHARMACEUTICALS INC.-2020-00905		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Hepatic Cirrhosis	Azithromycin			S	Unknown	Unk, 5-Day Course		Lupin	
	Ceftriaxone			S	Unknown	1 Dosage Form (One Dose)		Lupin	
	Prednisone			C	Unknown	20 Milligram, Qd, 5-Day Course		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17467107	NON-EXPEDITED			US-TEVA-2020-US- 1189468			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Wrong Technique In Product Usage Process	Azithromycin			S	Unknown			Teva	
	Creon			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17467498	NON-EXPEDITED			US-PFIZER INC-2020087404		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Casein			S		Unk		Not Reported	
	Cipro [Ciprofloxacin]			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17467871	EXPEDITED (15-DAY)		OT	US-ZYDUS-047587		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Linear Iga Disease; Rash; Skin Lesion	Azithromycin			S	Unknown			Zydus Pharm	
	Ibuprofen			S	Unknown			Not Reported	
	Vancomycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17467926	EXPEDITED (15-DAY)		DE, HO, OT	US-GLAXOSMITHKLINE-US2020GSK028366		58 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Cough; Death; Diarrhoea; Drug Ineffective; Drug Resistance; Gastrointestinal Haemorrhage; Graft Versus Host Disease; Hypotension; Hypoxia; Influenza; Influenza; Lung Infiltration; Mental Status Changes; Pathogen Resistance; Pneumonia; Pyrexia; Therapy Non-	Zanamivir			S	Respiratory (inhalation)	10 Mg, Bid		Glaxosmithkline	
	Sirolimus			S		Unk		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Antithymocyte Globulin			S		Unk		Not Reported	
	Oseltamivir			S	Oral	75 Mg, Bid		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Responder; Viral Mutation
Identified

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17467958	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2020087684		56 YR	Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Asthma; Pneumonia	Zmax			S		Unk		Pfizer	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17468172	EXPEDITED (15-DAY)		HO	IT-MYLANLABS- 2020M1020825		15 YR	Female	ITA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Diarrhoea; Medication Error	Azithromycin			S	Oral	1.5 Gram, Qd		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17469703	EXPEDITED (15-DAY)		HO	HR-MYLANLABS- 2020M1020951		34 YR	Female	HRV
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Acute Febrile Neutrophilic Dermatosis; Erythema Nodosum; Product Use In Unapproved Indication; Pyrexia; Rash	Azithromycin			S	Unknown	Unk		Not Reported	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Feb-2020	17470030	NON-EXPEDITED			US-AKRON, INC.- 2081041			Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation; Eye Pruritus; Ocular Hyperaemia; Retinal Vein Occlusion	Azasite			S				Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2020	17470053	NON-EXPEDITED			US-AKRON, INC.- 2081042			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pruritus; Eyelid Margin Crusting; Ocular Hyperaemia	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2020	13120526	NON-EXPEDITED			US-PFIZER INC- 2017015982		49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Nausea; Vomiting	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2020	17463495	EXPEDITED (15-DAY)		HO	ES-MYLANLABS- 2020M1020600		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Ibuprofen			S	Oral	600 Milligram, Q6h (1-1-1-1)		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd (500 Mg Dia)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2020	17473130	EXPEDITED (15-DAY)		HO	NVSC2020ES050068		72 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dyspnoea; Fatigue; Malaise	Azithromycin			S	Oral	500 Mg, Qd		Novartis	
	Pantoprazole			C	Unknown	Unk		Not Reported	
	Clopidogrel Cinfa			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Carvedilol Cinfa

C

Unknown

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2020	17432757	EXPEDITED (15-DAY)		OT	NL-AUROBINDO-AUR-APL-2019-070242		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Decreased Appetite; Feeding Disorder; Hepatotoxicity; Hypertriglyceridaemia; Nausea; Poor Feeding Infant; Product Administered To Patient Of Inappropriate Age; Product Use In Unapproved Indication; Vomiting	Azithromycin			S	Oral	10 Milligram/Kilogram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Minocycline			S	Unknown	Unk		Aurobindo
	Cilastatin;Imipenem			S	Topical	3 Gtt Drops, 3 Times A Day (5/5 Mg/MI)		Not Reported
	Cilastatin;Imipenem			S	Intravenous (not otherwise specified)	60 Milligram/Kilogram, Daily (In 2 To 4 Doses)		Not Reported
	Cilastatin;Imipenem			S				Not Reported
	Cilastatin;Imipenem			S	Unknown	Unk		Not Reported
	Clofazimine			S	Oral	50 Milligram, Once A Day (If Weight Is Above 40 Kg Then 100 Mg)		Not Reported
	Clofazimine			S	Unknown	Unk		Not Reported
	Clofazimine			S				Not Reported
	Granisetron			S	Unknown	Unk		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Milligram/Kilogram, Once A Day In 2 Doses		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Milligram/Kilogram, Once A Day In 2 Doses		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	Reduced Dose		Not Reported
	Tigecycline			S	Unknown	Unk		Not Reported
Tigecycline			S	Topical	3 Gtt Drops, 3 Times A Day (9 Drops,Qd)		Not Reported	
Tigecycline			S				Not Reported	
Sodium Chloride 0.9%			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Feb-2020	17477044	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-010082			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Transient Tachypnoea Of The Newborn	Azithromycin			S	Unknown	Unk		Aurobindo	
	Dexamethasone			S	Unknown	Unk		Aurobindo	
	Methylprednisolone			S	Transplacental	Completed First Course		Aurobindo	
	Methylprednisolone			S	Transplacental	Received 2-Day Course		Aurobindo	
	Oseltamivir			S	Transplacental	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2020	17480605	EXPEDITED (15-DAY)		OT	NVSC2020GB054209		82 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis	Azithromycin			S	Unknown	1500 Mg, Qw		Novartis	
	Ventolin			C	Respiratory (inhalation)	1 Df		Not Reported	
	Metformin			C	Unknown	2 Df, Qd		Not Reported	
	Braltus			C	Respiratory (inhalation)	1 Df, Qd (Using The Zonda Inhale)		Not Reported	
	Clarithromycin			C	Unknown	1 Df, Q12h		Not Reported	
	Doxycycline			C	Unknown	Unk (Two Now Then One Daily (Alternative 1st Line))		Not Reported	
	Prednisolone			C	Unknown	6 Df, Qd (Immediately Then Six Tablets)		Not Reported	
	Symbicort			C	Respiratory (inhalation)	2 Df, Qd (To Control Chest)		Not Reported	
	Cetraben			C	Unknown	Unk (Use Regularly On Dry Skin)		Not Reported	
	Atorvastatin			C	Unknown	1 Df, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Codeine Phosphate	C	Unknown	Unk (Take One Or Two Every 4 Hours)	Not Reported
Carbocisteine	C	Unknown	6 Df, Qd	Not Reported
Thiamine	C	Unknown	2 Df, Qd (If Still Drinking)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2020	17483674	DIRECT		DE			63 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Cardiac Arrest; Chest Discomfort; Consciousness Fluctuating; Dialysis; Fungal Infection; Hypopnoea; Myocardial Infarction; Panic Reaction; Pyrexia; Respiratory Failure; Septic Shock	Azithromycin		Y	S	Oral	Quantity:10 Tablet(S);		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	16029900	EXPEDITED (15-DAY)		OT	PHHY2019AT046376			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; C-Reactive Protein Increased; Candida Infection; Drug Ineffective; Infection	Cubicin			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Novartis
	Tigecycline			S	Unknown	Unk		Not Reported
	Sulbactam			S	Unknown	Unk		Not Reported
	Rifoldin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Colistin Sulfate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	17481296	EXPEDITED (15-DAY)		OT	CA-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-238021			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchitis; Drug Interaction; Maternal Exposure During Pregnancy	Isotretinoin			S	Unknown	Unk		Ranbaxy	
	Azithromycin			S	Unknown	Unk		Sun	
	Mirena			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	17482375	EXPEDITED (15-DAY)		OT	US-AUROBINDO-AUR- APL-2020-010116		45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiolitis; Condition Aggravated; Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S				Aurobindo	
	Albuterol Sulfate			S	Unknown	Unk		Aurobindo	
	Albuterol Sulfate			S				Aurobindo	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S				Not Reported	
	Prednisone			S	Unknown	10 Day Prednisone Burst		Not Reported	
	Prednisone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	17482553	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020088471		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abscess; Anaemia; Anal Abscess; Arthralgia; Bipolar li Disorder; Diarrhoea; Fistula; Gastrooesophageal Reflux	Methotrexate Sodium			S	Unknown	Unk		Pfizer	
	Azithromycin			S	Unknown	Unk		Pfizer	
	Humira			S	Subcutaneous	Unk		Not Reported	
	Azathioprine			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Disease; General Physical Health Deterioration; Hypothyroidism; Post-Traumatic Stress Disorder; Therapeutic Product Effect Decreased	Prednisone	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	17482625	EXPEDITED (15-DAY)		OT	GB-PFIZER INC-2020086033		27 YR	Female	GBR

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Diarrhoea Haemorrhagic; Dizziness	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Multivitamin [Vitamins Nos]			C		Unk		Not Reported
	Gaviscon [Alginic Acid;Aluminium Hydroxide Gel, Dried;Magnesium Trisil			C		Unk		Not Reported
	Propranolol			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	17483380	EXPEDITED (15-DAY)		HO	FR-ABBVIE-20K-056-3296118-00		16 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nasal Septum Perforation	Humira			S	Subcutaneous			Not Reported
	Novatrex			S	Oral	Compressed		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Mar-2020	17484674	EXPEDITED (15-DAY)		OT	NVSC2020CA058057			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Salinex [Sodium Chloride]			S	Nasal			Not Reported
	Alprazolam			S	Unknown			Novartis
	Amoxicillin			S	Unknown			Not Reported
	Atorvastatin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clarithromycin		S	Unknown		Not Reported
Diphenhydramine Hydrochloride	Y	S	Unknown		Not Reported
Pregabalin		S	Unknown		Not Reported
Pantoprazole		S	Unknown		Not Reported
Nadolol		S	Unknown		Not Reported
Colecalciferol		S	Unknown		Not Reported
Triamcinolone Acetonide		S	Unknown		Not Reported
Prednisone		S	Unknown		Not Reported
Cetirizine		S	Unknown		Not Reported
Acetaminophen (Paracetamol)		S	Unknown	Unk	Not Reported
Azithromycin Dihydrate		S	Unknown		Not Reported
Amoxicillin Trihydrate		S	Unknown		Not Reported
Betamethasone Dipropionate		S	Unknown		Not Reported
Bisacodyl		S	Unknown		Not Reported
Clotrimazole		S	Unknown		Not Reported
Metronidazole		S	Unknown		Not Reported
Macrogol 3350, Potassium Chloride, Sodium Chloride, Sodium Hydrogen Carbo		S	Unknown		Not Reported
Desonide		S	Unknown		Not Reported
Gramicidin, Neomycin Sulfate, Polymycin B Sulphate		S	Unknown		Not Reported
Ertapenem Sodium		S	Unknown		Not Reported
Sulfamethoxazole, Trimethoprim		S	Unknown		Not Reported
Mupirocin		S	Topical		Not Reported
Apo Hydro		S	Unknown		Not Reported
Avamys		S	Unknown		Not Reported
Bactroban		S	Unknown		Not Reported
Betaderm		S	Unknown		Not Reported
Biaxin XI		S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Citirizine [Cetirizine Hydrochloride]	S	Unknown		Not Reported
Dilaudid	S	Unknown		Not Reported
Entocort	S	Unknown		Not Reported
Flovent	S	Unknown		Not Reported
Glycerine	S	Oral		Not Reported
Habitrol	S	Unknown		Not Reported
Humira	S	Subcutaneous		Not Reported
Kenalog	S	Intra-articular		Not Reported
Lomotil	S	Oral	4 Ot, Qd	Not Reported
Ms Ir	S	Unknown		Not Reported
Nicoderm	S	Unknown	Patch	Not Reported
Nicotine Polacrilex	S	Unknown		Not Reported
Pentasa	S	Unknown		Not Reported
Pulmicort	S	Unknown		Not Reported
Refresh Tears	S	Ophthalmic	Drops Ophthalmic	Not Reported
Sinus Rinse	S	Nasal		Not Reported
Statex (Morphine Sulfate)	S	Unknown		Not Reported
Vitamin D3	S	Unknown		Not Reported
Diphenhydramine	S	Unknown		Not Reported
Calcium & Vitamin D3	S	Unknown		Not Reported
Valsartan	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	14314060	NON-EXPEDITED			US-PFIZER INC-2017542064			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Urticaria	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	16179037	EXPEDITED (15-DAY)		OT	PHHY2019CA076015		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia; Rash Pustular; Staphylococcal Infection; Syncope	Xolair			S	Unknown	300 Mg, Unknown		Not Reported	
	Azithromycin			S	Oral	1 Df, Qd		Novartis	
	Fluoxetine			S	Unknown	Unk		Not Reported	
	Quetiapine			C	Unknown	Unk		Not Reported	
	Avamys			C	Unknown	Unk		Not Reported	
	Prozac			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17441465	EXPEDITED (15-DAY)		LT, OT	GB-MYLANLABS-2020M1018641		97 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Interaction; Erythema; Eye Irritation; Eye Pain; Eye Swelling; Genital Burning Sensation; Hypersensitivity; Inappropriate Schedule Of Product Administration; Incorrect Product Administration Duration; Ocular Hyperaemia; Peripheral Swelling; Product Use In	Lansoprazole			S	Oral	Unk		Not Reported	
	Azyter			S	Ophthalmic	Unk		Mylan	
	Azyter			S	Ophthalmic	Unk		Mylan	
	Azyter			S	Ophthalmic	Unk		Mylan	
	Pradaxa			C	Unknown			Mylan	
	Torasemide			C	Unknown			Mylan	
	Digoxin			C	Unknown	Unk		Mylan	
	Eliquis			C	Unknown	Unk		Mylan	
	Furosemide			C	Unknown	100 Milligram, Qd		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unapproved Indication; Rash; Sudden Visual Loss; Systemic Lupus Erythematosus		Colchicine	C	Unknown		Mylan			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17487189	NON-EXPEDITED			US-LUPIN PHARMACEUTICALS INC.-2020-00923		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea	Azithromycin Tablets Usp, 250 Mg			S	Oral	250 Milligram, Qd		Lupin	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17487226	EXPEDITED (15-DAY)		OT	UA-TEVA-2020-UA- 1194336		4 YR	Male	UKR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Clostridial Infection; Diarrhoea	Sumamed			S	Unknown	Suspension		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17487819	EXPEDITED (15-DAY)		HO	US-MYLANLABS- 2020M1021638		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Drug-Induced Liver Injury; Hepatic Cirrhosis; Hepatic Necrosis	Azithromycin			S	Unknown			Not Reported	
	Ceftriaxone			S	Unknown	Received One Dose Of Ceftriaxone		Mylan	
	Prednisone			C	Unknown	Received 5 Day Course Of Prednisone		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17488066	NON-EXPEDITED			US-PFIZER INC- 2020093026		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Drug Hypersensitivity	Flagyl	S	Unk	Pfizer
	Zithromax	S	Unk	Pfizer
	Diclofenac Sodium	S	Unk	Pfizer
	Codeine	S	Unk	Not Reported
	Bactrim	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17488934	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020090104		76 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Off Label Use; Product Use In Unapproved Indication; Somnolence	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Invanz			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17489512	EXPEDITED (15-DAY)		HO, OT	US-QILU PHARMACEUTICAL CO.LTD.-QLU-000055-2020		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury; Hepatitis	Ceftriaxone			S	Unknown	Unk, Single		Qilu Pharmaceutical	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Prednisone			C	Unknown	20 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2020	17489623	EXPEDITED (15-DAY)		HO	NO-MYLANLABS-2020M1022907		55 YR	Female	NOR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eosinophilic Oesophagitis; Gastroenteritis Eosinophilic	Klacid Od			S	Oral	Unk		Mylan	
	Rifampicin			S	Oral	600 Milligram, Qd		Mylan	
	Myambutol			S	Oral	900 Milligram, Qd		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Azitromax	S	Oral	250 Milligram, Qd	Mylan
Seretide Discus	C	Respiratory (inhalation)	1 Dosage Form, Bid	Mylan
Singulair	C	Oral	10 Milligram, Qd	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	16507826	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2019AMR114737		75 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count	Salbutamol Sulphate			S		100 Ug, Prn		Glaxosmithkline
Abnormal; Blood Pressure	Azithromycin			S		500 Mg, Tid		Glaxosmithkline
Increased; Chest Pain;	Clavulin			S		Unk		Glaxosmithkline
Chronic Obstructive	Avalox			S		Unk		Glaxosmithkline
Pulmonary Disease;	Breo Ellipta			S		1 Puff(S), Qd		Glaxosmithkline
Cough; Dyspnoea;	Prednisone			S		50 Mg, Qd		Not Reported
Fev1/Fvc Ratio Abnormal;	Prednisone			S		40 Mg, Qd		Not Reported
Haemoglobin Decreased;	Prednisone			S		30 Mg, Qd		Not Reported
Haemoptysis; Heart Rate	Prednisone			S		20 Mg, Qd		Not Reported
Decreased; Hilar	Levaquin			S		Unk		Not Reported
Lymphadenopathy; Liver	Symbicort			S		2 Puff(S), Bid		Not Reported
Disorder; Loss Of	Symbicort			S		3 Unk, Tid		Not Reported
Personal Independence In	Spiriva Respimat			S		2 Puff(S), Qd		Not Reported
Daily Activities; Lung	Spiriva			S		2 Puff(S), Qd		Not Reported
Diffusion Disorder; Lung								
Disorder; Lung								
Hyperinflation; Lung								
Hyperinflation; Lung								
Neoplasm Malignant;								
Lymphadenopathy								
Mediastinal; Middle								
Insomnia; Obstructive								
Airways Disorder;								
Productive Cough;								
Pulmonary Cavitation;								
Pulmonary Fibrosis;								
Pulmonary Mass;								
Respiratory Gas								
Exchange Disorder; Sleep								

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Disorder Due To A
General Medical
Condition; Therapeutic
Product Effect Incomplete;
Wheezing

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	17491170	EXPEDITED (15-DAY)		DE, HO, LT, OT	US-AUROBINDO-AUR- APL-2020-010214		79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown	Unk		Aurobindo	
	Atovaquone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	17492292	EXPEDITED (15-DAY)		OT	CA-ROCHE-2555182			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Bone Pain; Bronchitis; Colitis; Dizziness; Drug Ineffective; Haemorrhoids; Lip Ulceration; Nervous System Neoplasm; Osteoarthritis; Rhinalgia; Sjogren'S Syndrome	Rituxan			S	Subcutaneous	Every 3 Months Since 1.5 Years		Not Reported	
	Rituxan			S				Not Reported	
	Rituxan			S				Not Reported	
	Inflectra [Infliximab]			S	Intravenous (not otherwise specified)	5 Mg/Kg At 0, 2, 6 And Then Every 8 Weeks		Not Reported	
	Inflectra [Infliximab]			S				Not Reported	
	Pregabalin			S	Oral			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Solu-Medrol			S	Intravenous (not otherwise specified)			Not Reported	
	Methotrexate			S	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Salbutamol			C	Unknown	Inhaled		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Flovent	C	Unknown	Not Reported
	Accutane	C	Oral	Not Reported
	Calcium	C	Oral	Not Reported
	Pantoprazole	C	Oral	Not Reported
	Naproxen	C	Oral	Not Reported
	D-Tabs	C	Unknown	Not Reported
	Candesartan	C	Unknown	Not Reported
	Tylenol	C	Oral	Not Reported
	Cefuroxime	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	17492765	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1116		24 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abscess; Anaemia; Anal Abscess; Arthralgia; Bipolar li Disorder; Cholecystectomy; Diarrhoea; Fistula; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Hypothyroidism; Post- Traumatic Stress Disorder; Therapeutic Product Effect Decreased; Tonsillectomy; Uterine Dilation And Curettage	Methotrexate (Trade Name Unknown) Azithromycin Humira Azathioprine Prednisone			S S S C C	Unknown Unknown Subcutaneous Unknown Unknown			Not Reported Not Reported Not Reported Not Reported Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
04-Mar-2020	17495152	EXPEDITED (15-DAY)		OT	NVSC2020CA059309		43 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma-Chronic	Xolair	S	Unknown	Unk	Not Reported
Obstructive Pulmonary Disease Overlap	Azithromycin	S	Unknown	Unk	Novartis
Syndrome; Bronchiectasis;	Ciprofloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Cardiac Murmur; Chronic Obstructive Pulmonary Disease; Chronic	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
Obstructive Pulmonary Disease;	Prednisone	S	Unknown	Unk	Not Reported
Gastroesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps; Oedema Peripheral;	Seebri Breezhaler	S	Unknown	Unk	Not Reported
Rhinitis Allergic;	Ultibro Breezhaler	S	Unknown	Unk	Not Reported
Sarcoidosis; Total Lung Capacity Increased;	Advair	S	Unknown	Unk	Not Reported
Wheezing	Atraven	S	Unknown	Unk	Not Reported
	Avamys	S	Unknown	Spray, Metered Dose	Not Reported
	Breo Ellipta	S	Respiratory (inhalation)	Unk	Not Reported
	Combivent	S	Unknown	Unk	Not Reported
	Duaklir Genuair	S	Unknown	Unk	Not Reported
	Inspiolto Respimat	S	Unknown	Unk	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Nasonex	S	Unknown	Unk	Not Reported
	Omnaris	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	18 Ug (Respimat)	Not Reported
	Symbicort	S	Unknown	Unk	Not Reported
	Tudorza Genuair	S	Unknown	Unk	Not Reported
	Umeclidinium Bromide	S	Unknown	Unk	Not Reported
	Umeclidinium Bromide	S	Unknown	Vilanterol Trifenatate	Not Reported
	Ventolin	S	Unknown	400 Mg	Not Reported
	Zenhale	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	17496704	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2020M1022350		62 YR	Female	CZE

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Renal Impairment	Azithromycin			S	Unknown	Unk		Not Reported
	Cefepime			C	Unknown			Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	17498269	EXPEDITED (15-DAY)		OT	NVSC2020CA059494		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased; Coccydynia; Contusion; Crying; Discomfort; Dizziness Exertional; Dry Skin; Dyspnoea; Dyspnoea Exertional; Ear Pain; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Headache; Heart Rate Increased; Myalgia; Nausea; Oxygen Saturation Decreased; Pain In Extremity; Respiratory Rate Increased; Scratch; Vision Blurred	Xolair			S	Subcutaneous	375 Mg, Q2w (1 Every 2 Weeks)		Not Reported
	Pantoprazole			S	Unknown	Unk		Novartis
	Montelukast			S	Unknown	Unk		Not Reported
	Fentanyl Citrate			S	Unknown	Unk (Liquid Epidural)		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown	Unk		Not Reported
	Advair			C	Unknown	Unk		Not Reported
	Prednisone			C	Unknown	Unk		Not Reported
	Reactine			C	Unknown	Unk		Not Reported
	Spiriva			C	Unknown	Unk		Not Reported
	Ventolin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Mar-2020	17498276	NON-EXPEDITED			US-PFIZER INC-2020094128			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Drug Hypersensitivity	Zithromax			S		Unk		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	15343688	EXPEDITED (15-DAY)		OT	CO-ACTELION-A-CH2018-177386		63 YR	Female	COL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Asthenia; Blood Pressure	Opsumit			S	Oral	10 Mg, Qd		Actelion
Decreased; Chills; Crying;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Erythema; Feeling	Opsumit			S	Oral	10 Mg, Qd		Actelion
Abnormal; Furuncle; Gait	Opsumit			S	Oral	10 Mg, Qd		Actelion
Disturbance; Headache;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Hepatitis; Hypoacusis;	Opsumit			S	Oral	10 Mg, Qd		Actelion
Influenza; Joint Swelling;	Azithromycin			S	Unknown	500 Mg, Bid		Not Reported
Lung Disorder; Muscle	Riociguat			C	Oral	1.5 Mg, Tid		Not Reported
Spasms; Nasopharyngitis;								
Oropharyngeal Pain; Pain								
In Extremity; Product								
Supply Issue; Productive								
Cough; Pyrexia;								
Screaming; Tachycardia;								
Vomiting								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	16405475	EXPEDITED (15-DAY)		DE, HO, OT	CA-TEVA-2019-CA-1060291		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cryptococcosis; Drug	Mycophenolic Acid			S	Unknown			Teva
Ineffective; Drug	Mycophenolic Acid			S				Teva
Intolerance; Drug	Prednisone			S	Unknown			Actavis
Resistance; Enterocolitis;	Prednisone			S				Actavis
Multiple Organ	Moxifloxacin Hydrochloride			S	Unknown			Teva
Dysfunction Syndrome;	Azithromycin			S	Intravenous (not			Pliva
Mycobacterium Avium					otherwise specified)			
Complex Infection;	Clarithromycin			S	Oral			Not Reported
Nosocomial Infection	Fluconazole			S	Oral			Teva
	Tacrolimus			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tacrolimus	S		Not Reported
Rifabutin	S	Oral	Not Reported
Tacrolimus	S	Unknown	Not Reported
Ethambutol	C	Oral	Not Reported
Amikacin	C	Parenteral	Not Reported
Rifampin	C	Intravenous (not otherwise specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17129373	NON-EXPEDITED			US-PFIZER INC-2019529797		75 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Neosporin			S		Unk		Pfizer
	Vicodin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17362638	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1177901		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Biopsy	Ciprofloxacin			S	Oral			Not Reported
Colon Abnormal; Blood Pressure Decreased; C-Reactive Protein	Azithromycin			S	Unknown			Not Reported
Increased; Diarrhoea; Dysbiosis; Enteritis; Frequent Bowel Movements; Gastroenteritis	Azithromycin			S	Unknown			Not Reported
Staphylococcal; Gastrointestinal Mucosa Hyperaemia; Haematochezia; Heart Rate Increased; Nausea; Purulence; Staphylococcal	Azithromycin			S	Unknown			Not Reported
	Moxifloxacin			S	Unknown			Teva
	Cefixime			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17495695	NON-EXPEDITED			US-PFIZER INC- 2020095459			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Headache; Influenza Like Illness; Respiratory Disorder; Swelling Face	Zithromax			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17499469	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1192793		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Blood Cholesterol Increased; Blood Immunoglobulin E Increased; Blood Urine Present; Bronchitis; Chest Discomfort; Chest Pain; Cough; Drug Ineffective; Dyspnoea; Fatigue; Malaise; Nasopharyngitis; Nausea; Productive Cough; Upper Respiratory Tract Infection; Vomiting; Wheezing	Pantoprazole Azithromycin Cholecalciferol Omalizumab Budesonide/Formoterol Fumarate Calcium Desoximetasone Ergocalciferol Estrogel Spiriva Synthroid Ventolin [Salbutamol]			S S S S C C C C C C C C	Oral Unknown Oral Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	1 Dosage Forms Daily;		Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17499860	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1192928			Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Alendronate Sodium			S				Actavis
	Alendronate Sodium			S				Actavis
	Azithromycin			S	Oral	250 Mg		Pliva
	Azithromycin			S				Pliva
	Omalizumab			S	Subcutaneous			Not Reported
	Omalizumab			S	Subcutaneous			Not Reported
	Ventolin			S	Unknown			Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Ciclesonide/Formoterol Fumarate			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort Turbuhaler			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17500038	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020094298		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal; Device Related Infection; Diarrhoea; Fatigue; Pneumonia	Azithromycin			S		Unk		Pfizer
	Jakafi			S		15 Mg, 2x/Day		Not Reported
	Jakafi			S	Oral	5 Mg, 2x/Day		Not Reported
	Jakafi			S	Oral	10 Mg, 1x/Day, (10 Mg Qam (Every Morning), 5 Mg Qpm (Every Evening))		Not Reported
	Jakafi			S	Oral	5 Mg, 1x/Day, [5 Mg Qpm (Every Evening)]		Not Reported
	Fish Oil			C		Unk		Not Reported
	Vitamin D3			C		Unk		Not Reported
	Vitamin B12			C		Unk		Not Reported
	Vitamin D			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Myrbetriq			C		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17500136	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1192921			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lymphoma	Alendronate			S	Oral			Actavis	
	Alendronate			S	Unknown			Actavis	
	Azithromycin			S	Oral			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Omalizumab			S	Subcutaneous			Not Reported	
	Ventolin			S	Unknown			Not Reported	
	Calcium Carbonate			C	Unknown			Not Reported	
	Ciclesonide			C	Unknown			Not Reported	
	Montelukast Sodium			C	Unknown			Not Reported	
	Spiriva			C	Unknown			Not Reported	
	Symbicort Turbuhaler			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17500347	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS, INC./RIDGEFIELD-2020-BI-01		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Cough; Decreased Appetite; Diarrhoea; Drug Interaction; Dry Mouth; Dyspnoea; Eye Colour Change; Feeling Abnormal; Intercepted Product Prescribing Error; Labelled Drug-Drug Interaction Medication	Ofev			S	Oral			Boehringer Ingelheim	
	Ofev			S	Oral			Boehringer Ingelheim	
	Azithromycin			S	Unknown			Not Reported	
	Loperamide			C	Unknown			Not Reported	
	Ultram [Tramadol Hydrochloride]			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Error; Myocardial
Infarction;
Nasopharyngitis; Oral
Fungal Infection; Oxygen
Therapy; Pneumonia;
Productive Cough; Stent
Placement; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17501814	NON-EXPEDITED			US-PFIZER INC- 2020098520		72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Tetracycline Hcl			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17504570	NON-EXPEDITED			US-PFIZER INC- 2020098481			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Celecoxib			S		Unk		Pfizer	
	Codeine			S		Unk		Not Reported	
	Sulfanilamide			S		Unk		Not Reported	
	Tramadol			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17505501	NON-EXPEDITED			US-TEVA-2020-US- 1192906			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain;	Azithromycin			S	Unknown			Not Reported	
Diarrhoea; Headache;	Oseltamivir			S	Unknown			Teva	
Nausea	Benzonatate			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Mar-2020	17505775	EXPEDITED (15-DAY)		OT	FR-009507513-2002FRA008935		76 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Somnolence	Invanz			S	Intravenous (not otherwise specified)			Merck	
	Zithromax			S	Oral	250 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17408068	EXPEDITED (15-DAY)		OT	NVSC2019FR036067		10 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Drug Ineffective; Off Label Use; Product Administered To Patient Of Inappropriate Age	Amoxicillin			S	Unknown	Unk		Novartis	
	Amoxicillin And Clavulanate			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17506825	NON-EXPEDITED			US-TEVA-2020-US-1192812		82 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Diarrhoea; Dizziness; Malaise; Presyncope	Azithromycin			S	Unknown	Two Tablets For Her Initial Dose Without Food		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17510121	NON-EXPEDITED			US-PFIZER INC-2020100694			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Depakote	S	Unk	Not Reported
	Tramadol	S	Unk	Not Reported
	Uloric	S	Unk	Not Reported
	Valproic Acid	S	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17510370	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA-2020SE33010		3 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury; Intentional Misuse Of Drug Delivery System	Mopral			S	Oral			Not Reported	
	Zithromax			S	Oral			Not Reported	
	Creon			C				Not Reported	
	Pulmozyme			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17510810	EXPEDITED (15-DAY)		HO, LT	NVSC2020GB062710		52 YR	Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chromaturia; Drug-Induced Liver Injury; Faeces Pale; Hepatitis Cholestatic; Jaundice	Azithromycin			S	Unknown	1500 Mg, Qw		Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17512198	EXPEDITED (15-DAY)		OT	US-SUNOVION-2020SUN000779		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Bronchiectasis; Cardiac Murmur; Chronic Obstructive Pulmonary Disease;	Glycopyrrolate			S	Unknown	Unk		Sunovion	
	Indacaterol And Glycopyrrolate			S	Unknown	Unk		Sunovion	
	Xolair			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Ciprofloxacin Hydrochloride			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gastroesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps; Oedema Peripheral; Rhinitis Allergic; Sarcoidosis; Total Lung Capacity Increased; Wheezing	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Advair	S	Unknown	Unk	Not Reported
	Atraven	S	Unknown	Unk	Not Reported
	Avamys	S	Unknown	Spray, Metered Dose	Not Reported
	Breo Ellipta	S	Respiratory (inhalation)	Unk	Not Reported
	Combivent	S	Unknown	Unk	Not Reported
	Duaklir Genuair	S	Unknown	Unk	Not Reported
	Inspiroto Respimat	S	Unknown	Unk	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Nasonex	S	Unknown	Unk	Not Reported
	Omnaris	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	18 Ug (Respimat)	Not Reported
	Symbicort	S	Unknown	Unk	Not Reported
	Tudorza Genuair	S	Unknown	Unk	Not Reported
	Umeclidinium Bromide	S	Unknown	Unk	Not Reported
	Umeclidinium Bromide	S	Unknown	Vilanterol Trifenatate	Not Reported
	Ventolin	S	Unknown	400 Mg	Not Reported
	Zenhale	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Mar-2020	17514272	EXPEDITED (15-DAY)		OT	CA-ROCHE-2562771		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased; Coccydynia; Contusion;	Xolair			S	Subcutaneous	375 Mg, Q2w (1 Every 2 Weeks)		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Crying; Discomfort;	Montelukast	S	Unknown	Unk	Not Reported
Dizziness Exertional; Dry	Fentanyl Citrate	S	Unknown	Unk (Liquid Epidural)	Not Reported
Skin; Dyspnoea;	Azithromycin	S	Unknown	Unk	Not Reported
Dyspnoea Exertional; Ear	Atorvastatin	S	Unknown	Unk	Not Reported
Pain; Emotional Disorder;	Advair	C	Unknown	Unk	Not Reported
Fall; Fatigue; Feeling	Prednisone	C	Unknown	Unk	Not Reported
Abnormal; Headache;	Reactine [Cetirizine	C	Unknown	Unk	Not Reported
Heart Rate Increased;	Hydrochloride]	C	Unknown	Unk	Not Reported
Myalgia; Nausea; Oxygen	Spiriva	C	Unknown	Unk	Not Reported
Saturation Decreased;	Ventolin [Salbutamol]	C	Unknown	Unk	Not Reported
Pain In Extremity;					
Respiratory Rate					
Increased; Scratch; Vision					
Blurred					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2020	17511935	EXPEDITED (15-DAY)		LT, OT	US-FRESENIUS KABI-FK202002342		62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Torsade De Pointes	Haloperidol Injection (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Haloperidol Injection (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Fresenius Medical Care
	Azithromycin (Manufacturer Unknown)			S	Unknown	Unknown		Fresenius Medical Care
	Ceftriaxone			C	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2020	17511540	EXPEDITED (15-DAY)		HO	FR-ZYDUS-048202		23 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Anuria; Decreased Appetite; General Physical Health Deterioration; Myalgia; Rhabdomyolysis; Transaminases Increased;	Oxomemazine			S	Oral	()		Not Reported
	Azithromycin			S	Oral			Zydus Pharm
	Fluticasone			C	Unknown			Not Reported
	Propionate/Salmeterol Xinafoate							

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2020	17512189	EXPEDITED (15-DAY)		OT	NVSC2020ES063329		35 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Dyspnoea	Azithromycin			S	Oral	500 Mg, Qd		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Mar-2020	17565796	DIRECT		HO			37 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Paraesthesia; Paraesthesia; Paraesthesia Oral; Paraesthesia Oral	Zithromax Mircette Rutin Garlic Fish Oil Trucalm B Complex Vitamin Hawthorne Coq10 Holy Basil Sam-E Claritin			S C C C C C C C C C C	Oral	Quantity:1 Capsule(S);		Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	15593174	NON-EXPEDITED			US-PFIZER INC- 2018444343			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diarrhoea; Drug Hypersensitivity; Drug Intolerance	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	16860529	NON-EXPEDITED			US-PFIZER INC- 2019414796		40 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Depo-Provera			S		Unk		Pfizer
	Effexor Xr			S		Unk		Pfizer
	Zoloft			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Benzonatate			S		Unk		Pfizer
	Doxycycline Hyclate			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Verapamil Hcl			S		Unk		Pfizer
	Celexa [Celecoxib]			S		Unk		Not Reported
	Compazine [Prochlorperazine Edisylate]			S		Unk		Not Reported
	Prozac			S		Unk		Not Reported
	Topamax			S		Unk		Not Reported
	Wellbutrin			S		Unk		Not Reported
	Amantadine			S		Unk		Not Reported
	Amitriptyline			S		Unk		Not Reported
	Nortriptyline			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Celex [Celecoxib]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17271873	NON-EXPEDITED		HO, OT	JP-CHEPLA-491704		64 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertriglyceridaemia; Immune Reconstitution Inflammatory Syndrome; Kaposi'S Sarcoma; White Blood Cell Count Decreased	Ganciclovir			S	Intravenous drip	Form Reported As Infusion.		Not Reported
	Kaletra			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Valixa			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valixa	S	Oral		Not Reported
Zerit	S	Oral		Not Reported
Doxorubicin Hydrochloride	S	Unknown		Not Reported
Pariet	S	Oral	First Therapy: From Unknown To 21 July 2005. Second Therapy: From 22 July 2005 To 31 March 2006. Bo+	Not Reported
Rabeprazole Sodium	S	Oral		Not Reported
Bactrim	S	Oral		Not Reported
Zithromax	S	Oral		Not Reported
Acecol	C	Oral		Not Reported
Aludrox	C			Not Reported
Bayaspirin	C	Oral		Not Reported
Depas	C	Oral		Not Reported
Emtricitabine, Tenofovir	C			Not Reported
Disoproxil				
Epivir	C	Oral		Not Reported
Filgrastim	C	Subcutaneous	Filgrastim Was Administered On 04 July 2005 And On 07 July 2005.	Not Reported
Maalox Product Nos	C	Oral	First Therapy: From Unknown To 21 July 2005. Second Therapy: From 22 July 2005 To 31 March 2006. Bo+	Not Reported
Magnesium Oxide	C			Not Reported
Ondansetron Hydrochloride	C	Unknown		Not Reported
Sucralfate	C			Not Reported
Tenofovir	C			Not Reported
Ulcerlmin	C	Oral	First Therapy: From Unknown To 21 July 2005. Second Therapy: From 22 July 2005 To 31 March 2006. Bo+	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17421170	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020053402		80 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug-Induced Liver Injury	Meropenem			S	Unknown	Unk		Pfizer	
	Azithromycin			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17515815	EXPEDITED (15-DAY)		HO	NVSC2020IT066075		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Diarrhoea; Jaundice; Liver Disorder	Azithromycin			S	Oral	1 Df, Qd		Novartis	
	Fidato			S	Intramuscular	1 Df, Qd (1 Gm/3.5 MI)		Not Reported	
	Augmentin			S	Oral	2 G, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17515889	EXPEDITED (15-DAY)		OT	CA-GLAXOSMITHKLINE-CA2020AMR039774			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchitis; Chronic Obstructive Pulmonary Disease; Dyspnoea; Loss Of Personal Independence In Daily Activities; Wheezing	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	
	Symbicort			S		2 Puff(S), Bid,200		Not Reported	
	Spiriva Respimat			S		2 Puff(S), 1d		Not Reported	
	Pulmicort			S		Unk		Not Reported	
	Prednisone			S		Unk,Prn		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17516800	NON-EXPEDITED			US-PFIZER INC-2020100530		64 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough	Zithromax			S		Unk		Pfizer	
	Zithromax			S				Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17516902	EXPEDITED (15-DAY)		HO	DE-MYLANLABS-2020M1023655		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Cardiovascular Disorder; Chills; Dehydration; Diarrhoea; Nausea	Azithromycin			S	Oral	1 Tablette Genommen		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17517045	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1023565		80 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Wall Haematoma; Anaemia	Azithromycin			S	Oral	250 Mg, Qod		Not Reported	
	Coumadine			S	Oral	1 Dosage Form, Qd		Mylan	
	Seretide			C				Mylan	
	Amiodarone			C				Mylan	
	Bronchodual			C				Mylan	
	Spiriva			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17517130	EXPEDITED (15-DAY)		OT	RU-JNJFOC-20200241797			Unknown	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Electrocardiogram Qt Prolonged; Gastrointestinal Disorder;	Bedaquiline			S	Oral			Not Reported	
	Moxifloxacin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatitis; Sinus
Bradycardia; Tendon
Disorder; Torsade De
Pointes

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17518888	NON-EXPEDITED			US-PFIZER INC- 2020103208			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin			S		Unk		Pfizer	
	Aleve			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Mar-2020	17518904	NON-EXPEDITED			US-PFIZER INC- 2020102425		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	16183012	EXPEDITED (15-DAY)		OT	CA-ROCHE-2301752		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain;	Xolair			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Fluoxetine			S	Unknown			Not Reported	
	Quetiapine			C	Unknown			Not Reported	
	Avamys			C	Unknown			Not Reported	
	Prozac			C	Unknown			Not Reported	
	Intuniv			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pharyngeal Paraesthesia;
Rash Pustular;
Staphylococcal Infection;
Syncope

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17256312	NON-EXPEDITED			US-BRISTOL-MYERS SQUIBB COMPANY- BMS-2020-001986			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis;	Eliquis			S	Oral	5 Milligram, Bid		Bristol Myers Squibb	
Bronchitis; Multiple	Z-Pak			S	Unknown	Unk		Not Reported	
Allergies; Myalgia; Neck	Pepcid Ac			C	Unknown	Unk		Not Reported	
Pain; Pruritus; Rash;	Vitamins Nos			C	Unknown	Unk		Not Reported	
Vision Blurred									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17493614	NON-EXPEDITED		HO, OT	US-AMGEN- USASP2020033092		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaemia;	Enbrel			S	Unknown	Unk		Amgen	
Anxiety; Bundle Branch	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Block Left; Carditis; Chest	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Pain; Fibromyalgia;	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Gastrooesophageal Reflux	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Disease; Insomnia; Major	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
Depression; Nausea;	Azithromycin			S	Unknown	Unk		Not Reported	
Osteoporosis; Pancreatitis	Depakote			S	Unknown	Unk		Not Reported	
Acute; Restless Legs	Dilaudid			C				Not Reported	
Syndromes; Tobacco	Benadryl [Diphenhydramine			C				Not Reported	
Abuse	Hydrochloride]								
	Lyrica			C	Oral	Unk		Not Reported	
	Prilosec [Omeprazole]			C		Unk		Not Reported	
	Zofran [Ondansetron]			C	Oral	4 Milligram, Q8h As Needed		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trintellix	C		10 Milligram	Not Reported
Trintellix	C	Oral	20 Milligram, Qd	Not Reported
Remeron	C	Oral	15 Milligram	Not Reported
Mirapex	C	Oral	0.5 Milligram, Qd	Not Reported
Vitamin D3	C	Oral	5000 Units Total	Not Reported
Theragran [Vitamins Nos]	C	Oral	Unk Unk, Qd	Not Reported
Zegerid [Omeprazole;Sodium Bicarbonate]	C		Unk	Not Reported
Albuterol Hfa	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17519332	EXPEDITED (15-DAY)		OT	CA-ROCHE-2562207		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma-Chronic	Xolair			S	Unknown	Unk		Not Reported
Obstructive Pulmonary Disease Overlap	Azithromycin			S	Unknown	Unk		Not Reported
Syndrome; Bronchiectasis;	Ciprofloxacin Hydrochloride			S	Unknown	Unk		Not Reported
Cardiac Murmur; Chronic	Moxifloxacin Hydrochloride			S	Unknown	Unk		Not Reported
Obstructive Pulmonary Disease;	Prednisone			S	Unknown	Unk		Not Reported
Gastroesophageal Reflux Disease; Lung Neoplasm	Seebri Breezhaler			S	Unknown	Unk		Not Reported
Malignant; Nasal Polyps;	Ultibro Breezhaler			S	Unknown	Unk		Not Reported
Oedema Peripheral;	Advair			S	Unknown	Unk		Not Reported
Rhinitis Allergic;	Atraven			S	Unknown	Unk		Not Reported
Sarcoidosis; Total Lung Capacity Increased;	Avamys			S	Unknown	Spray, Metered Dose		Not Reported
Wheezing	Breo Ellipta			S	Respiratory (inhalation)	Unk		Not Reported
	Combivent			S	Unknown	Unk		Not Reported
	Duaklir Genuair			S	Unknown	Unk		Not Reported
	Inspiolto Respimat			S	Unknown	Unk		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nasonex	S	Unknown	Unk	Not Reported
Omnaris	S	Unknown	Unk	Not Reported
Singulair	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	18 Ug (Respimat)	Not Reported
Symbicort	S	Unknown	Unk	Not Reported
Tudorza Genuair	S	Unknown	Unk	Not Reported
Umeclidinium Bromide	S	Unknown	Unk	Not Reported
Umeclidinium Bromide	S	Unknown	Vilanterol Trifenatate	Not Reported
Ventolin [Salbutamol]	S	Unknown	400 Mg	Not Reported
Zenhale	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17521240	EXPEDITED (15-DAY)		HO, LT	US-MYLANLABS-2020M1026658		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Pulse Absent; Torsade De Pointes; Unresponsive To Stimuli	Azithromycin			S	Parenteral			Not Reported	
	Azithromycin			S				Not Reported	
	Haloperidol			S	Intravenous (not otherwise specified)	Second Dose After 3 Hours		Not Reported	
	Ceftriaxone			C	Parenteral			Mylan	
	Ceftriaxone			C				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17523691	EXPEDITED (15-DAY)		OT	BE-MYLANLABS-2020M1025621		35 YR	Female	BEL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Pharyngeal Swelling	Azithromycin			S	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17524272	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1198670		24 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Abscess; Anaemia; Anal Abscess; Arthralgia; Bipolar II Disorder; Cholecystectomy; Diarrhoea; Fistula; Gastrooesophageal Reflux Disease; General Physical Health Deterioration; Hypothyroidism; Post-Traumatic Stress Disorder; Therapeutic Product Effect Decreased; Tonsillectomy; Uterine Dilation And Curettage	Methotrexate			S	Unknown			Barr	
	Azithromycin			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Azathioprine			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2020	17556006	DIRECT	Y					Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Product Use Issue	Levofloxacin			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17506116	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC-2020097204		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaemia; Anxiety; Blood Glucose Increased; Bundle Branch Block Left; Carditis; Chest Pain; Fibromyalgia; Gastrooesophageal Reflux Disease; Insomnia; Major Depression; Nausea;	Enbrel			S	Unknown	Unk		Pfizer	
	Azithromycin			S	Unknown	Unk		Pfizer	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	
	Humira			S	Subcutaneous	40 Milligram, Q2wk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Osteoporosis; Pancreatitis Acute; Restless Legs Syndrome; Tobacco Abuse	Depakote	S	Unknown	Unk	Not Reported
	Dilaudid	C		Unk	Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	C		Unk	Not Reported
	Lyrica	C	Oral	Unk	Not Reported
	Prilosec [Omeprazole]	C		Unk	Not Reported
	Zofran [Ondansetron]	C	Oral	4 Milligram, Q8h As Needed	Not Reported
	Trintellix	C		10 Milligram	Not Reported
	Trintellix	C	Oral	20 Milligram, Qd	Not Reported
	Remeron	C	Oral	15 Milligram	Not Reported
	Mirapex	C	Oral	0.5 Milligram, Qd	Not Reported
	Vitamin D3	C	Oral	5000 Units Total	Not Reported
	Theragran [Vitamins Nos]	C	Oral	Unk Unk, Qd	Not Reported
	Zegerid [Omeprazole;Sodium Bicarbonate]	C		Unk	Not Reported
	Albuterol Hfa	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17510123	NON-EXPEDITED			US-PFIZER INC- 2020099102			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Reglan [Metoclopramide]			S		Unk		Not Reported	
	Lisinopril			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17523789	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US- 1196866		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Autoimmune Hepatitis; Drug-Induced Liver Injury;	Azithromycin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatic Cirrhosis; Hepatic Necrosis	Ceftriaxone	S	Unknown	Received One Dose Of Ceftriaxone	Not Reported
	Prednisone	C	Unknown	20 Milligram Daily; Received 5 Day Course Of Prednisone	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17527241	NON-EXPEDITED			US-PFIZER INC-2020012740		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Bronchitis; Multiple Allergies; Myalgia; Neck Pain; Pruritus; Rash; Vision Blurred	Eliquis			S	Oral	5 Mg, 2x/Day		Not Reported	
	Azithromycin			S	Unknown	Unk		Pfizer	
	Pepcid Ac			C	Unknown	Unk		Not Reported	
	Vitamins Nos			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17527260	NON-EXPEDITED			US-PFIZER INC-2020105997		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17529582	EXPEDITED (15-DAY)		HO, LT, OT	CZ-MYLANLABS-2020M1025795		62 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Diarrhoea; Haematuria; Oliguria; Proteinuria; Renal Tubular Necrosis; Vomiting	Azithromycin			S	Unknown	Unk		Not Reported	
	Cefepime			S	Unknown	Unk		Mylan	
	Prednisone			C	Unknown	Unk		Mylan	
	Heparin			C	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17529955	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1025879		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Cholesterol Increased; Hepatotoxicity; Hypertriglyceridaemia	Azithromycin			S		Unk		Not Reported
	Azithromycin			S	Oral	10 Mg/Kg Once Daily		Not Reported
	Azithromycin			S				Not Reported
	Imipenem + Cilastatina			S	Topical	5/5 Mg/MI; Three Drops Three Times Daily		Mylan
	Imipenem + Cilastatina			S		Unk		Mylan
	Imipenem + Cilastatina			S	Unknown	Unk		Mylan
	Imipenem + Cilastatina			S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2-4 Doses		Mylan
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg/Day In 2 Doses		Mylan
	Tigecycline			S	Intravenous (not otherwise specified)	Reduced Dosage		Mylan
	Tigecycline			S	Topical	5 Mg/MI; Three Drops Three Times Daily		Mylan
	Tigecycline			S	Unknown	Unk		Mylan
	Clofazimine			S	Oral	50mg Once Daily; If Weight More Than 40kg, Then 100mg Once Daily		Mylan
	Clofazimine			S		Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17530893	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020HU058685		36 YR	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Distension; Alanine Aminotransferase	Azithromycin			S	Unknown	Unk		Novartis	
	Levofloxacin			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Altered State Of Consciousness;	Doxycycline	C	Unknown	Unk	Not Reported
Anxiety; Aspartate Aminotransferase	Klion	C	Unknown	Unk	Not Reported
Increased; Blood Albumin	Noacid	C	Unknown	40 Mg, Qd (In The Morning)	Not Reported
Increased; Blood Iron; Blood Sodium Increased; Blood Urea; Bradycardia; Brain Oedema; Burning Sensation; C-Reactive Protein Increased; Cholelithiasis; Coma; Consciousness Fluctuating; Dehydration; Diverticulitis; Dizziness; Dry Skin; Dysphonia; Gallbladder Polyp; Gastrointestinal Bacterial Overgrowth; Haematocrit Decreased; Haemorrhoids; Headache; Hypertriglyceridaemia; Hyponatraemia; Hypoosmolar State; Loss Of Consciousness; Mean Cell Haemoglobin Increased; Mean Cell Volume Increased; Mean Platelet Volume Decreased; Monocyte Count Increased; Nausea; Oedema Peripheral; Pain; Panic Attack; Polydipsia; Polyuria; Protein Total Increased; Pupil Fixed; Pyrexia; Red Blood Cell Count Decreased; Retrograde Amnesia; Somnolence; Urine Chloride Decreased; Urine Osmolarity; Urine Potassium Decreased;					

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Urine Sodium Decreased;
Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2020	17532267	NON-EXPEDITED			NVSC2020US069370			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S	Unknown			Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	15235411	NON-EXPEDITED			US-PFIZER INC-2018311112		67 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Clindamycin			S		Unk		Pfizer	
	Zithromax			S		Unk		Pfizer	
	Ambien			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	16257966	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2019M1030863		62 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Transitional Cell Carcinoma	Pantoprazole			S	Unknown	Unk		Not Reported	
	Pantoprazole			S		Unk		Not Reported	
	Lercanidipine			S	Unknown	Unk		Mylan	
	Sulfamethoxazol W/Trimetoprim			S	Unknown	Unk		Mylan	
	Sulfamethoxazol W/Trimetoprim			S	Unknown	Unk		Mylan	
	Moronal			S	Unknown	Unk		Mylan	
	Moronal			S	Unknown	Unk		Mylan	
	Ibu 1a Pharma			S	Unknown	Unk		Mylan	
	Ibu 1a Pharma			S	Unknown	Unk		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ciprofloxacin Al	S		Unk	Mylan
Ciprofloxacin Al	S	Unknown	Unk	Mylan
Ciprofloxacin Al	S	Unknown	Unk	Mylan
Valsartan Comp	S	Unknown	Unk	Mylan
Valsartan Comp	S	Unknown	Unk	Mylan
Azithromycin 1a Pharma /00944301/	S	Unknown	Unk	Mylan
Azithromycin 1a Pharma /00944301/	S	Unknown	Unk	Mylan
Roxithromycin	S	Unknown	Unk	Mylan
Roxithromycin	S	Unknown	Unk	Mylan
Ibuflam [Ibuprofen]	S	Unknown	Unk	Mylan
Ibuflam [Ibuprofen]	S	Unknown	Unk	Mylan
Linola H Fett N	S	Unknown	Unk	Mylan
Linola H Fett N	S	Unknown	Unk	Mylan
Decortin H	S	Unknown	Unk	Mylan
Decortin H	S	Unknown	Unk	Mylan
L-Thyrox Hexal	S	Unknown	Unk	Mylan
L-Thyrox Hexal	S	Unknown	Unk	Mylan
Doxagamma	S	Unknown	Unk	Mylan
Doxagamma	S	Unknown	Unk	Mylan
Ampicillin Ratiopharm	S	Unknown	Unk	Mylan
Ampicillin Ratiopharm	S	Unknown	Unk	Mylan
Valsartan Ratiopharm Comp	S	Unknown	Unk	Mylan
Valsartan Ratiopharm Comp	S	Unknown	Unk	Mylan
Spironolacton Aristo	S	Unknown	Unk	Mylan
Spironolacton Aristo	S	Unknown	Unk	Mylan
Eferox	S	Unknown	Unk	Mylan
Eferox	S	Unknown	Unk	Mylan
Ciprofloxacin Aristo	S	Unknown	Unk	Mylan

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Ciprofloxacin Aristo	S	Unknown	Unk	Mylan
Euthyrox	S	Unknown	Unk	Mylan
Euthyrox	S	Unknown	Unk	Mylan
Ampho Moronal	S	Unknown	Unk	Mylan
Ampho Moronal	S	Unknown	Unk	Mylan
Alfason Crelo	S	Unknown	Unk	Mylan
Alfason Crelo	S	Unknown	Unk	Mylan
Mometahexal	S	Nasal	Unk	Mylan
Mometahexal	S	Unknown	Unk	Mylan
Pantoprazol Pensa	S	Unknown	Unk	Mylan
Hct Hexal	S	Unknown	Unk	Mylan
Cotrimoxazol Al	S	Unknown	Unk	Mylan
Clindamycin Al	S	Unknown	Unk	Mylan
Clindamycin Al	S	Unknown	Unk	Mylan
Valsacor Comp	S	Unknown	Unk	Mylan
Valsacor Comp	S		Unk	Mylan
Novaminsulfon	S	Unknown	Unk	Mylan
Hygroton	S	Unknown	Unk	Mylan
Hygroton	S	Unknown	Unk	Mylan
Locacorten Vioform	S	Unknown	Unk	Mylan
Locacorten Vioform	S	Unknown	Unk	Mylan
Cefpo	S	Unknown	Unk	Mylan
Clindasol [Clindamycin Hydrochloride]	S	Unknown	Unk	Mylan
Clindasol [Clindamycin Hydrochloride]	S	Unknown	Unk	Mylan
Cefpodoxim Hexal	S	Unknown	Unk	Mylan
Valsartan Hexal Comp	S	Unknown	Unk	Mylan
Fluconazol Puren	S	Unknown	Unk	Mylan
Clinda-Saar	S	Unknown	Unk	Mylan

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Clinda-Saar	S	Unknown	Unk	Mylan
Valsartan 1a Pharma Plus	S	Unknown	Unk	Mylan
Valsartan 1a Pharma Plus	S	Unknown	Unk	Mylan
Doxazosin	S	Unknown	Unk	Mylan
Codeintropfen Ct	S	Unknown	Unk	Mylan
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Mylan
Cefpodoxim 1 A Pharma	S	Unknown	Unk	Mylan
Nebivolol Actavis	S	Unknown	Unk	Mylan
Nebivolol Actavis	S	Unknown	Unk	Mylan
Monuril	S	Unknown	Unk	Mylan
Doxycyclin 1a Pharma	S	Unknown	Unk	Mylan
Doxycyclin 1a Pharma	S	Unknown	Unk	Mylan
Cotrimox Forte	S	Unknown	Unk	Mylan
Cotrimox Forte	S	Unknown	Unk	Mylan
Cotrimox Forte	S	Unknown	Unk	Mylan
Lonolox	S	Unknown	Unk	Mylan
Lonolox	S	Unknown	Unk	Mylan
Valsartan Hexal	S	Unknown	Unk	Mylan
Valsartan Hexal	S	Unknown	Unk	Mylan
Dolgit	S	Unknown	Unk	Mylan
Dolgit	S	Unknown	Unk	Mylan
Rasilez	S	Unknown	Unk	Mylan
Rasilez	S	Unknown	Unk	Mylan
Clindahexal	S	Unknown	Unk	Mylan
Clindahexal	S	Unknown	Unk	Mylan
Cipro	S	Unknown	Unk	Mylan
Doxazosin 1 A Pharma	S	Unknown	Unk	Mylan
Doxazosin 1 A Pharma	S		Unk	Mylan
Cefpo	S		Unk	Mylan

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cefpodoxime Proxetil	S	Unknown	Unk	Mylan
Eutirox	S	Unknown	Unk	Mylan
Fluconazole	S		Unk	Mylan
Fluconazole	S	Unknown	Unk	Mylan
Monuril	S		Unk	Mylan
Monuril	S	Unknown	Unk	Mylan
Ciprofloxacin	S	Unknown	Unk	Mylan
Ciprofloxacin	S	Unknown	Unk	Mylan
Lercanidipine Ratiopharm	S	Unknown	Unk	Mylan
Lercanidipine Ratiopharm	S	Unknown	Unk	Mylan
Cefpodoxime	S	Unknown	Unk	Mylan
Cefpodoxime	S	Unknown	Unk	Mylan
Hydrochlorothiazide	S	Unknown	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17282884	EXPEDITED (15-DAY)		OT	NVSC2020BR010617		19 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Product Use In Unapproved Indication; Syphilis	Azithromycin			S	Oral	1 G		Novartis
	Ceftriaxone			S	Intravenous (not otherwise specified)	1 G		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17283909	EXPEDITED (15-DAY)		CA, HO, OT	NVSC2020BR010619			Unknown	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Syphilis; Foetal Exposure During Pregnancy	Azithromycin			S	Transplacental	1 G		Novartis
	Ceftriaxone			S	Transplacental	1 G		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17445277	NON-EXPEDITED			US-PFIZER INC-2020078158		73 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Pen V [Phenoxymethylpenicillin]			S		Unk		Not Reported	
	Asa			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17467486	NON-EXPEDITED			US-PFIZER INC-2020087280		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Marcaïne			S		Unk		Pfizer	
	Iodine			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17529215	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020-1278			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Arthritis; Drug Hypersensitivity; Gait Disturbance; Inflammation; Musculoskeletal Pain; Pain In Extremity; Thyroid Cancer	Methotrexate (Trade Name Unknown)			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Tetracycline Hcl			S	Unknown			Not Reported	
	Cefuroxime Axetil			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	
	Ibuprofen			C	Unknown			Not Reported	
	Plaquenil			C	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17532850	NON-EXPEDITED			US-PFIZER INC-2020108231		69 YR	Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Zolpidem Tartrate			S		Unk		Pfizer	
	Ambien			S		Unk		Not Reported	
	Ketolide			S		Unk		Not Reported	
	Azithromycin Dihydrate			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17532903	EXPEDITED (15-DAY)		DE, HO	JP-MYLANLABS-2020M1026831			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Vancomycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Mylan	
	Piperacillin & Tazobactam			S	Unknown			Mylan	
	Sultamicillin			S	Unknown			Mylan	
	Meropenem			S	Unknown			Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17532956	EXPEDITED (15-DAY)		DE, HO	JP-MYLANLABS-2020M1026840			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Vancomycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Mylan	
	Azithromycin			S				Mylan	
	Piperacilin/Tazobactam			S	Unknown			Mylan	
	Piperacilin/Tazobactam			S				Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Mar-2020	17533121	EXPEDITED (15-DAY)		DE	QA-PFIZER INC-2020100208		17 YR	Female	QAT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Oral	Unk		Pfizer	
	Fluticasone Propionate			S	Respiratory (inhalation)	Unk		Not Reported	
	Fluticasone Propionate			S				Not Reported	
	Trimethoprim Sulfamethoxazole			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	13375018	NON-EXPEDITED			US-PFIZER INC-2017126364		57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Imitrex			S		Unk		Not Reported	
	Penicillin V Potassium			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17134752	EXPEDITED (15-DAY)		HO, OT	NVSC2019PT062724		83 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Abdomen; Diaphragmatic Hernia; Drug Ineffective; Incarcerated Hernia; Pneumonia	Amoxicillin,Clavulanic Acid			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17393636	EXPEDITED (15-DAY)		OT	NVSC2020TR032213			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Foetal Exposure During Pregnancy; Premature Baby	Betamethasone	S	Transplacental	12 Mg, Qd	Novartis
	Ampicillin	S	Transplacental	1 G, Qid (For 10 Days)	Not Reported
	Azithromycin	S	Transplacental	500 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17535973	EXPEDITED (15-DAY)		HO, OT	US-P&L DEVELOPMENTS OF NEWYORK CORPORATION-2081592		11 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Linear Iga Disease	Ibuprofen			S	Unknown			PI Developments
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17537701	EXPEDITED (15-DAY)		HO, OT	US-GYP-000088		68 YR	Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Cardiac Tamponade; Cryptococcosis; Hypogammaglobulinaemia ; Infection; Pericardial Effusion; Pericarditis Constrictive; Product Use In Unapproved Indication; Pulmonary Oedema	Prednisone			S	Unknown	10 Mg Daily		Geneyork Pharma
	Prednisone			S	Unknown	30 Mg Daily		Geneyork Pharma
	Prednisone			S	Unknown			Geneyork Pharma
	Antithymocyte Immunoglobulin			S	Unknown			Not Reported
	Tacrolimus			S	Unknown	3 Mg Twice Daily		Not Reported
	Tacrolimus			S	Unknown			Not Reported
	Mycophenolate Mofetil			S	Unknown	250 Mg Twice Daily		Not Reported
	Mycophenolate Mofetil			S	Unknown			Not Reported
	Sulfamethoxazole, Trimethoprim			S	Unknown	3 Times Weekly		Not Reported
	Valganciclovir			S	Unknown			Not Reported
	Azithromycin			S	Unknown	250 Mg 3 Times Weekly		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17537774	EXPEDITED (15-DAY)		HO	NVSC2020FR068874		58 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; General Physical Health Deterioration; Pyrexia	Azithromycin			S	Unknown	Unk		Novartis	
	Tavanic			S	Unknown	Unk		Not Reported	
	Furadantine			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17537942	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020102186		36 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Jarisch-Herxheimer Reaction	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk, (Her Dose Was Increased)		Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	Unk, Continued (To Complete A 10-Day Course)		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	Unk, (To Complete A 10-Day Course)		Pfizer	
	Doxycycline			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17538108	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA068609		84 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain; Asthenia; Blood Pressure	Sandostatin			S	Intramuscular	30 Mg, Qmo		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Decreased; Blood Pressure Diastolic	Codeine Phosphate	S	Unknown	Unk	Not Reported
Decreased; Blood Pressure Systolic	Zithromax	C	Unknown	Unk	Not Reported
Increased; Body Temperature Decreased;					
Cellulitis; Cerebrovascular Accident; Cholelithiasis;					
Contusion; Decreased Appetite; Diarrhoea;					
Discomfort; Erythema; Fall; Furuncle; Heart Rate					
Decreased; Heart Rate Irregular; Hyperhidrosis;					
Hypotension; Injection Site Pain; Malaise; Needle					
Issue; Pain In Extremity; Peripheral Swelling;					
Productive Cough; Pruritus; Pulmonary Congestion; Septic Rash;					
Skin Laceration; Skin Ulcer; Yellow Skin					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17541196	EXPEDITED (15-DAY)		OT	FR-SA-2020SA065201		72 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mechanical Urticaria; Pruritus	Rifadine			S	Oral	2 Df, Qd		Sanofi
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Ethambutol			S	Oral	2 Df, Qd		Not Reported
	Venlafaxine Hydrochloride			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2020	17542144	NON-EXPEDITED			US-FDC LIMITED-2020RIS00045		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure Via Skin	Ofloxacin	S	Ophthalmic	1 Drop, 3x/Day "In Both Eyes"	Fdc
Contact; Fatigue; Off					
Label Use; Product Use	Azithromycin	S		2 Tablets, Once	Not Reported
Complaint	Azithromycin	S		1 Tablets, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17288678	EXPEDITED (15-DAY)		HO, OT	JP-ROCHE-2526034		64 YR	Male	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypertriglyceridaemia; Immune Reconstitution Inflammatory Syndrome; Kaposi'S Sarcoma; White Blood Cell Count Decreased	Denosine [Ganciclovir]			S	Intravenous drip			Not Reported
	Denosine [Ganciclovir]			S				Not Reported
	Denosine [Ganciclovir]			S				Not Reported
	Valixa			S	Oral			Not Reported
	Valixa			S	Oral			Not Reported
	Bactrim			S	Oral			Not Reported
	Kaletra			S	Oral			Not Reported
	Zerit			S	Oral			Not Reported
	Doxorubicin Hydrochloride			S	Unknown			Not Reported
	Pariet			S	Oral			Not Reported
	Pariet			S	Oral			Not Reported
	Rabeprazole Sodium			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Epivir			C	Oral			Not Reported
	Acecol [Temocapril Hydrochloride]			C	Oral			Not Reported
	Aluminium Hydroxide;Magnesium Carbonate			C	Unknown			Not Reported
	Bayaspirin			C	Oral			Not Reported
	Depasan			C	Oral			Not Reported
	Emtricitabine;Tenofovir			C	Unknown			Not Reported
	Disoproxil Fumarate							

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Filgrastim	C	Unknown	Filgrastim Was Administered On 04/Jul/2005, And On 07/Jul/2005.	Not Reported
Magnesium Oxide	C	Unknown		Not Reported
Ondansetron Hydrochloride	C	Unknown		Not Reported
Sucralfate	C	Unknown		Not Reported
Tenofovir	C	Unknown		Not Reported
Ulcerlin	C	Unknown	First Therapy: From Unknown To 21/Jul/2005. Second Therapy: From 22/Jul/2005 To 31/Mar/2006	Not Reported
Etizolam	C	Unknown	First Therapy: From Unknown To 21/Jul/2005. Second Therapy: From 22/Jul/2005 To 31/Mar/2006	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17543703	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1200304		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mechanical Urticaria; Pruritus	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported	
	Venlafaxine			S	Oral			Teva	
	Rifadine 300 Mg, Gélule			S	Oral	2 Dosageform		Not Reported	
	Dexambutol 500 Mg, Comprimé Pelliculé			S	Oral	2 Dosageform		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544057	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2019SP008176		33 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exposure During Pregnancy	Metronidazole	S	Unknown	Unk	Strides
	Metronidazole	S			Strides
	Amoxicillin	S	Unknown	Unk	Not Reported
	Amoxicillin	S			Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Azithromycin	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544601	NON-EXPEDITED			US-PFIZER INC-2020111394		49 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Zithromax			S		Unk		Pfizer	
	Rituxan			C		Unk		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			C		Unk		Not Reported	
	Zyrtec [Cetirizine Hydrochloride]			C		Unk		Not Reported	
	Singulair			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17544935	NON-EXPEDITED			US-PFIZER INC-2020112586		63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Augmentin [Amoxicillin;Clavulanic Acid]			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17545840	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1026606		27 YR	Female	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Pain Upper;	Azithromycin	S	Oral	500 Milligram, Qd	Not Reported
Diarrhoea Haemorrhagic;	Gaviscon /00237601/	C		Unk	Mylan
Dizziness	Propranolol	C		Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17547076	EXPEDITED (15-DAY)		OT	NVSC2020FR070157		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Respiratory Tract Infection	Prednisolone			S	Oral	Unk		Novartis
	Esomeprazole			S	Oral	1 Df, Qd		Not Reported
	Novatrex			S	Oral	4 Df, Qw		Not Reported
	Aclasta			C	Intravenous drip	1 Df, Q12mo		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2020	17547315	EXPEDITED (15-DAY)		HO	FR-VERTEX PHARMACEUTICALS- 2020-005156		3 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatocellular Injury; Intentional Misuse Of Drug Delivery System	Orkambi			S	Oral	2 Dosage Form, Qd		Vertex
	Mopral			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Creon			C				Not Reported
	Pulmozyme			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	14334309	EXPEDITED (15-DAY)		OT	ES- GLAXOSMITHKLINE- ES2017197792			Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Apnoea; Deafness; Off Label Use; Tonsillitis	Flixotide			S	Unknown	Unk		Glaxosmithkline
	Zitromax			S	Unknown	1 MI, From Monday To Thursday On, From Friday		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zitromax	S	Unknown	To Sunday Off 1.5 MI, From Monday To Thursday On, From Friday To Sunday Off	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	16644494	EXPEDITED (15-DAY)		OT	AT-MYLANLABS- 2019M1069891			Male	AUT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anuria; C-Reactive Protein Increased; Candida Infection; Drug Ineffective; Infection	Azithromycin			S	Unknown	Unk		Not Reported
	Tigecycline			S	Unknown	Unk		Not Reported
	Sulbactam			S	Unknown	Unk		Mylan
	Rifoldin			S	Intravenous (not otherwise specified)	Unk		Mylan
	Colistin Sulfate			S	Unknown	Unk		Mylan
	Cubicin			S	Unknown	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17174660	EXPEDITED (15-DAY)		HO	US-ABBVIE-19K-163- 3196295-00			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia; Anxiety; Bundle Branch Block Left; Carditis; Chest Pain; Fibromyalgia; Gastroesophageal Reflux Disease; Insomnia; Major Depression; Nausea; Osteoporosis; Pancreatitis Acute; Restless Legs Syndrome; Tobacco Abuse	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Humira 40mg/0.4ml			S	Subcutaneous			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Depakote			S	Unknown			Not Reported
	Enbrel			S	Unknown			Not Reported
	Lyrica			C	Oral			Not Reported
	Prilosec			C		20 Mg As Needed		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zofran	C		Take 4 Mg By Mouth Every 8 Hrs As Needed.	Not Reported
Trintellix	C			Not Reported
Trintellix	C	Oral	Every Morning	Not Reported
Remeron	C	Oral	Bedtime	Not Reported
Mirapex	C	Oral	Bedtime	Not Reported
Vitamin D3	C	Oral	5000 Units Total	Not Reported
Theragra	C	Oral		Not Reported
Zegerid	C			Not Reported
Albuterol Hfa	C			Not Reported
Benadryl	C			Not Reported
Dilaudid	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17548445	EXPEDITED (15-DAY)		DE, HO	JP-TEVA-2020-JP-1203628			Unknown	JPN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Vancomycin			S	Unknown			Actavis
	Azithromycin			S	Unknown			Not Reported
	Meropenem			S	Unknown			Not Reported
	Piperacillin/Tazobactam			S	Unknown			Not Reported
	Sultamicillin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17550097	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020107453		16 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Nasal Septum Perforation	Novatrex			S	Oral	10 Mg, Weekly		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk (Every 15 Days)		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17550213	NON-EXPEDITED			US-PFIZER INC-2020115177			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17551402	EXPEDITED (15-DAY)		DE, HO	JP-TEVA-2020-JP-1203627			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Vancomycin			S	Unknown			Actavis	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Piperacillin/Tazobactam			S	Unknown			Not Reported	
	Piperacillin/Tazobactam			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Mar-2020	17551950	EXPEDITED (15-DAY)		OT	NVSC2020CA074799		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Seebri Breezhaler			S	Unknown	1 Df		Novartis	
	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Breo Ellipta			S	Respiratory (inhalation)	1 Df		Not Reported	
	Atrovent			S	Unknown			Not Reported	
	Ipratropium Bromide And Albuterol Sulfate			S	Respiratory (inhalation)			Not Reported	
	Prednisone			S	Oral	45 Mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Theophylline	S	Oral	45 Mg	Not Reported
Singulair	S	Oral	10 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	14184547	EXPEDITED (15-DAY)	DE, OT		FR-PFIZER INC-2017485104		80 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Drug Level Increased; Hepatic Failure; Hepatitis; Hepatocellular Injury	Vfend			S	Intravenous (not otherwise specified)	400 Mg, 1x/Day (Day3 Night)		Pfizer
	Vfend			S	Intravenous (not otherwise specified)	400 Mg, 2x/Day (Day 4 To D7 Morning-Night)		Pfizer
	Vfend			S	Intravenous (not otherwise specified)	400 Mg, 1x/Day (D8 Morning)		Pfizer
	Vfend			S	Intravenous (not otherwise specified)	200 Mg, 1x/Day (D8 Night)		Pfizer
	Vfend			S	Oral	200 Mg, 1x/Day (Day 9 Morning)		Pfizer
	Zithromax			S	Oral	500 Mg, Single (D2)		Pfizer
	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Zithromax			S				Pfizer
	Hydrocortisone Sodium Succinate			S	Intravenous (not otherwise specified)	100 Mg, 1x/Day (Occasionally)		Not Reported
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	1 G, 2x/Day		Not Reported
	Trimebutine Arrow			S	Oral	100 Mg, 2x/Day		Not Reported
	Lasilix /00032601/			S	Oral	40 Mg, 1x/Day		Not Reported
	Lasilix /00032601/			S	Oral	20 Mg, 1x/Day		Not Reported
	Bisocel			S	Oral	5 Mg, 1x/Day		Not Reported
	Hydrea			S	Oral	500 Mg, 2x/Day		Not Reported
	Polaramine			S	Intravenous (not otherwise specified)	5 Mg, 1x/Day		Not Reported
	Zyloric			S	Oral	100 Mg, 2x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zyloric	S	Oral	100 Mg, Daily	Not Reported
Zyloric	S	Oral	100 Mg, Daily	Not Reported
Iclusig	S	Oral	45 Mg, 1x/Day (D1 To D9, At Noon)	Not Reported
Fasturtec	C	Intravenous (not otherwise specified)	7.5 Mg, Single	Not Reported
Zophren /00955301/	C		Unk	Not Reported
Cortancyl	C		40 Mg, Daily (Occasionally)	Not Reported
Movicol	C		2 Df, Daily	Not Reported
Spasfon /00765801/	C		80 Mg, As Needed	Not Reported
Topalgic	C		50 Mg, As Needed	Not Reported
Stilnox	C		10 Mg, As Needed	Not Reported
Atarax /00058401/	C		12.5 Mg, 1x/Day	Not Reported
Renagel /01459901/	C		800 Mg, 2x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	15283208	EXPEDITED (15-DAY)		OT	CA-ROCHE-2169947		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Contact; Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported
	Seebri Breezhaler			S	Unknown	1 Df, Qd		Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Theophylline			S	Oral	450 Mg, Qd		Not Reported
	Atrovent			S	Unknown			Not Reported
	Breo Ellipta			S	Unknown	1 Df, Qd		Not Reported
	Prednisone			S	Oral			Not Reported
	Singulair			S	Oral	10 Mg, Qd		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17030298	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019484941			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Pantoprazole			S	Unknown	Unk		Pfizer	
	Alprazolam			S	Unknown	Unk		Pfizer	
	Atorvastatin Calcium			S	Unknown	Unk		Pfizer	
	Atorvastatin Calcium			S	Unknown	Unk		Pfizer	
	Lomotil			S	Oral	Unk, 4x/Day		Pfizer	
	Atropine Sulfate/Diphenoxylate Hydrochloride			S	Oral	Unk		Pfizer	
	Metronidazole			S	Unknown	Unk		Pfizer	
	Pregabalin			S	Unknown	Unk		Pfizer	
	Amoxicillin Trihydrate			S	Unknown	Unk		Pfizer	
	Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cholecalciferol/Vitamin D			S	Unknown	Unk		Pfizer	
	Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cholecalciferol/Vitamin D			S		Unk		Pfizer	
	Diphenhydramine Hcl			S	Unknown	Unk		Pfizer	
	Morphine Sulfate			S	Unknown	Unk		Pfizer	
	Triamcinolone Acetonide			S	Intra-articular	Unk		Pfizer	
	Calcium Carbonate			S	Unknown	Unk		Pfizer	
	Magnesium Sulfate			S	Unknown	Unk		Not Reported	
	Acetaminophene			S	Unknown	Unk		Not Reported	
	Apo Hydro			S	Unknown	Unk		Not Reported	
	Avamys			S	Unknown	Unk		Not Reported	
	Azithromycin Dihydrate			S	Unknown	Unk		Not Reported	
	Bactroban [Mupirocin Calcium]			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Betaderm [Betamethasone]	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	S	Unknown	Unk	Not Reported
Biaxin XL	S	Unknown	Unk	Not Reported
Bisacodyl	S	Unknown	Unk	Not Reported
Calcium Magnesium With Vitamin D3	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Clotrimazole	S	Unknown	Unk	Not Reported
Desonide	S	Unknown	Unk	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Entocort	S	Unknown	Unk	Not Reported
Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk	Not Reported
Glycerine	S	Oral	Unk	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown	Unk	Not Reported
Habitrol [Nicotine]	S	Transdermal	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;So	S	Unknown	Unk	Not Reported
Mupirocin	S	Topical	Unk	Not Reported
Mupirocin	S	Unknown	Unk	Not Reported
Nadolol	S	Unknown	Unk	Not Reported
Nicoderm	S	Transdermal	Unk	Not Reported
Nicotine Polacrilex	S	Unknown	Unk	Not Reported
Pentasa	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pulmicort	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Refresh Tears	S	Ophthalmic	Unk	Not Reported
Salinex [Sodium Chloride]	S	Nasal	Unk	Not Reported
Sinus Rinse	S	Nasal	Unk	Not Reported
Statex [Morphine Sulfate]	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	S	Unknown	Unk	Not Reported
Vitamin D3	S	Unknown	Unk	Not Reported
Ascorbic Acid/Copper/Tocopherol/Xantofyl	S	Unknown	Unk	Not Reported
I/Zeaxanthin/Zinc Sodium Chloride	S	Nasal	Unk	Not Reported
Xantofyl Palmitate	S	Unknown	Unk	Not Reported
Zeaxanthin	S	Unknown	Unk	Not Reported
Zinc Oxide	S	Unknown	Unk	Not Reported
Mupirocin Calcium	S	Unknown	Unk	Not Reported
Cupric Oxide	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	S	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	C	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17032657	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2019SF62239		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adenocarcinoma; Asthma; Blood Count Abnormal; Breath Sounds Abnormal; Emphysema; Eosinophilia; Gastroesophageal Reflux Disease; Hypercapnia; Hypertension; Hyperthyroidism;	Symbicort			S	Respiratory (inhalation)	Unk		Astrazeneca
	Roflumilast			S	Oral	Unk		Not Reported
	Metoprolol			S	Unknown	Unk		Not Reported
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Influenza; Multiple	Calcium	S	Unknown	Unk	Not Reported
Allergies; Osteoporosis;	Thyroxine	S	Unknown	Unk	Not Reported
Pain In Extremity;	Azithromycin	S	Unknown	Unk	Not Reported
Pneumonitis;	Potassium Chloride	S	Unknown	Unk	Not Reported
Pneumothorax	Prednisone	S	Unknown	Unk	Not Reported
Spontaneous; Polymyalgia	Rabeprazole	S	Unknown	Unk	Not Reported
Rheumatica; Productive	Salbutamol	S	Unknown	Unk	Not Reported
Cough; Respiratory Tract	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
Infection; Upper	Tiotropium	S	Unknown	Unk	Not Reported
Respiratory Tract Infection	Vitamin D	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17036654	EXPEDITED (15-DAY)	OT		CA-PFIZER INC-2019492072		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchiectasis;	Pantoprazole			S	Unknown	Unk		Pfizer
Bronchomalacia; Cataract;	Pantoprazole			S	Unknown	Unk		Pfizer
Dyspnoea; Dyspnoea	Esomeprazole Magnesium			S	Unknown	Unk		Pfizer
Exertional; Eosinophil	Azithromycin			S	Unknown	Unk		Pfizer
Count Increased;	Quinapril Hcl			S	Unknown	Unk		Pfizer
Gastroesophageal Reflux	Alvesco			S	Unknown	Unk		Not Reported
Disease; Hypertension;	Aspirin [Acetylsalicylic Acid]			S	Unknown	Unk		Not Reported
Osteoporosis; Productive	Risedronate Sodium			S	Unknown	Unk		Not Reported
Cough; Spinal	Advair			S	Unknown	Unk		Not Reported
Osteoarthritis; Therapeutic	Ezetrol			S	Unknown	Unk		Not Reported
Product Effect Incomplete;	Fluticasone			S	Unknown	Unk		Not Reported
Tooth Disorder; Wheezing	Propionate/Salmeterol Xinafoate							
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Rhinocort [Beclometasone Dipropionate]			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ventolin [Salbutamol]	S	Unknown	Unk Unk, Monthly	Not Reported
Ventolin [Salbutamol]	S	Unknown	Unk, Monthly	Not Reported
Zantac	S	Unknown	Unk	Not Reported
Zenhale	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17037711	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2019494085		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adenocarcinoma; Asthma; Blood Count Abnormal; Breath Sounds Abnormal; Emphysema; Eosinophilia; Gastroesophageal Reflux Disease; Hypercapnia; Hypertension; Hyperthyroidism; Influenza; Multiple Allergies; Osteoporosis; Pain In Extremity; Pneumonitis; Pneumothorax Spontaneous; Polymyalgia Rheumatica; Productive Cough; Respiratory Tract Infection; Upper Respiratory Tract Infection	Pantoprazole			S	Unknown	Unk		Pfizer
	Calcium Carbonate			S	Unknown	Unk		Pfizer
	Calcium Carbonate			S		Unk		Pfizer
	Azithromycin			S		Unk		Pfizer
	Potassium Chloride			S		Unk		Pfizer
	Roflumilast			S		Unk		Not Reported
	Thyroxine			S		Unk		Not Reported
	Hydrochlorothiazide			S		Unk		Not Reported
	Metoprolol			S		Unk		Not Reported
	Prednisone			S		Unk		Not Reported
	Rabeprazole			S		Unk		Not Reported
	Salbutamol			S		Unk		Not Reported
	Salbutamol Sulfate			S		Unk		Not Reported
	Symbicort			S		Unk		Not Reported
	Tiotropium			S		Unk		Not Reported
	Vitamin D [Ergocalciferol]			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17517082	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200243766		58 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Candida Infection; Pneumonia	Stelara	S	Subcutaneous	Not Reported
	Stelara	S		Not Reported
	Amoxicillin	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17555549	EXPEDITED (15-DAY)		OT	NVSC2020CA074664		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Seebri Breezhaler			S	Unknown	1 Df, Qd		Novartis
	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported
	Singulair			S	Oral	10 Mg, Qd		Not Reported
	Theophylline			S	Oral	450 Mg, Qd		Not Reported
	Ratio-Ipra Sal Udv			S	Unknown			Not Reported
	Atrovent			S	Unknown			Not Reported
	Breo Ellipta			S	Unknown	1 Df, Qd		Not Reported
	Prednisone			S	Oral	45 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17556033	EXPEDITED (15-DAY)		HO	IT-PERRIGO- 20IT003949			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Stevens-Johnson Syndrome	Ibuprofen			S	Unknown	Unk, Unk		Perrigo
	Acetaminophen			S	Unknown	Unk, Unk		Perrigo
	Azithromycin			S	Unknown	Unk, Unk		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17556582	EXPEDITED (15-DAY)		HO, LT	US-TEVA-2020-US-1204121		62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Pulse Absent; Torsade De Pointes; Unresponsive To Stimuli	Haloperidol			S	Intravenous (not otherwise specified)	1 Mg; Second Dose After 3 Hours		Actavis	
	Azithromycin			S	Parenteral			Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxone			C	Parenteral			Not Reported	
	Ceftriaxone			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17557507	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020112351			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia; Choking; Cough; Drug Ineffective; Dry Mouth; Finger Deformity; Headache; Malaise; Pain; Rheumatoid Arthritis; Sinusitis; Skin Reaction	Xeljanz			S	Oral	5 Mg, 2x/Day		Pfizer	
	Methotrexate Sodium			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Etanercept			S		Unk		Pfizer	
	Meloxicam			S		Unk		Not Reported	
	Cetirizine			C		Unk		Not Reported	
	Hydroxychloroquine			C		Unk		Not Reported	
	Tylenol [Paracetamol]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Mar-2020	17558848	EXPEDITED (15-DAY)		HO	US-GLAND PHARMA LIMITED-2081768		11 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Linear Iga Disease	Azithromycin Monohydrate			S				Gland Pharma	
	Ibuprofen			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	14337697	EXPEDITED (15-DAY)		DE, DS, HO, LT, OT	CA-PFIZER INC-2017553277		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Amiodarone Hcl			S		Unk		Pfizer	
	Amiodarone Hcl			S		Unk		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day (Qd)		Pfizer	
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg, 1x/Day		Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	1 G, 1x/Day (Qd)		Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Pfizer	
	Ceftriaxone Sodium			S	Intravenous (not otherwise specified)	1 G, Every 4 Hrs		Pfizer	
	Doxorubicin Hcl			S	Intravenous (not otherwise specified)	106 Mg, Cyclic (Q2weeks (Once Every 14 Days); 1 Every 2 Week(S))		Pfizer	
	Doxorubicin Hcl			S	Intravenous (not otherwise specified)	106 Mg, Unk		Pfizer	
	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	0.25-0.5 Mg (Once In 4 To 6 Hrs Prn)		Pfizer	
	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Hydromorphone Hydrochloride			S	Intravenous (not otherwise specified)	Unk		Pfizer	
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	125 Mg, 4x/Day (Every 6 Hours)		Pfizer	
	Methylprednisolone Sodium Succinate			S	Intravenous (not otherwise specified)	125 Mg, 4x/Day		Pfizer	
	Morphine Sulfate			S	Intravenous (not otherwise specified)	1-2 Mg (Once In 10 Minutes, Prn)		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Morphine Sulfate	S	Intravenous (not otherwise specified)	Unk	Pfizer
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Q2weeks (Once Every 14 Days) (1 Every 2 Week(S))	Pfizer
Paclitaxel	S	Intravenous (not otherwise specified)	297 Mg, Unk	Pfizer
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Once Every Hour	Pfizer
Pantoprazole	S	Intravenous (not otherwise specified)	8 Mg, Unk (Q1hr)	Pfizer
Furosemide	S	Oral	40 Mg, 1x/Day (Qd)	Not Reported
Furosemide	S	Oral	40 Mg, 1x/Day (Qd)	Not Reported
Trastuzumab	S	Unknown	Unk	Not Reported
Dimenhydrinate	S	Intravenous (not otherwise specified)	50 Mg, Every 4 Hrs	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg (One Every Four Hours)	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Mg, (1 Every 1 Hour (S))	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	10 Mg, Unk	Not Reported
Digoxin	S	Intravenous (not otherwise specified)	0.25 Mg, Unk	Not Reported
Diltiazem Cd	S	Oral	180 Mg, Unk	Not Reported
Diltiazem Cd	S	Oral	180 Mg, Unk	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, 1x/Day (Qd)	Not Reported
Enoxaparin	S	Subcutaneous	40 Mg, 1x/Day (Qd)	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, Every Four Hours (6 Every 1 Days)	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	10 Mg, 4x/Day (1 Every 6 Hour(S))	Not Reported
Metoprolol	S	Intravenous (not	2.5 Mg, 4x/Day (Every 6	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		otherwise specified)	Hours)	
Metoprolol	S	Intravenous (not otherwise specified)	5 Mg, 4x/Day (Every 6 Hours)	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Q2weeks (Once Every 14 Days) (1 Every 2 Week(S))	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Q2weeks (Once Every 14 Days)	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, Q2weeks (Once Every 14 Days)	Not Reported
Procytox	S	Intravenous (not otherwise specified)	1060 Mg, 1x/Day	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Cyclic (1 Every 2 Week(S))	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Cyclic (1 Every 2 Week(S))	Not Reported
Cyclophosphamide	S	Intravenous (not otherwise specified)	1060 Mg, Cyclic (1 Every 2 Week(S))	Not Reported
Filgrastim	C	Subcutaneous	300 Ug, 1x/Day (Qd)	Not Reported
Filgrastim	C		Unk	Not Reported
Gabapentin	C	Oral	100 Mg, 3x/Day (Tid)	Not Reported
Gabapentin	C		Unk	Not Reported
Metoclopramide	C	Oral	10 Mg, 4x/Day (Q6hr)	Not Reported
Metoclopramide	C		10.0 Mg, Unk	Not Reported
Ondansetron	C	Oral	8 G, 2x/Day (Bid)	Not Reported
Ondansetron	C		Unk	Not Reported
Dexamethasone	C	Oral	20 Mg, 1x/Day (Qd)	Not Reported
Dexamethasone	C		Unk	Not Reported
Aprepitant	C	Oral	125 Mg, Unk	Not Reported
Aprepitant	C		Unk	Not Reported
Acetaminophen-Caffeine-Codeine	C		Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	16847978	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-061188		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchiectasis;	Azithromycin			S	Unknown	Unk		Aurobindo
Bronchomalacia; Cataract;	Pantoprazole			S	Unknown	Unk		Aurobindo
Dyspnoea; Dyspnoea	Risedronate			S	Unknown	Unk		Aurobindo
Exertional; Eosinophil	Advair			S	Unknown	Unk		Not Reported
Count Increased;	Alvesco			S	Unknown	Unk		Not Reported
Gastroesophageal Reflux	Aspirin			S	Unknown	Unk		Not Reported
Disease; Hypertension;	Beclomethasone Dipropionate			S	Unknown	Unk		Not Reported
Osteoporosis; Productive	Esomeprazole Magnesium			S	Unknown	Unk		Not Reported
Cough; Spinal	Trihydrate							
Osteoarthritis; Therapeutic	Ezetrol			S	Unknown	Unk		Not Reported
Product Effect Incomplete;	Fluticasone			S	Unknown	Unk		Not Reported
Tooth Disorder; Wheezing	Propionate;Salmeterol Xinafoate							
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Quinapril			S	Unknown	Unk		Not Reported
	Rhinocort			S	Unknown	Unk		Not Reported
	Ventolin			S	Unknown	Unk		Not Reported
	Zantac			S	Unknown	Unk		Not Reported
	Zenhale			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17036359	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA- 2019SF62417		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchiectasis;	Alvesco			S	Respiratory	Unk		Not Reported
Bronchomalacia; Cataract;					(inhalation)			
Dyspnoea; Dyspnoea								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Exertional; Eosinophil Count Increased; Gastroesophageal Reflux Disease; Hypertension; Osteoporosis; Productive Cough; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Tooth Disorder; Wheezing	Esomeprazole Magnesium	S	Unknown	Unk	Astrazeneca
	Aspirin	S	Unknown	Unk	Not Reported
	Azithromycin	S	Unknown	Unk	Not Reported
	Rhinocort	S	Unknown	Unk	Not Reported
	Ezetrol	S	Unknown	Unk	Not Reported
	Fluticasone Propionate W/Salmeterol Xinafoate Advair	S	Unknown	Unk	Not Reported
	Zenhale	S	Unknown	Unk	Not Reported
	Hydrochlorothiazide	S	Unknown	Unk	Not Reported
	Pantoprazole Sodium	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Quinapril	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported
	Risedronate Sodium	S	Unknown	Unk	Not Reported
	Ventolin	S	Unknown		Not Reported
	Ventolin	S	Unknown	Once Monthly	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17396881	NON-EXPEDITED			US-PFIZER INC-2020056038		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Alprazolam			S		Unk		Pfizer	
	Lorazepam			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Diphenhydramine Hcl			S		Unk		Pfizer	
	Propanolol Hcl			S		Unk		Pfizer	
	Hydrocodone			S		Unk		Not Reported	
	Imipramine			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17420028	NON-EXPEDITED			US-PFIZER INC-2020066730		91 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ageusia; Anosmia; Malaise	Azithromycin			S		Unk		Pfizer	
	Metformin			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17562618	EXPEDITED (15-DAY)		OT	NVSC2020CA074644		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Seebri Breezhaler			S	Unknown	1 Df, Qd		Novartis	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Montelukast			S	Oral	10 Mg, Qd		Not Reported	
	Omalizumab			S	Intravenous (not otherwise specified)	Unk, Intravenous (Nos)		Not Reported	
	Breo Ellipta			S	Respiratory (inhalation)	1 Df, Qd Inhalation		Not Reported	
	Ipratropium Bromide			S	Unknown	Unk		Not Reported	
	Ipratropium Bromide And Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Prednisone			S	Oral	45 Mg		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Theophyllin			S	Oral	450 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17563035	NON-EXPEDITED			NVSC2020US078821			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia	Azithromycin			S	Unknown	Unk		Novartis	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Mar-2020	17563065	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020115940		72 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mechanical Urticaria; Pruritus	Venlafaxine Hcl			S	Oral	Unk		Pfizer	
	Rifadine [Rifampicin]			S	Oral	2 Df, 1x/Day		Not Reported	
	Azithromycin Anhydrous			S	Oral	250 Mg, 1x/Day		Not Reported	
	Dexambutol			S	Oral	2 Df, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	16815325	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20190913993			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Nicoderm			S	Transdermal			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Paracetamol			S	Unknown			Not Reported	
	Nicotine			S	Unknown			Not Reported	
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Not Reported	
	Amoxicillin Trihydrate			S	Unknown			Not Reported	
	Apo Hydro			S	Unknown			Not Reported	
	Atorvastatin Calcium			S	Unknown			Not Reported	
	Atorvastatin Calcium			S	Unknown			Not Reported	
	Desonide			S	Unknown			Not Reported	
	Dilaudid			S	Unknown			Not Reported	
	Entocort			S	Unknown			Not Reported	
	Ertapenem Sodium			S	Unknown			Not Reported	
	Flovent			S	Unknown			Not Reported	
	Glycerine			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Gramicidin W/Neomycin Sulfate/Polymyxin B Sul Habitrol /01033301/	S	Unknown		Not Reported
Kenalog /00031902/	S	Transdermal		Not Reported
Humira	S	Unknown		Not Reported
Lomotil /00034001/	S	Subcutaneous		Not Reported
Lomotil /00034001/	S	Oral		Not Reported
Salinex /06366101/	S	Oral	Unk	Not Reported
Sinus Rinse	S	Nasal		Not Reported
Statex /00036302/	S	Nasal		Not Reported
Bactrim	S	Unknown		Not Reported
Bactrim	S	Unknown		Not Reported
Triamcinolone Acetonide	S	Intra-articular		Not Reported
Vitamin D3	S	Unknown		Not Reported
Avamys	S	Unknown	Metered Dose	Not Reported
Azithromycin Dihydrate	S	Unknown		Not Reported
Bactroban /00753901/	S	Unknown		Not Reported
Betaderm /00008501/	S	Unknown		Not Reported
Betamethasone Dipropionate	S	Unknown		Not Reported
Biaxin XL	S	Unknown	Tablet (Extended Release)	Not Reported
Bisacodyl	S	Unknown		Not Reported
Calcium Carbonate/Magnesium Sulfate/Vitamin D3	S	Unknown		Not Reported
Clarithromycin	S	Unknown		Not Reported
Clotrimazole	S	Unknown		Not Reported
Macrogol 3350 W/Potassium Chloride//01618701/	S	Unknown		Not Reported
Metronidazole	S	Unknown		Not Reported
Ms Ir	S	Unknown		Not Reported
Mupirocin	S	Unknown		Not Reported
Mupirocin	S	Topical		Not Reported
Mupirocin	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nadolol	S	Unknown	Not Reported
Pantoprazole	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Pregabalin	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Not Reported
Sodium Chloride	S	Unknown	Not Reported
Xantofyl Palmitate	S	Unknown	Not Reported
Zeaxanthin	S	Unknown	Not Reported
Zinc Oxide	S	Unknown	Not Reported
Cupric Oxide	S	Unknown	Not Reported
D-Alpha Tocopheryl Acetate	S	Unknown	Not Reported
Magnesium Sulfate	S	Unknown	Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	C	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17373476	EXPEDITED (15-DAY)		HO, OT	CA-APOTEX-2020AP007020		55 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Back Pain;	Esomeprazole			S	Oral	1 Df, Bid		Apotex
Headache; Herpes Zoster;	Azithromycin			S	Oral	1 Df, Unk		Apotex
Lung Cancer Metastatic;	Diltiazem			S	Oral	1 Df, Qd		Apotex
Lymphoma; Nasal Congestion;	Omalizumab			S	Subcutaneous	375 Mg, Q.O.Wk.		Not Reported
Nasopharyngitis; Poor Quality Sleep; Productive	Xoliar			S	Subcutaneous	375 Mg, Q.O.Wk.		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cough; Skin Lesion	Asa	C	Oral	1 Df, Qd	Not Reported
	Rhinocort /00212602/	C	Nasal	4 Df, Bid	Not Reported
	Rhinocort /00212602/	C			Not Reported
	Singulair	C	Oral	1 Df, Qd	Not Reported
	Spiriva	C	Respiratory (inhalation)	2 Df, Qd (Inhalation)	Not Reported
	Symbicort	C	Respiratory (inhalation)	2 Df, Tid (Inhalation)	Not Reported
	Synthroid	C	Oral	1 Df, Qd	Not Reported
	Ventolin /00139501/	C	Respiratory (inhalation)	2 Df, Unk (Inhalation)	Not Reported
	Diltiazem Hydrochloride	C	Oral	1 Df, Qd	Not Reported
	Esomeprazole	C	Oral	1 Df, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17449007	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2020-008596		35 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Asthma; Bronchial Obstruction; Chest Discomfort; Conjunctivitis; Cough; Dizziness; Dyspnoea; Eosinophilia; Exposure During Pregnancy; Feeling Abnormal; Feeling Hot; Hypersensitivity; Hyperventilation; Increased Bronchial Secretion; Middle Insomnia; Nasal Congestion; Nausea; Palpitations; Productive Cough; Rhinitis; Therapeutic Product Effect Incomplete; Urticaria;	Azithromycin			S	Unknown	250 Milligram, 3 Times A Day		Aurobindo
	Montelukast			S	Unknown	10 Milligram, Once A Day		Aurobindo
	Advair			S	Unknown	Unk		Not Reported
	Alvesco			S	Unknown	Unk		Not Reported
	Benralizumab			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S	Unknown	20 Milligram, Two Times A Day		Not Reported
	Cetirizine Hydrochloride;Pseudoephedrine Hydrochloride			S				Not Reported
	Glycopyrronium Bromide			S	Unknown	1 Dosage Form		Not Reported
	Medrol			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Wheezing	Methylprednisolone Sodium Succinate	S	Unknown	Unk	Not Reported
	Omalizumab	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	Unk, Once A Day	Not Reported
	Prednisone	S	Unknown	15 Milligram, Once A Day	Not Reported
	Salbutamol Sulfate	S	Unknown	As Required	Not Reported
	Singulair	S	Unknown	100 Milligram	Not Reported
	Symbicort Turbuhaler	S	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Symbicort Turbuhaler	S	Unknown	4 Dosage Form 1 Every 2 Days	Not Reported
	Symbicort Turbuhaler	S	Unknown	4 Dosage Form 1 Every 2 Weeks	Not Reported
	Synthroid	S	Unknown	0.1 Milligram	Not Reported
	Tiotropium	S	Unknown	2 Dosage Form	Not Reported
	Uniphyll	S	Unknown	600 Milligram	Not Reported
	Uniphyll	S	Unknown	200 Milligram	Not Reported
	Vitamin D	S	Unknown	Unk	Not Reported
	Zenhale	S	Unknown	2 Dosage Form, Two Times A Day	Not Reported
	Benadryl	S	Unknown	As Required	Not Reported
	Ergocalciferol	S	Unknown	1000 International Unit,1 Every 1 Week	Not Reported
	Solumedrol	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	2 Dosage Form	Not Reported
	Nucala	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17550603	NON-EXPEDITED			US-PFIZER INC-2020113302		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abdominal Discomfort; Diarrhoea; Flatulence; Muscle Spasms; Rash; Urticaria	Zithromax	S	Unk	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17564152	EXPEDITED (15-DAY)		OT	CA-ORION CORPORATION ORION PHARMA-TREX2020- 1435			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Asthenia; Choking; Cough; Drug Ineffective; Dry Mouth; Finger Deformity; Headache; Malaise; Pain; Rheumatoid Arthritis; Sinusitis; Skin Reaction	Methotrexate (Trade Name Unknown) Xeljanz Azithromycin Etanercept Meloxicam Cetirizine Hydroxychloroquine Tylenol			S S S S S C C C	Unknown Oral Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17565430	NON-EXPEDITED			US-PFIZER INC- 2020119680		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Fatigue	Azithromycin Azithromycin Ofloxacin			S S S		500 Mg, Single 250 Mg, 1x/Day Days 2-5 2 Gtt, 3x/Day (1 Gtt In Each Eye, 3x/Day)		Pfizer Pfizer Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17566027	NON-EXPEDITED			NVSC2020US080146		71 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Resistance; Product Use In Unapproved Indication	Azithromycin			S	Unknown	Unk		Novartis	
	Moxifloxacin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17566575	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020119949		11 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysentery	Zitromax			S	Oral	10 MI, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17567032	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-014419		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Blood Blister; Purpura; Thrombocytopenia	Azithromycin			S	Oral	500 Mg À J1 Puis 250 Mg/Jour À J2 Et J3		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Mar-2020	17567826	EXPEDITED (15-DAY)		OT	IT-PFIZER INC-2020116013		8 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Erythema; Face Oedema; Oedema Peripheral	Zithromax			S	Oral	1 Df, Cyclic		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Mar-2020	17568987	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020-BI-01		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Atrovent	S	Unknown		Boehringer Ingelheim
	Azithromycin	S	Oral		Not Reported
	Breo Ellipta	S	Respiratory (inhalation)		Not Reported
	Omalizumab	S	Intravenous (not otherwise specified)	Intravenous (Not Otherwise Specified)	Not Reported
	Prednisone	S	Oral		Not Reported
	Ratio-Ipra Sal Udv	S	Unknown	Solution Inhalation	Not Reported
	Salbutamol Sulfate	S	Unknown		Not Reported
	Seebri Breezhaler	S	Unknown		Not Reported
	Singulair	S	Oral		Not Reported
	Theophylline	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2020	17569306	NON-EXPEDITED			US-TEVA-2020-US- 1206651		78 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Diarrhoea; Dizziness; Musculoskeletal Chest Pain; Nausea; Vomiting	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	15028227	NON-EXPEDITED			US-PFIZER INC- 2018249105		68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Mesalamine			S		Unk		Not Reported	
	Remicade			S		Unk		Not Reported	
	Infliximab			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	16219164	EXPEDITED (15-DAY)		HO	US-ACTELION-A-US2017-152592		78 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anaemia; Blood Iron Decreased; Blood Pressure Abnormal; Diarrhoea; Dizziness; Drug Hypersensitivity; Ear Infection Fungal; Feeling Abnormal; Haemoglobin Decreased; Haemorrhage; Haemorrhoidal Haemorrhage; Haemorrhoids; Hospitalisation; Loss Of Consciousness; Oral Mucosal Erythema; Otorrhoea; Packed Red Blood Cell Transfusion; Pharyngeal Erythema; Rectal Haemorrhage; Swollen Tongue; Tongue Coated; Tongue Discomfort; Weight Increased	Opsumit			S	Oral	10 Mg, Qd		Actelion
	Augmentin			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Levothyroxine			C		100 Mcg, Qd		Not Reported
	Adempas			C		2.5 Mg, Tid		Not Reported
	Xarelto			C		20 Mg, Qd		Not Reported
	Biogen			C		500 Mcg, Qd		Not Reported
	Phenylephrine			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17393679	EXPEDITED (15-DAY)		OT	NVSC2020TR032221			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Betamethasone			S	Transplacental	12 Mg, Qd		Novartis	
	Ampicillin			S	Transplacental	1 G, Qid		Not Reported	
	Azithromycin			S	Transplacental	500 Mg, Qd		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17440355	EXPEDITED (15-DAY)		DE, OT	NVSC2020ES045714			Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury;	Azithromycin			S	Transplacental	Maternal Dose: Unk		Novartis	
Bloody Discharge;	Gentamicin			S	Transplacental	Maternal Dose: Unk		Not Reported	
Congenital Syphilis; Death	Ampicillin			S	Transplacental	Maternal Dose: Unk		Not Reported	
Neonatal; Disseminated	Cefotaxime			C	Transplacental	Maternal Dose: Unk		Not Reported	
Intravascular Coagulation;	Nitric Oxide			C	Transplacental	Maternal Dose: Unk		Not Reported	
Foetal Exposure During									
Pregnancy; Haemorrhagic									
Stroke; Hepatic Necrosis;									
Hydrops Foetalis;									
Intraventricular									
Haemorrhage; Multiple									
Organ Dysfunction									
Syndrome; Premature									
Baby; Pulmonary									
Hypertension									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569467	EXPEDITED (15-DAY)		OT	PT-TEVA-2020-PT-1206710		11 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Macular	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569528	EXPEDITED (15-DAY)		HO, OT	US-GLAND PHARMA LIMITED-2081859		76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Cirrhosis;	Azithromycin Monohydrate			S				Gland Pharma	
Hepatitis	Ceftriaxone			S				Not Reported	
	Prednisone			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569803	EXPEDITED (15-DAY)		OT	CA-ROCHE-2570350		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Seebri Breezhaler			S	Unknown	1 Df		Not Reported	
	Azithromycin			S	Oral	250 Mg, Qd		Not Reported	
	Salbutamol			S	Unknown			Not Reported	
	Breo Ellipta			S	Respiratory (inhalation)	1 Df		Not Reported	
	Atrovent			S	Unknown			Not Reported	
	Ipratropium Bromide And Albuterol Sulfate Solution			S	Respiratory (inhalation)			Not Reported	
	Prednisone			S	Oral	45 Mg		Not Reported	
	Theophylline			S	Oral	45 Mg		Not Reported	
	Singulair			S	Oral	10 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17569863	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1206667		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Toxic	Azitromicina (7019a)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17570194	EXPEDITED (15-DAY)		OT	CA-ROCHE-2571113		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Positive	Seebri Breezhaler	S	Unknown	1 Df, Qd	Not Reported
	Salbutamol Sulfate	S	Unknown		Not Reported
	Azithromycin	S	Oral	250 Mg, Qd	Not Reported
	Singulair	S	Oral	10 Mg, Qd	Not Reported
	Theophylline	S	Oral	450 Mg, Qd	Not Reported
	Ipratropium Bromide;Salbutamol Sulfate	S	Unknown		Not Reported
	Atrovent	S	Unknown		Not Reported
	Breo Ellipta	S	Unknown	1 Df, Qd	Not Reported
	Prednisone	S	Oral	45 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17571794	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020121409		53 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sepsis	Zithromax			S		Unk		Pfizer
	Rocephin			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2020	17572500	EXPEDITED (15-DAY)		HO	NVSC2020FR080062		58 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
General Physical Health Deterioration; Pyrexia	Azithromycin			S	Unknown	Unspecified Dosage Regimen		Novartis
	Tavanic			S	Unknown	Unspecified Dosage Regimen		Not Reported
	Furadantine			S	Unknown	Unspecified Dosage Regimen		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17393680	EXPEDITED (15-DAY)		OT	NVSC2020TR032217			Unknown	TUR

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Betamethasone			S	Transplacental	12 Mg, Qd		Novartis	
	Ampicillin			S	Transplacental	1 Mg, Qid		Not Reported	
	Azithromycin			S	Transplacental	500 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574320	EXPEDITED (15-DAY)		HO	CA-AUROBINDO-AUR-APL-2020-014763		74 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Eosinophil Count Increased; Hospitalisation; Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	Unk		Aurobindo	
	Alvesco			S	Unknown	2 Dosage Form, Once A Day		Not Reported	
	Mepolizumab			S	Unknown	100 Milligram		Not Reported	
	Metoprolol			S	Unknown	25 Milligram, Two Times A Day		Not Reported	
	Prednisone			S	Unknown	10 Milligram, Once A Day		Not Reported	
	Propranolol			S	Unknown	Unk		Not Reported	
	Ventolin			S	Unknown	Unk		Not Reported	
	Olodaterol Hydrochloride;Tiotropium Bromide			S	Unknown	2 Dosage Form, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17574526	EXPEDITED (15-DAY)		OT	CA-ROCHE-2572085		53 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Seebri Breezhaler			S	Unknown			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Montelukast			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Breo Ellipta	S	Respiratory (inhalation)	Not Reported
Ipratropium Bromide	S	Unknown	Not Reported
Ipratropium Bromide;Salbutamol Sulfate	S	Unknown	Not Reported
Prednisone	S	Oral	Not Reported
Salbutamol Sulfate	S	Unknown	Not Reported
Theophyllin	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575068	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Atrovent			S	Unknown			Boehringer Ingelheim
	Combivent			S	Unknown			Boehringer Ingelheim
	Azithromycin			S	Oral			Not Reported
	Breo Ellipta			S	Respiratory (inhalation)			Not Reported
	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Seebri Breezhaler			S	Unknown			Not Reported
	Singulair			S	Oral			Not Reported
	Theophylline			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575469	EXPEDITED (15-DAY)		OT	NVSC2020CA082231		25 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Xolair	S	Subcutaneous	300 Mg, Unknown	Not Reported
	Xolair	S			Not Reported
	Azithromycin	S	Unknown	Unk	Novartis
	Levofloxacin	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	S	Unknown	20 Mg, Bid	Not Reported
	Cetirizine Hydrochloride	S	Unknown	10 Mg, Unknown	Not Reported
	Diphenhydramin Hydrochloride	S	Unknown	Unk	Not Reported
	Diphenhydramin Hydrochloride	S			Not Reported
	Diphenhydramin Hydrochloride	S			Not Reported
	Diphenhydramin Hydrochloride	S			Not Reported
	Rifadin	S	Unknown	Unk	Not Reported
	Rifampin	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575748	EXPEDITED (15-DAY)		HO	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		72 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Chest Discomfort; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Gastroesophageal Reflux Disease; Lung Disorder; Lung Disorder; Lung Hyperinflation; Malaise; Nasal Congestion; Obstructive Airways Disorder; Obstructive Airways Disorder; Oropharyngeal Pain; Pain In Extremity; Rhinorrhoea;	Spiriva			S	Unknown			Boehringer Ingelheim
	Inspiroto Respimat			S	Unknown			Boehringer Ingelheim
	Atrovent			S	Unknown			Boehringer Ingelheim
	Amlodipine			S	Unknown			Not Reported
	Breo Ellipta			S	Unknown	Form: Inhalation		Not Reported
	Ciprallex [Escitalopram]			S	Unknown			Not Reported
	Escitalopram Oxalate			S	Unknown			Not Reported
	Levothyroxine			S	Unknown			Not Reported
	Piperacillin Sodium;Tazobactam Sodium			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Singulair			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sputum Discoloured; Therapeutic Product Effect	Solu-Medrol	S	Unknown		Not Reported
Incomplete; Total Lung Capacity Abnormal;	Synthroid	S	Unknown		Not Reported
Weight Increased; Wheezing	Uniphyl	S	Unknown	Tablet (Extended Release)	Not Reported
	Zantac	S	Unknown		Not Reported
	Zithromax	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17575898	EXPEDITED (15-DAY)		OT	ES-PFIZER INC- 2020123802		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Toxic	Azithromycin			S	Oral	Every 2 Days		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2020	17577149	EXPEDITED (15-DAY)		OT	NVSC2020CA082846		44 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Vaginal Infection; Vulvovaginal Pruritus	Sandoz Azithromycin			S	Unknown	250.0 Mg, Unknown		Novartis	
	Clotrimazole			S	Unknown	Unk Unk, Unknown		Not Reported	
	Desoximetasone			S	Unknown	Unk Unk, Unknown		Not Reported	
	Stelara			S	Intravenous (not otherwise specified)	Unk Unk, Q2mo		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17094146	EXPEDITED (15-DAY)		HO	CA-ALLERGAN- 1948844US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Chest Discomfort; Chest X-Ray Abnormal; Condition Aggravated; Cough; Dyspnoea; Forced	Escitalopram Oxalate - Bp			S	Unknown			Allergan	
	Amlodipine			S	Unknown			Not Reported	
	Atrovent			S	Unknown			Not Reported	
	Levothyroxine			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Expiratory Volume Decreased; Forced Vital Capacity Decreased;	Piperacillin Sodium	S	Unknown		Not Reported
Gastroesophageal Reflux Disease; Lung Disorder;	W/Tazobactam Sodium				
Lung Hyperinflation; Lung Opacity; Malaise; Nasal Congestion; Obstructive Airways Disorder;	Prednisone	S		7.5 Mg, Qd	Not Reported
Oropharyngeal Pain; Pain In Extremity; Rhinorrhoea;	Prednisone	S		10 Mg, Qd	Not Reported
Sputum Discoloured;	Prednisone	S		15 Mg, Qd	Not Reported
Therapeutic Product Effect Incomplete; Total Lung Capacity Abnormal;	Prednisone	S		20 Mg, Qd	Not Reported
Weight Increased;	Prednisone	S	Unknown	50 Mg, Qd	Not Reported
Wheezing	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown		Not Reported
	Solu Medrol	S	Unknown		Not Reported
	Spiriva	S	Unknown		Not Reported
	Synthroid	S	Unknown		Not Reported
	Theophylline	S	Unknown	400 Mg, Qd	Not Reported
	Uniphyl	S	Unknown		Not Reported
	Zantac	S	Unknown		Not Reported
	Zithromax	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17127504	EXPEDITED (15-DAY)			BR-GLAXOSMITHKLINE-BR2019AMR136108			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Back Pain; Breast Discharge; Breast Discolouration; Breast Inflammation; Breast Pain; Breast Swelling; Candida Infection; Drug Ineffective; Erythema; Inappropriate Schedule Of Product Administration; Inflammation; Oropharyngeal Discomfort; Pain;	Benlysta			S		760 Mg		Glaxosmithkline	
	Azithromycin			S		Unk		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pharyngeal Inflammation;
Pustule; Pyrexia; Throat
Lesion; Wound

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579187	NON-EXPEDITED			NVSC2020US082445		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Novartis	
	Azithromycin			S				Novartis	
	Azithromycin			S				Novartis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17579461	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma-Chronic	Spiriva Respimat			S	Unknown			Boehringer Ingelheim	
Obstructive Pulmonary Disease Overlap	Inspiolto Respimat			S	Unknown			Boehringer Ingelheim	
Syndrome; Bronchiectasis;	Combivent			S	Unknown			Boehringer Ingelheim	
Cardiac Murmur; Chronic Obstructive Pulmonary Disease; Chronic	Atrovent			S	Unknown			Boehringer Ingelheim	
Obstructive Pulmonary Disease;	Advair			S	Unknown			Not Reported	
Gastroesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps;	Avamys			S	Unknown	Spray Metered Dose		Not Reported	
Oedema Peripheral;	Azithromycin			S	Unknown			Not Reported	
Rhinitis Allergic;	Breo Ellipta			S	Unknown	Inhalation		Not Reported	
Sarcoidosis; Total Lung Capacity Increased; Wheezing	Ciprofloxacin Hydrochloride			S	Unknown			Not Reported	
	Mepolizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Moxifloxacin Hydrochloride			S	Unknown			Not Reported	
	Nasonex			S	Unknown			Not Reported	
	Omnaris			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Not Reported
Seebri	S	Unknown	Not Reported
Singulair	S	Unknown	Not Reported
Symbicort	S	Unknown	Not Reported
Ultibro Breezhaler	S	Unknown	Not Reported
Umeclidinium Bromide	S	Unknown	Not Reported
Umeclidinium Bromide; Vilanterol Trifenatate	S	Unknown	Not Reported
Ventolin	S	Unknown	Not Reported
[Guaifenesin; Salbutamol Sulfate]	S	Unknown	Not Reported
Xolair	S	Unknown	Not Reported
Zenhale	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17580024	EXPEDITED (15-DAY)		HO, LT, OT	HU-PFIZER INC-2020121852		36 YR	Female	HUN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort;	Azithromycin			S		Unk		Pfizer
Abdominal Distension;	Levofloxacin			C		Unk		Not Reported
Alanine Aminotransferase Increased; Altered State Of Consciousness;	Doxycycline			C		Unk		Not Reported
Anxiety; Aspartate Aminotransferase Increased; Biliary Colic;	Klion			C		Unk		Not Reported
Blood Albumin Increased; Blood Iron Increased; Blood Osmolarity Abnormal; Blood Sodium Increased; Blood Urea Decreased; Bradycardia; Brain Oedema; Burning Sensation; C-Reactive Protein Increased; Coma; Consciousness Fluctuating; Dehydration; Diverticulitis; Dizziness;	Noacid [Dihydroxyaluminum Sodium Carbonate]			C		40 Mg, 1x/Day (In The Morning)		Not Reported

Dry Skin; Dysphonia;
Gallbladder Polyp;
Gastrointestinal Bacterial
Overgrowth; Haematocrit
Decreased;
Haemorrhoids; Headache;
Hypertriglyceridaemia;
Hyponatraemia;
Hypoosmolar State; Loss
Of Consciousness; Mean
Cell Haemoglobin
Increased; Mean Cell
Volume Increased; Mean
Platelet Volume
Decreased; Monocyte
Count Increased; Nausea;
Oedema Peripheral; Pain;
Panic Attack; Polydipsia;
Polyuria; Protein Total
Increased; Pupil Fixed;
Pyrexia; Red Blood Cell
Count Decreased;
Respiratory Syncytial
Virus Test Positive;
Retrograde Amnesia;
Somnolence; Urine
Chloride Decreased; Urine
Potassium Decreased;
Urine Sodium Decreased;
Varicella Virus Test
Positive; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17581165	EXPEDITED (15-DAY)		OT	FR-ABBVIE-20K-056-3335747-00		38 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Premature Menopause	Humira			S	Subcutaneous			Not Reported	
	Novatrex			S	Oral			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17582189	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC-2020125327		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Blood Blister; Purpura; Thrombocytopenia	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Mar-2020	17582289	EXPEDITED (15-DAY)		OT	NVSC2020US083352			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Feeling Abnormal; Hiccups; Tinnitus	Azithromycin			S	Oral	250 Mg, Qd		Novartis	
	Crestor			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	16728626	EXPEDITED (15-DAY)		HO, OT	CA-AUROBINDO-AUR-APL-2019-054758		74 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adenocarcinoma; Asthma; Blood Count Abnormal; Breath Sounds Abnormal; Emphysema; Eosinophilia; Gastroesophageal Reflux Disease; Hypercapnia; Hypertension; Hyperthyroidism; Influenza; Multiple Allergies; Osteoporosis; Pain In Extremity; Pneumonitis; Pneumothorax Spontaneous; Polymyalgia Rheumatica; Productive	Azithromycin			S	Unknown	Unk		Aurobindo	
	Pantoprazole			S	Unknown	Unk		Aurobindo	
	Calcium			S	Unknown	Unk		Not Reported	
	Hydrochlorothiazide			S	Unknown	Unk		Not Reported	
	Metoprolol			S	Unknown	Unk		Not Reported	
	Potassium Chloride			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Rabeprazole			S	Unknown	Unk		Not Reported	
	Roflumilast			S	Oral	Unk		Not Reported	
	Salbutamol			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cough; Respiratory Tract Infection; Upper Respiratory Tract Infection	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
	Symbicort	S		Unk	Not Reported
	Thyroxine	S	Unknown	Unk	Not Reported
	Tiotropium	S	Unknown	Unk	Not Reported
	Vitamin D	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17002104	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-081133		59 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Cough; Dyspnoea; Hypotension; Pneumonia; Rheumatoid Arthritis; Sinusitis; Tooth Fracture	Abatacept			S	Subcutaneous	125 Milligram, Qwk		Bristol Myers Squibb
	Prednisone			S	Unknown	Unk		Not Reported
	Zithromax			S	Unknown	Unk		Not Reported
	Nexium [Esomeprazole Sodium]			C	Unknown			Not Reported
	Synthroid			C	Unknown			Not Reported
	Cardizem [Diltiazem Hydrochloride]			C	Unknown			Not Reported
	Gabapentin			C	Unknown			Not Reported
	Crestor			C	Unknown			Not Reported
	Plaquenil [Hydroxychloroquine Sulfate]			C	Unknown			Not Reported
	Feramax			C	Unknown			Not Reported
	Ambien			C	Unknown			Not Reported
	Celebrex			C	Unknown			Not Reported
	Trazodone			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17229600	NON-EXPEDITED			US-PFIZER INC-2019561903			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Hypersensitivity		Zithromax		S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17389388	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020050670			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oesophageal Injury	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17575178	EXPEDITED (15-DAY)		OT	DE-TEVA-2019-DE-1158227		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alcohol Intolerance; Anxiety; Condition Aggravated; Fatigue; Gait Disturbance; Hyperacusis; Impaired Quality Of Life; Limb Discomfort; Muscle Twitching; Muscular Weakness; Myalgia; Neuralgia; Neuropathy Peripheral; Restlessness; Sleep Disorder; Social Avoidant Behaviour	Ciprofloxacin 500mg			S	Oral	2* 500 Mg Over 5 Days		Not Reported	
	Ciprofloxacin 500mg			S				Not Reported	
	Ciprofloxacin 500mg			S				Not Reported	
	Ceftriaxon			S	Intramuscular			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Cannabidiol			C				Not Reported	
	Cannabidiol			C				Not Reported	
	Valium			C		2-3 Times A Month In Case Of Severe Agitation		Not Reported	
	Laif 900			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583330	NON-EXPEDITED			US-STRIDES ARCOLAB LIMITED-2020SP001567		37 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy	Oseltamivir			S	Unknown	Unk		Strides	
	Methylprednisolone			S	Intravenous (not otherwise specified)	Unk		Not Reported	
	Methylprednisolone			S	Intravenous (not	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	otherwise specified)	Unknown	Unk	Not Reported
Dexamethasone	S		Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17583516	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Atrovent			S	Unknown			Boehringer Ingelheim
	Combivent			S	Unknown			Boehringer Ingelheim
	Azithromycin			S	Oral			Not Reported
	Breo Ellipta			S	Unknown	Dosage Form:Inhalation		Not Reported
	Montelukast			S	Oral			Not Reported
	Omalizumab			S	Intravenous (not otherwise specified)			Not Reported
	Prednisone			S	Oral			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Seebri Breezhaler			S	Unknown			Not Reported
	Theophylline			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584334	EXPEDITED (15-DAY)		DE, HO	US-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020R1-241566		58 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Drug Resistance	Azithromycin			S	Unknown	Unk		Sun
	Oseltamivir			S	Unknown	75 Milligram, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584433	NON-EXPEDITED			US-PFIZER INC-2020126759			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584448	NON-EXPEDITED			US-PFIZER INC-2020128046		14 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17584655	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020125314		8 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury;	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
Rash Maculo-Papular	Laroxyl			S	Intravenous bolus	8 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17586719	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020125794		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alcohol Intolerance; Anxiety; Condition Aggravated;	Azithromycin			S	Oral	1.5 G, 1x/Day		Pfizer	
Fatigue; Gait Disturbance; Hyperacusis; Limb Discomfort; Loss Of Personal Independence In Daily Activities; Muscle Twitching; Muscular	Ceftriaxon			S	Intramuscular	2 G, 1x/Day		Not Reported	
	Ciprofloxacin			S	Oral	1000 Mg, 1x/Day (Over 5 Days)		Not Reported	
	Ciprofloxacin			S				Not Reported	
	Laif 900			C		Unk		Not Reported	
	Valium			C		5 Mg, 2-3 X Per Month In		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weakness; Myalgia; Neuralgia; Neuropathy Peripheral; Restlessness; Sleep Disorder; Social Avoidant Behaviour	Cannabidiol Cannabidiol	C C	The Event Of Severe Restlessness 50 Mg, 1x/Day	Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17586959	NON-EXPEDITED			NVSC2020US083458			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chest Discomfort; Decreased Appetite; Muscular Weakness; Rash	Azithromycin 250 Mg			S	Unknown			Novartis
	Probiotic			S	Unknown			Not Reported
	Warfin			C	Unknown	5 Mg, Qd		Not Reported
	Ocuvite			C	Unknown			Not Reported
	Muro 128			C	Unknown			Not Reported
	Tylenol			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17587174	EXPEDITED (15-DAY)		HO, OT	US-PFIZER INC- 2020125396		64 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation; Chills; Chronic Obstructive Pulmonary Disease; Palpitations; Pneumonia; Pyrexia	Zithromax			S		Unk		Pfizer
	Humira			S	Subcutaneous	40 Mg, Unk(40 Mg 1 In 2 Wk)		Not Reported
	Humira			S	Subcutaneous	40 Mg, Unk(40 Mg 1 In 2 Wk)		Not Reported
	Glucosamine			C		Unk		Not Reported
	Fish Oil			C		Unk		Not Reported
	Centrum Jr [Ascorbic Acid;Biotin;Calcium;Calcium Carbonate;Calcium Pan Pyridoxine Hydrochloride Biotin Folic Acid			C C C C C C C				Not Reported Not Reported Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Colecalciferol	C	Not Reported
Cyanocobalamin	C	Not Reported
Phytomenadione	C	Not Reported
Nicotinamide	C	Not Reported
Sodium Ascorbate	C	Not Reported
Calcium Pantothenate	C	Not Reported
Thiamine Mononitrate	C	Not Reported
Zinc Oxide	C	Not Reported
Potassium Iodide	C	Not Reported
DL-Alpha Tocopheryl Acetate	C	Not Reported
Manganese Sulfate	C	Not Reported
Chromic Chloride	C	Not Reported
Sodium Molybdate Dihydrate	C	Not Reported
Sodium Selenate	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Mar-2020	17590223	DIRECT		OT			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Discomfort; Balance Disorder; Dizziness; Nausea; Suspected Product Contamination; Vomiting	Azithromycin Tablet Usp, 250 Mg			S	Oral	Quantity:1 Capsule(S);		Teva Pharmaceuticals Industries

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	15275953	EXPEDITED (15-DAY)		OT	PHHY2018CA068452		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Contact; Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Xolair			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Seebri Breezhaler			S	Unknown	1 Df, Qd (1 Every 1 Day)		Novartis
	Azithromycin			S	Oral	250 Mg, Qd (1 Every 1 Day)		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Combivent			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Theophylline	S	Oral	450 Mg, Qd (1 Every 1 Day)	Not Reported
Atrovent	S	Unknown	Unk	Not Reported
Breo Ellipta	S	Unknown	1 Df, Qd (Powder)	Not Reported
Prednisone	S	Oral	45 Mg, Qd (1 Every 1 Day)	Not Reported
Singulair	S	Oral	10 Mg, Qd (1 Every 1 Day)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	16943438	EXPEDITED (15-DAY)		DE	IT-TEVA-2019-IT-1123575		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister; Conjunctivitis; Epidermolysis; Mucosal Inflammation; Oropharyngeal Pain; Pyrexia; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown			Not Reported	
	Allopurinol			S	Unknown	150mg/ Day		Actavis	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17574974	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1207679		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Blood Blister; Purpura; Thrombocytopenia	Azithromycine Anhydre			S	Oral	500 Mg To J1 Then 250 Mg/Day To J2 And J3; 500mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17577622	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1212186		58 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Decreased Activity; Drug Ineffective; Dyspnoea; Eosinophil	Salbutamol Sulfate			S	Unknown	100 Microgram Daily;		Barr	
	Spiriva			S	Unknown	2 Dosage Forms Daily;		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Count Abnormal;	Zenhale	S	Unknown	2 Dosage Forms Daily;	Not Reported
Oesophageal Carcinoma;	Alvesco	S	Unknown		Not Reported
Wheezing	Zithromax	S	Unknown		Not Reported
	Prednisone	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590164	EXPEDITED (15-DAY)		HO, LT, OT	US-HIKMA PHARMACEUTICALS USA INC.-US-H14001- 20-509		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Pneumonia Streptococcal; Stenotrophomonas Infection	Vancomycin			S	Unknown			Hikma	
	Vancomycin			S				Hikma	
	Ceftriaxone			S	Unknown			Hikma	
	Ceftriaxone			S				Hikma	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Oseltamivir			C	Unknown			Not Reported	
	Oseltamivir			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17590263	EXPEDITED (15-DAY)		DS	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-241977		34 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis; Tinnitus	Azithromycin			S	Oral	1000 Milligram, Daily		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591132	NON-EXPEDITED			US-PFIZER INC- 2020124787			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591370	EXPEDITED (15-DAY)		HO, LT, OT	US-AXELLIA-003062		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Pneumonia Pneumococcal; Stenotrophomonas Infection	Vancomycin			S				Not Reported	
	Ceftriaxone			S				Not Reported	
	Azithromycin			S				Not Reported	
	Oseltamivir/Oseltamivir Phosphate			C				Not Reported	
	Oseltamivir			C				Not Reported	
	Azithromycin			S				Not Reported	
	Vancomycin			S				Not Reported	
	Ceftriaxone			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591533	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2020124467		16 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Hypoalbuminaemia; Nephrotic Syndrome; Oedema; Off Label Use; Product Use In Unapproved Indication; Proteinuria	Azithromycin			S		Unk		Pfizer	
	Atovaquone			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17591856	EXPEDITED (15-DAY)		HO, LT, OT	US-STRIDES ARCOLAB LIMITED- 2020SP004036		61 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Oxygen Saturation Decreased; Pneumonia Streptococcal; Pyrexia; Rales; Stenotrophomonas	Vancomycin			S	Unknown	Unk		Strides	
	Vancomycin			S				Strides	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Ceftriaxone			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Infection	Azithromycin	S	Unknown	Unk	Not Reported
	Azithromycin	S			Not Reported
	Oseltamivir	C	Unknown	Unk	Not Reported
	Oseltamivir	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17592159	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1033127		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Blood Blister; Purpura; Thrombocytopenia	Azithromycin			S	Oral	500 Mg À J1 Puis 250 Mg/Jour À J2 Et J3		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17592713	EXPEDITED (15-DAY)		DS	FR-MYLANLABS-2020M1032970		34 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypoacusis; Tinnitus	Azithromycin			S	Oral	1000 Milligram, Qd		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17592821	EXPEDITED (15-DAY)		DS, HO, LT, OT	US-009507513-2003USA009477		50 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Drug Ineffective For Unapproved Indication; Multiple Sclerosis; Product Use In Unapproved Indication	Sivextro			S	Oral	200 Milligram Daily For 6 Days		Merck	
	Keflex			S		Unk		Not Reported	
	Augmentin			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17593120	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020128158		41 YR	Female	CHN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Nausea; Peritoneal Tuberculosis; Vomiting	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17593239	EXPEDITED (15-DAY)		OT	CZ-MYLANLABS-2020M1032055			Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Erythema Nodosum; Hyperkeratosis; Hyperplasia; Limb Discomfort; Mass; Pyoderma; Pyoderma Gangrenosum; Skin Cancer	Azithromycin			S	Oral	Unk		Not Reported	
	Doxycycline			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2020	17598104	DIRECT					46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Dyskinesia; Feeling Abnormal; Muscle Twitching; Tremor; Tremor	Azithromycin Tablets Usp 250 Mg			S	Oral	Quantity:6 Tablet(S);Other Frequency:2 Tabs Day 1, 1 Da;		Wockhardt	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	16918180	EXPEDITED (15-DAY)		DE, LT	IT-ACCORD-157633		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister; Conjunctivitis; Epidermolysis; Mucosal Inflammation; Oropharyngeal Pain; Pyrexia; Toxic Epidermal Necrolysis	Allopurinol			S				Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	17511626	EXPEDITED (15-DAY)		HO, OT	NVSC2020CZ061249			Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hyperkeratosis; Hyperplasia; Limb Discomfort; Mass; Product Use In Unapproved Indication; Pyoderma Gangrenosum; Vasculitis	Doxyhexal			S	Oral	Unk		Novartis
	Doxyhexal			S	Oral	100 Mg, Bid		Novartis
	Azithromycin			S	Oral	Unk		Not Reported
	Clindamycin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Clobetasol Propionate			C	Unknown	Unk		Not Reported
	Pentasa			C	Unknown	2 G (0-0-2)		Not Reported
	Salofalk			C	Unknown	1 G, Qw		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	17594587	EXPEDITED (15-DAY)		DS, OT	DE-DRREDDYS- GER/GER/20/0121068		44 YR	Male	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Alcohol Intolerance; Anxiety; Condition Aggravated; Fatigue; Gait Disturbance; Hyperacusis; Impaired Quality Of Life; Limb Discomfort; Muscle Twitching; Muscular Weakness; Myalgia; Neuralgia; Neuropathy Peripheral; Restlessness; Sleep Disorder; Social Avoidant Behaviour	Ciprofloxacin			S	Oral	2*500 Mg Over 5 Days (2*500 Mg Uber 5 Tage)		Not Reported
	Ciprofloxacin			S				Not Reported
	Ciprofloxacin			S				Not Reported
	Ceftriaxon			S	Intramuscular			Not Reported
	Azithromycin			S	Oral			Not Reported
	Cannabidiol			C				Not Reported
	Cannabidiol			C				Not Reported
	Valium			C		2-3 Times Per Month In Case Of Severe Agitation (2-3 X Pro Monat Bei Starker Unruhe)		Not Reported
	Laif 900			C				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2020	17595178	EXPEDITED (15-DAY)		OT	DE-HIKMA PHARMACEUTICALS USA INC.-DE-H14001- 20-509		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alcohol Intolerance; Anxiety; Fatigue; Gait Disturbance; Hyperacusis; Impaired Quality Of Life; Limb Discomfort; Muscle Twitching; Muscular Weakness; Myalgia; Neuralgia; Neuropathy; Peripheral; Restlessness; Sleep Disorder; Social Avoidant Behaviour	Ceftriaxone			S	Intramuscular			Hikma	
	Ciprofloxacin			S	Oral			Not Reported	
	Ciprofloxacin			S				Not Reported	
	Ciprofloxacin			S				Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Cannabidiol			C	Unknown			Not Reported	
	Cannabidiol			C				Not Reported	
	Valium			C	Unknown			Not Reported	
	Laif 900			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	14716367	EXPEDITED (15-DAY)		OT	PHHY2018AU058280			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Dyspnoea; Fungal Infection; Graft Versus Host Disease In Lung; Immunosuppression; Infection; Pneumothorax Spontaneous; Respiratory Disorder; Treatment Failure	Imatinib			S	Unknown	400 Mg, Unk		Novartis	
	Montelukast Sodium			S	Unknown	10 Mg, Qd		Not Reported	
	Montelukast Sodium			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S				Not Reported	
	Tacrolimus			S	Unknown	1 Mg, Unk		Not Reported	
	Tacrolimus			S				Not Reported	
	Valaciclovir			S	Unknown	500 Mg, Bid		Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S				Not Reported	
	Penicillin			C	Unknown	500 Mg, Bid		Not Reported	
	Bactrim			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	14744348	EXPEDITED (15-DAY)		OT	AU-ACCORD-065446		54 YR	Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Fungal Infection; Respiratory Distress; Treatment Failure	Montelukast			S				Not Reported	
	Tacrolimus			S				Accord	
	Prednisolone			S				Not Reported	
	Azithromycin			S				Not Reported	
	Valaciclovir			C		Dose: 500 Mg Twice A Day		Not Reported	
	Bactrim			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	16929781	EXPEDITED (15-DAY)		DE	IT-PFIZER INC-2019447097		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister; Conjunctivitis; Epidermolysis; Mouth Ulceration; Oropharyngeal Pain; Pyrexia; Toxic Epidermal Necrolysis	Azithromycin			S		Unk		Pfizer	
	Allopurinol			S		150 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17440002	NON-EXPEDITED			US-PFIZER INC-2020074946		56 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Drug Hypersensitivity; Fungal Infection	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17518908	NON-EXPEDITED		OT	US-PFIZER INC-2020101762		87 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Deafness; Disease Recurrence; Gastric Disorder; Gastrooesophageal Reflux Disease; Irritable Bowel Syndrome; Nausea; Off Label Use; Off Label Use; Product Prescribing Issue	Azithromycin			S		500 Mg, Unk		Pfizer
	Azithromycin			S		250 Mg, (3x A Week, Year Round)		Pfizer
	Azithromycin			S		250 Mg, (3x A Week, Year Round)		Pfizer
	Famotidine			C		40 Mg, Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17571652	EXPEDITED (15-DAY)		HO, LT, OT	US-PFIZER INC- 2020122252		61 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Infection; Drug Ineffective; Stenotrophomonas Infection	Azithromycin			S		Unk		Pfizer
	Azithromycin			S				Pfizer
	Ceftriaxone Sodium			S		Unk		Pfizer
	Ceftriaxone Sodium			S				Pfizer
	Vancomycin Hcl			S		Unk		Pfizer
	Vancomycin Hcl			S				Pfizer
	Oseltamivir			C				Not Reported
	Oseltamivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596805	NON-EXPEDITED			US-TEVA-2020-US- 1213775		72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Therapeutic Product Effect Incomplete	Proair Hfa			S	Respiratory (inhalation)			Ivax
	Proair Hfa			S				Ivax
	Azithromycin			S	Unknown			Not Reported
	Azithromycin			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17596823	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-242081		61 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Blood Blister; Purpura; Thrombocytopenia	Azithromycin			S	Oral	500 Mg A J1 Puis 250 Mg/Jour A J2 Et J3		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597388	EXPEDITED (15-DAY)		OT	DE-MYLANLABS- 2020M1032135		44 YR	Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agitation; Alcohol Intolerance; Anxiety; Condition Aggravated;	Azithromycin			S	Oral	1.5 Gram, Qd		Not Reported	
Fatigue; Gait Disturbance;	Ceftriaxon			S	Intramuscular	2 Gram, Qd		Mylan	
Hyperacusis; Impaired Quality Of Life; Limb Discomfort; Muscle Twitching; Muscular	Ciprofloxacin			S	Oral	2*500 Mg Über 5 Tage		Mylan	
Weakness; Myalgia;	Ciprofloxacin			S				Mylan	
Neuralgia; Neuropathy	Ciprofloxacin			S				Mylan	
Peripheral; Restlessness;	Cannabidiol			C		50 Milligram, Qd		Mylan	
Sleep Disorder; Social Avoidant Behaviour	Cannabidiol			C				Mylan	
	Valium			C		2-3 X Pro Monat Bei Starker Unruhe		Mylan	
	Laif 900			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597657	EXPEDITED (15-DAY)		OT	NVSC2020CA086737		53 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Dactylitis; Drug Ineffective; Incorrect Dose Administered; Joint Swelling; Malaise;	Cosentyx			S	Subcutaneous	300 Mg, Qw		Novartis	
	Folic Acid			S	Unknown	Unk Unk, Unknown		Not Reported	
	Azithromycin			S	Unknown	Unk Unk, Unknown		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Musculoskeletal Stiffness; Psoriatic Arthropathy	Methotrexate	S	Unknown	25 Mg, Qw	Not Reported
	Desoximetasone	C	Unknown	Unk Unk, Unknown	Not Reported
	Enbrel	C	Unknown	Unk, Unknown	Not Reported
	Simponi	C	Subcutaneous	Unk Unk, Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597673	EXPEDITED (15-DAY)		OT	NVSC2020CA086767			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Xolair			S	Subcutaneous	150 Mg		Not Reported
	Alendronate Sodium Trihydrate			S	Oral	35 Mg		Not Reported
	Alendronate Sodium Trihydrate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	250 Mg		Novartis
	Azithromycin			S	Unknown	Unk		Novartis
	Salbutamol			S	Unknown	8 Df		Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Ciclesonide			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597835	NON-EXPEDITED			US-PFIZER INC- 2020126213			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17597846	NON-EXPEDITED			US-PFIZER INC- 2020126782		60 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapeutic Product Effect Incomplete	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17598196	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-242144		68 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Toxic	Azithromycin			S	Oral	()		Sun	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17599783	EXPEDITED (15-DAY)		HO, OT	NVSC2020US086554		22 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chorioretinitis; Optic Disc Disorder; Product Use In Unapproved Indication	Prednisone			S	Oral	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Mar-2020	17604086	DIRECT					29 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Chest Discomfort; Chest Pain; Dizziness; Palpitations; Tachycardia	Azithromycin 250mg Tablets 6-Pak			S	Oral	Quantity:2 Tablet(S);		Sandoz	
	D Amphetamine Salt Combo 10mg			C				Not Reported	
	Albuteral Hfa Inh 8/5mg			C				Not Reported	
	Magnesium Oxide 250mg			C				Not Reported	
	Melatonin 1mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17195249	EXPEDITED (15-DAY)		OT	DE-SUN PHARMACEUTICAL INDUSTRIES LTD-		44 YR	Male	DEU

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2019RR-231771

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Agitation; Alcohol Intolerance; Anxiety; Condition Aggravated; Fatigue; Gait Disturbance; Hyperacusis; Impaired Quality Of Life; Limb Discomfort; Muscle Twitching; Muscular Weakness; Myalgia; Neuralgia; Neuropathy; Peripheral; Restlessness; Sleep Disorder; Social Avoidant Behaviour	Ciprofloxacin			S	Oral	2*500 Mg Uber 5 Tage		Ranbaxy
	Ceftriaxon			S	Intramuscular	2 Gram, Daily		Not Reported
	Azithromycin			S	Oral	1.5 Gram, Daily		Not Reported
	Cannabidiol			C	Unknown	50 Milligram, Daily		Not Reported
	Valium			C	Unknown	2-3 X Pro Monat Bei Starker Unruhe		Not Reported
	Laif 900			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17324298	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR-APL-2020-003542		83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ascites; Asthenia; Cardiac Failure; Cystitis; Dyspnoea; Ejection Fraction Decreased; Hepatic Enzyme Increased; Hepatocellular Injury; Hepatomegaly; Mental Status Changes; Oedema Peripheral; Renal Impairment	Azithromycin			S	Intravenous (not otherwise specified)	500 Milligram, Once A Day		Aurobindo
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported
	Hydrocodone			C	Oral	5 Milligram, Four Times/Day		Not Reported
	Acetaminophen			C	Oral	325 Milligram, Four Times/Day		Not Reported
	Aspirin			C	Unknown	81 Milligram, Once A Day (Enteric Coated)		Not Reported
	Digoxin			C	Unknown	125 Microgram, Once A Day		Not Reported
	Donepezil			C	Unknown	10 Milligram, Once A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Memantine	C	Unknown	At Bedtime 10 Milligram, Two Times A Day	Not Reported
Fluoxetine	C	Unknown	40 Milligram, Once A Day	Not Reported
Latanoprost	C	Unknown	Unk	Not Reported
Metformin	C	Unknown	500 Milligram, Two Times A Day	Not Reported
Glipizide	C	Unknown	15 Milligram, Two Times A Day, Before Meals	Not Reported
Rosuvastatin	C	Unknown	5 Milligram, At Bedtime	Not Reported
Fenofibrate	C	Unknown	145 Milligram, At Bedtime	Not Reported
Rivaroxaban	C	Unknown	15 Milligram, Once A Day	Not Reported
Cholecalciferol	C	Unknown	5000 International Unit, Once A Day	Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	3.375 Gram, 3 Times A Day (Extended Infusion)	Not Reported
Piperacillin & Tazobactam	C	Intravenous (not otherwise specified)	4.5 Gram, Loading Dose	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	1500 Milligram, Once A Day	Not Reported
Vancomycin	C	Intravenous (not otherwise specified)	3000 Milligram (Loading Dose)	Not Reported
Hydrocodone;Paracetamol	C	Oral	1 Dosage Form, Four Times/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17603772	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal;	Spiriva			S	Unknown			Boehringer Ingelheim
Blood Pressure Increased; Body Temperature	Salbutamol Sulfate			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Cataract; Cough; Drug Dependence; Heart Rate Increased; Lung Diffusion Test Decreased; Nasal Disorder; Nasopharyngitis; Obstructive Airways Disorder; Pyrexia; Restrictive Pulmonary Disease; Therapeutic Response Decreased; Type 2 Diabetes Mellitus	Prednisone Advair Azithromycin Mometasone Cetirizine Pariet Rosuvastatin Calcium	S S S S C C C	Oral Unknown Oral Unknown Unknown Unknown Unknown	Enteric Coated	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17603878	EXPEDITED (15-DAY)		OT	NVSC2020CA087455		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased; Coccydynia; Contusion; Crying; Discomfort; Dizziness Exertional; Dry Skin; Dyspnoea; Dyspnoea Exertional; Ear Pain; Emotional Disorder; Fall; Fatigue; Feeling Abnormal; Headache; Heart Rate Increased; Myalgia; Nausea; Oxygen Saturation Decreased; Pain In Extremity; Respiratory Rate Increased; Scratch; Vision Blurred	Xolair Pantoprazole Sandoz Montelukast Sandoz Atorvastatin Calcium Fentanyl Azithromycin Advair Prednisone Reactine Spiriva Ventolin			S S S S S S C C C C C	Subcutaneous Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown			Not Reported Novartis Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17604083	EXPEDITED (15-DAY)		HO, OT	FR-ASTELLAS- 2011EU009547		14 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury; Acute Kidney Injury; Drug Interaction; Drug Level Increased; Product Use In Unapproved Indication	Modigraf			S	Unknown	Unk, Unknown Freq.		Astellas
	Modigraf			S	Oral	0.5 Mg, Twice Daily		Astellas
	Modigraf			S	Oral	0.2 Mg, Twice Daily		Astellas
	Modigraf			S	Unknown	0.5 Mg, Twice Daily		Astellas
	Vfend			S	Oral			Not Reported
	Vfend			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Zithromax			S	Oral			Not Reported
	Rifadine /00146901/			S	Oral	600 Mg, 1x/Day		Not Reported
	Cancidas			S	Intravenous (not otherwise specified)			Not Reported
	Cellcept			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Cellcept			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Creon			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	A 313			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Rimifon			C	Unknown	Unk Unk, Unknown Freq.		Not Reported
	Insulin			C	Unknown	Unk Unk, Unknown Freq.		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17604345	NON-EXPEDITED		OT	US-PFIZER INC-2020128687		41 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Seizure	Azithromycin			S				Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605037	EXPEDITED (15-DAY)		CA, OT	GR-GLAXOSMITHKLINE-GR2020051882		29 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abortion Missed;	Aerolin	S	Unknown	Unk	Glaxosmithkline
Exposure During	Xozal	S	Oral	Unk	Not Reported
Pregnancy; Uterine	Zithromax	S	Oral	Unk	Not Reported
Dilation And Curettage	Trebon-N	S	Oral	Unk	Not Reported
	Primolut Nor	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605311	EXPEDITED (15-DAY)		OT	US-MYLANLABS-2020M1033390		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective;	Methotrexate			S	Unknown			Not Reported	
Granuloma;	Methotrexate			S				Not Reported	
Histoplasmosis	Azithromycin			S	Unknown			Not Reported	
Disseminated; Mediastinal	Infliximab			S	Unknown			Mylan	
Mass	Infliximab			S				Mylan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605434	EXPEDITED (15-DAY)		DE, LT, OT	FR-PFIZER INC-2020127030		76 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Tygacil			S	Intravenous drip	100 Mg, 1x/Day		Pfizer	
	Bactrim Forte			S	Oral	2400 Mg, Weekly		Not Reported	
	Imipenem Cilastatine Mylan			S	Intravenous drip	1500 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605608	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA087453		66 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E	Seebri Breezhaler			S	Unknown	50 Ug, Qd		Novartis	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use In Unapproved Indication	Glycopyrronium Bromide	S	Unknown	1 Df	Novartis
	Azithromycin	S	Oral	250 Mg(3 Every 1 Day)	Not Reported
	Atorvastatin Calcium	S	Oral	20 Mg	Not Reported
	Alendronate Sodium	C	Unknown	Unk	Not Reported
	Calcium Carbonate	C	Unknown	Unk	Not Reported
	Dexilant	C	Unknown	Unk	Not Reported
	Montelukast	C	Unknown	Unk	Not Reported
	Pulmicort	C	Unknown	Unk	Not Reported
	Qvar	C	Unknown	Unk	Not Reported
	Remicade	C	Unknown	Unk	Not Reported
	Salbutamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17605825	EXPEDITED (15-DAY)		OT	FR-009507513-2003FRA010499		94 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Confusional State; Disorientation	Invanz			S	Intravenous (not otherwise specified)	1 Gram, Qd		Merck
	Zithromax			S	Oral	250 Milligrams, Qd		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17606938	NON-EXPEDITED			US-PFIZER INC-2020127830		57 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Erythromycin Base			S		Unk		Not Reported
	Tramadol Hcl			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2020	17608455	EXPEDITED (15-DAY)		HO, LT, OT	US-AUROBINDO-AUR-APL-2020-015523		61 YR	Male	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Infection; Pneumonia Pneumococcal; Stenotrophomonas Infection	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Vancomycin			S	Unknown	Unk		Aurobindo
	Vancomycin			S				Aurobindo
	Ceftriaxone			S	Unknown	Unk		Not Reported
	Ceftriaxone			S				Not Reported
	Oseltamivir			C	Unknown	Unk		Not Reported
	Oseltamivir			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17031475	NON-EXPEDITED			US-PFIZER INC- 2019491415		79 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer
	Spironolactone			S		Unk		Pfizer
	Erythromycin			S		Unk		Pfizer
	Bumetanide			S		Unk		Pfizer
	Promethazine Hcl			S		Unk		Pfizer
	Benzympenicillin Potassium			S		Unk		Pfizer
	Antivert [Meclozine Hydrochloride]			S		Unk		Not Reported
	Aspirin [Acetylsalicylic Acid]			S		Unk		Not Reported
	Caffeine			S		Unk		Not Reported
	Cipro [Ciprofloxacin]			S		Unk		Not Reported
	Flecainide			S		Unk		Not Reported
	Keflex [Cefalexin Monohydrate]			S		Unk		Not Reported
	Tamoxifen Citrate			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17377193	NON-EXPEDITED			NVSC2020US029929		23 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy; Premature Delivery; Product Use In Unapproved Indication	Betamethasone			S	Unknown	Unk		Novartis
	Azithromycin			S	Intravenous (not otherwise specified)	500 Mg Q 6 X 48 Hours		Not Reported
	Erythromycin			S	Unknown	Unk		Not Reported
	Magnesium Sulfate			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Ampicillin			S	Unknown	2 G Q 6 X 48 Hours		Not Reported
	Ampicillin			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17386592	EXPEDITED (15-DAY)		DE, LT, OT	NVSC2020US029927			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Pneumonia Escherichia; Premature Baby; Pulmonary Hypertension; Respiratory Distress; Sepsis Neonatal	Betamethasone			S	Transplacental	Unk		Novartis
	Azithromycin			S	Transplacental	Unk		Not Reported
	Erythromycin			S	Transplacental	Unk		Not Reported
	Ampicillin			S	Transplacental	Unk		Not Reported
	Magnesium Sulphate			S	Transplacental	Unk		Not Reported
	Gentamycin			C	Unknown	Unk		Not Reported
	Penicillin			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608831	EXPEDITED (15-DAY)		HO, OT	PT-TEVA-2020-PT-1214117		64 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pathogen Resistance	Amoxicillin W/Clavulanic Acid			S	Unknown			Teva
	Azithromycin			S	Unknown			Not Reported
	Levofloxacin			S	Unknown			Teva
	Piperacillin Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

W/Tazobactam Sodium
Vancomycin Hydrochloride
Imipenem

S Unknown
S Unknown

Actavis
Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17608891	NON-EXPEDITED			US-UCBSA-2016018777		55 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Glucose Increased;	Metolazone			S		Unk		Not Reported
Conjunctivitis; Diarrhoea;	Azithromycin			S		Unk		Not Reported
Fluid Retention; Infection;	Remodulin			S	Subcutaneous	50 Ng/ Kg		Not Reported
Pain In Extremity;	Metformin			S		500 Mg, 2x/Day (Bid)		Not Reported
Peripheral Swelling	Adcirca			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17609521	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020129863		23 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Cyanosis; Feeling Cold; Heart Rate Decreased; Pyrexia; Tachypnoea; Temperature Intolerance	Azithromycin			S	Intravenous drip	0.500 G, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17609561	EXPEDITED (15-DAY)		CA, OT	GR-UCBSA-2020012605		29 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Missed; Maternal Exposure During Pregnancy; Uterine Dilation And Curettage	Xozal			S	Oral	Unk		Not Reported
	Aerolin			S		Unk		Not Reported
	Zithromax			S	Oral	Unk		Not Reported
	Trebon N			S	Oral	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Primolut Nor

S

Oral

Unk

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611700	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA086756		67 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Seebri Breezhaler			S	Unknown	50 Mg, Qd		Novartis
	Atorvastatin Calcium			S	Oral	20 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg, Bid		Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Dexilant			C	Unknown			Not Reported
	Fosamax			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Pulmicort			C	Unknown			Not Reported
	Qvar			C	Unknown	Inhalation		Not Reported
	Salbutamol			C	Unknown			Not Reported
Remicade			C	Unknown	Powder For Solution Intravenous		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Apr-2020	17611705	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA086782		67 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Seebri Breezhaler			S	Respiratory (inhalation)	50 Mg, Qd		Novartis
	Atorvastatin Calcium			S	Oral	20 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg, Bid		Not Reported
	Calcium Carbonate			C	Unknown	Unk		Not Reported
	Dexilant			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Pulmicort	C	Unknown	Unk	Not Reported
Qvar	C	Respiratory (inhalation)	Unk	Not Reported
Remicade	C	Unknown	Unk	Not Reported
Salbutamol	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17363924	EXPEDITED (15-DAY)	HO		IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-235454		15 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Medication Error	Azithromycin			S	Oral	1.5 Grams, Daily		Sun	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17613578	EXPEDITED (15-DAY)	OT		CA-ROCHE-2573628		25 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cystic Fibrosis Pancreatic; Drug Ineffective; Hepatic Cirrhosis; Injection Site Pain; Mechanical Urticaria; Pruritus; Pyrexia; Seasonal Allergy; Skin Reaction; Throat Irritation	Xolair			S	Subcutaneous			Not Reported	
	Xolair			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Levofloxacin			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown			Not Reported	
	Diphenhydramin Hydrochloride			S	Unknown			Not Reported	
	Diphenhydramin Hydrochloride			S	Unknown			Not Reported	
	Diphenhydramin Hydrochloride			S	Unknown			Not Reported	
	Diphenhydramin Hydrochloride			S	Unknown			Not Reported	
	Rifadin [Rifampicin]			S	Unknown			Not Reported	
	Rifampin			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17614764	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Blood Creatinine Increased; Blood Test Abnormal; Cough; Distal Intestinal Obstruction Syndrome; Dyspnoea; Eosinophil Count Increased; Glucose Tolerance Impaired; Infective Pulmonary Exacerbation Of Cystic Fibrosis; Obstructive Airways Disorder; Pancreatic Failure; Productive Cough; Renal Failure; Therapeutic Product Effect Incomplete	Spiriva			S	Unknown			Boehringer Ingelheim	
	Azithromycin			S	Unknown			Not Reported	
	Ceftazidime			S	Unknown	Powder For Solution		Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Fluticasone Propionate;Salmeterol Xinafoate			S	Unknown			Not Reported	
	Nucala			S	Intravenous (not otherwise specified)			Not Reported	
	Nystatin			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Pulmicort			S	Unknown			Not Reported	
	Septra			S	Oral			Not Reported	
	Singulair			S	Unknown			Not Reported	
	Ventolin [Salbutamol]			S	Unknown			Not Reported	
	Zopiclone			S	Unknown			Not Reported	
	Vitamin D [Vitamin D Nos]			C	Unknown			Not Reported	
	Pulmozyme			C	Unknown	1mg/ML Solution Inhalation		Not Reported	
	Cayston			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17615420	EXPEDITED (15-DAY)		HO, OT	CN-PFIZER INC- 2020135901		3 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Body Temperature	Zithromax			S	Intravenous drip	0.14 G, 1x/Day		Pfizer	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Increased; Erythema;
Heart Rate Increased; Off
Label Use; Product Use
Issue; Pruritus; Rash;
Swelling

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17615831	DIRECT	Y	OT			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anosmia	Azithromycin			S	Oral			Not Reported	
	Azithromycin			C				Not Reported	
	Solumedrol			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616565	EXPEDITED (15-DAY)		HO	PL-MYLANLABS-2020M1034675		3 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Reconstitution Inflammatory Syndrome	Azithromycin			S	Oral	Unk		Not Reported	
	Cefotaxime			S	Oral	Unk		Mylan	
	Isoniazid			S	Oral	10 Milligram/Kilogram		Mylan	
	Rifampicin			S	Oral	15 Milligram/Kilogram		Mylan	
	Pyrazinamide			S	Oral	35 Milligram/Kilogram		Mylan	
	Ethambutol			S	Oral	20 Milligram/Kilogram		Mylan	
	Prednisone			C	Unknown	1.5 Milligram/Kilogram		Mylan	
	Clarithromycin			C	Unknown	Unk		Mylan	
	Amikacin			C	Unknown	Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17616639	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA-1216873		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Atorvastatin Calcium Azithromycin Seebri Breezhaler Calcium Carbonate Dexilant Fosamax Montelukast Pulmicort Qvar Remicade Salbutamol	S S S C C C C C C C C	Oral Oral Unknown	500 Milligram Daily; 50 Milligram Daily;	Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17617768	EXPEDITED (15-DAY)		LT, OT	RU-TEVA-2020-RU-1217829			Male	RUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anamnestic Reaction; Angioedema; Asphyxia; Dyspnoea; Pharyngeal Swelling	Sumamed			S	Oral	1 Tablet Reception In May 2019		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17617848	EXPEDITED (15-DAY)		OT	US-ASTRAZENECA-2020SE45233		87 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness Unilateral; Dizziness; Gastric Disorder; Gastrooesophageal Reflux Disease; Irritable Bowel Syndrome; Nausea	Omeprazole Azithromycin Famotidine			S S C	Oral Unknown			Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17618194	EXPEDITED (15-DAY)		HO, OT	DE-DSJP-DSE-2020-110305			Unknown	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Delirium	Edoxaban	S	Oral	30 Mg	Daiichi
	Azithromycin	S	Oral	500 Mg	Not Reported
	Ampicillin And Sulbactam	C	Intravenous (not otherwise specified)	3 G, Once Every 8hr	Not Reported
	Sitagliptin	C	Oral	100 Mg, Qd	Not Reported
	Insuman Basal	C	Subcutaneous	4 Iu, Qd	Not Reported
	Candesartan	C	Oral	32 Mg, Qd	Not Reported
	Ceftriaxon	C	Oral	2 G, Qd	Not Reported
	Bisoprolol	C	Oral	2.5 Mg, Once Every 12hr	Not Reported
	Amlodipin /00972401/	C	Oral	5 Mg, Once Every 12hr	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17618200	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083-3348747-00		57 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra 100/25			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17618329	EXPEDITED (15-DAY)		HO, OT	DE-TEVA-2020-DE-1217225		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium	Azithromycin			S	Oral	500mg		Not Reported	
	Edoxaban			S	Oral	30mg		Not Reported	
	Ampicillin/Sulbactam			C	Intravenous (not otherwise specified)	3x3g		Not Reported	
	Bisoprolol			C	Oral	2.5-0-2.5mg		Not Reported	
	Insuman Basal			C	Subcutaneous	4 Iu (International Unit) Daily; 0-0-0-4ie		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Sitagliptin	C	Oral	100 Milligram Daily; 100-0-0mg	Not Reported
Ceftriaxon	C	Oral	1x2g	Not Reported
Candesartan	C	Oral	32 Milligram Daily; 32mg-0-0	Not Reported
Amlodipin	C	Oral	5-0-5mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Apr-2020	17619181	EXPEDITED (15-DAY)		HO, OT	NVSC2020CA087474		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Xolair			S	Unknown	Unk		Not Reported
Anaemia; Aspiration;	Azithromycin			S	Unknown	Unk		Novartis
Asthenia; Asthma; Blood	Candesartan			S	Oral	8 Mg, Qd		Not Reported
Calcium Increased; Blood	Lansoprazole			S	Unknown	Unk		Not Reported
Creatinine Increased;	Montelukast			S	Oral	10 Mg, Qd		Not Reported
Blood Test Abnormal;	Morphine			S	Unknown	10 Mg		Not Reported
Bronchiectasis;	Nitroglicerina Sandoz			S	Unknown	Unk		Not Reported
Bronchopulmonary	Pramipexole			S	Oral	0.5 Mg		Not Reported
Aspergillosis Allergic;	Pramipexole			S	Oral	0.25 Mg		Not Reported
Constipation; Cough; Drug	Pregabalin			S	Oral	75 Mg		Not Reported
Hypersensitivity; Drug	Quetiapine			S	Unknown	Unk		Not Reported
Ineffective; Dyspnoea;	Ranitidine			S	Unknown	Unk		Not Reported
Fatigue;	Risedronate			S	Unknown	Unk		Not Reported
Gastrooesophageal Reflux	Rosuvastatin Calcium			S	Unknown	Unk		Not Reported
Disease; Haemoptysis;	Sennosides		Y	S	Unknown	Unk		Not Reported
Headache; Hypoxia; Liver	Zopiclone			S	Unknown	Unk		Not Reported
Function Test Increased;	Acetaminophen			S	Unknown	1000 Mg		Not Reported
Lower Respiratory Tract	Prevnar			S	Unknown	Unk		Not Reported
Infection; Lung Opacity;	Budesonide			S	Unknown	Unk		Not Reported
Musculoskeletal Stiffness;								
Obstructive Airways								
Disorder; Oedema								
Peripheral; Pain; Pleural								
Effusion; Pneumonia;								
Pulmonary Fibrosis;								
Pyrexia; Rales; Sputum								
Discoloured; Total Lung								
Capacity Decreased;								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transaminases Increased; Tremor; Upper Respiratory Tract Infection; Wheezing	Dexilant	S	Unknown	Unk	Not Reported
	Domperidone	S	Unknown	Unk	Not Reported
	Efinaconazole	S	Unknown	Unk	Not Reported
	Flu Vaccine Vii	S	Unknown	Unk	Not Reported
	Levothyroxine Sodium	S	Unknown	Unk	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Nasonex	S	Unknown	Unk	Not Reported
	Pantoloc	S	Unknown	Unk	Not Reported
	Senokot	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	1 Df, Qd	Not Reported
	Statex (Morphine Sulfate)	S	Oral	10 Mg	Not Reported
	Symbicort	S	Unknown	2 Df, Bid	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	10 Mg	Not Reported
	Trazodone	S	Unknown	12.5 Mg	Not Reported
	Ventolin	S	Unknown	Unk	Not Reported
	Vitamin D	S	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	13755405	NON-EXPEDITED			US-PFIZER INC- 2017305436		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Demerol			S				Pfizer
	Zithromax			S		Unk		Pfizer
	Percocet			S		Unk		Not Reported
	Percodan			S		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16804408	NON-EXPEDITED			US-PFIZER INC-2019393430		54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Morphine Sulfate			S		Unk		Pfizer	
	Benzylpenicillin Sodium			S		Unk		Not Reported	
	Codeine Sulfate			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	16923698	EXPEDITED (15-DAY)		OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-2019VAL000576			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Demerol			S	Unknown	Unk		Validus	
	Arava			S	Unknown	Unk		Not Reported	
	Plaquenil /00072603/			S		Unk		Not Reported	
	Diphenhydramine Hydrochloride			S		Unk		Not Reported	
	Celecoxib			S	Oral	Unk		Not Reported	
	Levofloxacin			S	Unknown	Unk		Not Reported	
	Cyclophosphamide			S	Unknown	Unk		Not Reported	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	250 Mg, Qd		Not Reported	
	Cimzia			S	Unknown	Unk		Not Reported	
	Enbrel			S	Unknown	Unk		Not Reported	
	Humira			S	Unknown	Unk		Not Reported	
	Imuran /00001502/			S	Unknown	Unk		Not Reported	
	Simponi			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Xeljanz	S	Oral	5.0 Mg, Bid	Not Reported
Xeljanz	S	Oral	5 Mg, Bid	Not Reported
Xeljanz	S	Oral	5 Unk	Not Reported
Xeljanz	S	Oral	5 Unk	Not Reported
Ezetrol	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17620180	EXPEDITED (15-DAY)		CA, OT	GR-SA-2020SA081582		29 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Missed; Exposure During Pregnancy; Uterine Dilation And Curettage	Levocetirizine			S	Oral	Unk		Sanofi
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Azithromycin			S	Oral	Unk		Not Reported
	Acetylcysteine			S	Oral	Unk		Not Reported
	Norethisterone Acetate			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17620205	EXPEDITED (15-DAY)		HO, OT	IT-GLAXOSMITHKLINE- IT2020057146		57 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anaphylactic Shock; Chills; Nausea; Rash Pruritic; Syncope; Vomiting	Valaciclovir Hydrochloride			S	Oral	Unk		Glaxosmithkline
	Zitromax			S	Oral	Unk		Glaxosmithkline
	Tachidol			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17620392	EXPEDITED (15-DAY)		HO	FR-ASTRAZENECA- 2020SE44870		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Oedema; Weight Increased	Esomeprazole			S	Oral			Astrazeneca
	Novopulmon Novolizer			S	Respiratory			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		(inhalation)	
Zithromax	S	Oral	Not Reported
Rhinomaxil	S	Nasal	Not Reported
Aerius (Desloratadine)	S	Oral	Not Reported
Amlodipine	S	Oral	Not Reported
Lantus	C		Not Reported
Eucreas	C		Not Reported
Novatrex	C		Not Reported
Transipeg	C		Not Reported
Gliclazide	C		Not Reported
Speciafoldine	C		Not Reported
Kardegic	C		Not Reported
Inegy	C		Not Reported
Kardegic	C		Not Reported
Isoptine	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17621056	EXPEDITED (15-DAY)		CA, OT	GR-PFIZER INC-2020135438		29 YR	Female	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abortion Missed; Maternal Exposure During Pregnancy; Uterine Dilation And Curettage	Zithromax			S	Oral	Unk		Pfizer
	Xozal			S	Oral	Unk		Not Reported
	Aerolin			S		Unk		Not Reported
	Trebon N			S	Oral	Unk		Not Reported
	Primolut Nor			S	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623000	EXPEDITED (15-DAY)		HO	US-VERTEX PHARMACEUTICALS-2020-007639		25 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Diabetic Hepatopathy; Infective Pulmonary Exacerbation Of Cystic	Trikafta			S	Oral	2 Tabs In Qam And 1 Tab In Qpm		Vertex
	Acetaminophen			S	Unknown	1000-2000mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fibrosis	Acetaminophen	S						Not Reported	
	Azithromycin	S	Unknown	Unk				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623012	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217578			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Acetaminophene			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Actavis	
	Amoxicillin Trihydrate			S	Unknown			Teva	
	Atorvastatin Calcium			S	Unknown			Teva	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
	Betamethasone Dipropionate			S	Unknown			Actavis	
	Clarithromycin			S	Unknown			Actavis	
	Diphenhydramine Hydrochloride			S	Unknown			Not Reported	
	Morphine Sulfate			S	Unknown			Actavis	
	Nicotine			S	Unknown			Not Reported	
	Nicotine Polacrilex			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Teva	
	Prednisone			S	Unknown			Actavis	
	Pregabalin			S	Unknown			Teva	
	Sulfamethoxazole;Trimethoprim			S	Unknown			Teva	
	Zinc Oxide			S	Unknown			Teva	
	Apo Hydro			S	Unknown			Not Reported	
	Ascorbic Acid;Copper;Tocopherol;Xantofy I;Zeaxanthin;Zinc			S	Unknown			Not Reported	
	Atropine Sulfate/Diphenoxylate Hydrochloride			S	Oral			Not Reported	
	Avamys			S	Unknown			Not Reported	
	Betaderm [Betamethasone]			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Biacin XL	S	Unknown	Not Reported
Bisacodyl	S	Unknown	Not Reported
Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cholecalciferol/Vitamin D	S	Unknown	Not Reported
Calcium/Magnesium/Vitamin D3	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
Entocort	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Glycerine	S	Unknown	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Kenalog [Triamcinolone Acetonide]	S	Unknown	Not Reported
Lomotil (Atropine Sulfate/Diphenoxylate Hydrochloride)	S	Oral	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;Sodium Metronidazole	S	Unknown	Not Reported
Mupirocin	S	Unknown	Not Reported
Mupirocin	S	Topical	Not Reported
Mupirocin Calcium Dihydrate	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Pulmicort	S	Unknown	Not Reported
	Refresh Tears	S	Ophthalmic	Not Reported
	Salinex [Sodium Chloride]	S	Nasal	Not Reported
	Sinus Rinse	S	Nasal	Not Reported
	Sodium Chloride	S	Nasal	Not Reported
	Statex [Morphine Sulfate]	S	Unknown	Not Reported
	Triamcinolone Acetonide	S	Unknown	Not Reported
	Vitamin D3	S	Unknown	Not Reported
	Xantofyl Palmitate	S	Unknown	Not Reported
	Zeaxanthin	S	Unknown	Not Reported
	Calcium Carbonate/Vitamin D3	C		Not Reported
	Valsartan	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623040	DIRECT	Y	OT			78 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported
	Azithromycin			S	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17623232	EXPEDITED (15-DAY)		CA, OT	GR-PFIZER INC-2020136969			Unknown	GRC

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Congenital Anomaly; Maternal Exposure During Pregnancy	Zithromax			S	Transplacental	Unk		Pfizer
	Xozal			S	Transplacental	Unk		Not Reported
	Aerolin			S	Transplacental	Unk		Not Reported
	Trebon N			S	Transplacental	Unk		Not Reported
	Primolut Nor			S	Transplacental	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Apr-2020	17624945	EXPEDITED (15-DAY)			US-AKRON, INC.- 2082305			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Parkinson'S Disease	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2020	16959350	EXPEDITED (15-DAY)		DE	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2019RR-224829		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister; Conjunctivitis; Epidermolysis; Mucosal Inflammation; Oropharyngeal Pain; Pyrexia; Toxic Epidermal Necrolysis	Azithromycin Allopurinol			S S	Unknown Unknown	Unk 150 Milligrams, Daily		Sun Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2020	17625736	EXPEDITED (15-DAY)		HO, OT	CA-TEVA-2020-CA- 1217218		67 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Immunoglobulin E Increased; Dyspnoea; Dyspnoea At Rest; Dyspnoea Exertional; Malaise; Micturition Urgency; Mobility Decreased; Product Use Issue	Atorvastatin Calcium Azithromycin Seebri Breezhaler Alendronate Sodium Calcium Carbonate Dexilant Montelukast Pulmicort Qvar			S S S C C C C C	Oral Oral Respiratory (inhalation) Respiratory	500 Milligram Daily; 50 Milligram Daily;		Teva Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

					(inhalation)				
		Remicade		C					Not Reported
		Salbutamol		C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2020	17626643	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217581			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Acetaminophene			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Actavis	
	Amoxicillin			S	Unknown			Teva	
	Atorvastatin Calcium			S	Unknown			Teva	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
	Betamethasone Dipropionate			S	Unknown			Actavis	
	Betamethasone Dipropionate			S	Unknown			Actavis	
	Clarithromycin			S	Unknown			Actavis	
	Diphenhydramine			S	Unknown			Not Reported	
	Morphine Sulfate			S	Unknown			Actavis	
	Nicotine Polacrilex			S	Unknown			Not Reported	
	Nicotine Polacrilex			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Teva	
	Prednisone			S	Unknown			Actavis	
	Pregabalin			S	Unknown			Teva	
	Sulfamethoxazole And Trimethoprim			S	Unknown			Teva	
	Zinc Oxide			S	Unknown			Teva	
	Calcium Carbonate			S	Unknown			Not Reported	
	Magnesium Sulfate			S	Unknown			Not Reported	
	Apo Hydro			S	Endocervical			Not Reported	
	Atropine Sulfate/Diphenoxylate Hydrochloride			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Avamys	S	Unknown	Not Reported
Biaxin XI	S	Unknown	Not Reported
Bisacodyl	S	Unknown	Not Reported
Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cholecalciferol/Vitamin D	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Cupric Oxide	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
DL-Alpha Tocopheryl Acetate	S	Unknown	Not Reported
Entocort	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Glycerine	S	Oral	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride/Sodium Metronidazole	S	Unknown	Not Reported
Ms Ir	S	Unknown	Not Reported
Mupirocin	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sinus Rinse	S	Nasal	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D3	S	Unknown	Not Reported
Xantofyl Palmitate	S	Unknown	Not Reported
Zeaxanthin	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Valsartan	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2020	17626677	EXPEDITED (15-DAY)		OT	NVSC2020DE092579			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection	Azithromycin			S	Unknown	500 Mg			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2020	17627239	EXPEDITED (15-DAY)		HO, OT	CA-ALLERGAN-2013747US			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Risedronate Sodium Unk			S	Unknown				Allergan
Anaemia; Aspiration;	Acetaminophen			S	Unknown	1000 Mg, Unk			Not Reported
Asthenia; Asthma; Blood	Atrovent			S	Unknown	Unk			Not Reported
Calcium Increased; Blood	Azithromycin			S	Unknown	Unk			Not Reported
Creatinine Increased;	Budesonide			S	Unknown	Unk			Not Reported
Blood Test Abnormal;	Candesartan			S	Oral	8 Mg, Qd			Not Reported
Bronchiectasis;	Dexilant			S	Unknown	Unk			Not Reported
Bronchopulmonary	Domperidone			S	Unknown	Unk			Not Reported
Aspergillosis Allergic;	Efinaconazole			S	Unknown	Unk			Not Reported
Constipation; Cough; Drug	Fluvaccin			S	Unknown	Unk			Not Reported
Hypersensitivity; Drug	Lansoprazole			S	Unknown	Unk			Not Reported
Ineffective; Dyspnoea;	Levothyroxine Sodium			S	Unknown	Unk			Not Reported
Fatigue;	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk			Not Reported
Gastrooesophageal Reflux									
Disease; Haemoptysis;									
Headache; Hypoxia; Liver									
Function Test Increased;									
Lower Respiratory Tract									
Infection; Lung Opacity;									
Musculoskeletal Stiffness;									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Obstructive Airways Disorder; Oedema Peripheral; Pain; Pleural Effusion; Pneumonia; Pulmonary Fibrosis; Pyrexia; Rales; Sputum Discoloured; Total Lung Capacity Decreased; Transaminases Increased; Tremor; Upper Respiratory Tract Infection; Wheezing	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg, Unk	Not Reported
	Montelukast	S	Oral	10 Mg, Qd	Not Reported
	Morphine	S	Unknown	10 Mg, Unk	Not Reported
	Nasonex	S	Unknown	Unk	Not Reported
	Nitroglycerin	S	Unknown	Unk	Not Reported
	Pantoloc	S	Unknown	Unk	Not Reported
	Pantoloc	S	Unknown	Unk	Not Reported
	Pramipexole	S	Oral	0.5 Mg, Unk	Not Reported
	Pramipexole	S	Oral	0.25 Mg	Not Reported
	Pregabalin	S	Oral	75 Mg, Unk	Not Reported
	Prevnar	S	Unknown	Unk	Not Reported
	Quetiapine	S	Unknown	Unk	Not Reported
	Ranitidine	S	Unknown	Unk	Not Reported
	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
	Sennoside	S	Unknown	Unk	Not Reported
	Senokot	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	1 Df, Qd	Not Reported
	Statex (Morphine Sulfate)	S	Oral	10 Mg, Unknown	Not Reported
	Symbicort	S	Unknown	2 Df, Bid	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	10 Mg, Unk	Not Reported
	Trazodone	S	Unknown	10 Mg, Unk	Not Reported
	Ventolin	S	Unknown	Unk	Not Reported
	Vitamin D	S	Oral	Unk	Not Reported
	Xolair	S	Unknown	Unk	Not Reported
	Zopiclone	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17393676	EXPEDITED (15-DAY)		OT	NVSC2020TR032228			Unknown	TUR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Premature Baby	Betamethasone			S	Transplacental	12 Mg, Qd (Every 24 Hours)(Maternal Dose)		Novartis	
	Ampicillin			S	Transplacental	1 G, Qd (4x1) (Maternal Dose)		Not Reported	
	Azithromycin			S	Transplacental	500 Mg, Qd (1x1 For First 3 Days) (Maternal Dose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17546475	EXPEDITED (15-DAY)		OT	CA-ALLERGAN-2010970US			Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bronchiectasis; Bronchomalacia; Cataract; Dyspnoea; Dyspnoea Exertional; Eosinophil Count Increased; Gastrooesophageal Reflux Disease; Hypertension; Osteoporosis; Productive Cough; Spinal Osteoarthritis; Therapeutic Product Effect Incomplete; Tooth Disorder; Wheezing	Risedronate Sodium - Bp			S	Unknown			Allergan	
	Pantoprazole			S	Unknown			Not Reported	
	Alvesco			S	Unknown			Not Reported	
	Aspirin			S	Unknown			Not Reported	
	Advair			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Esomeprazole Magnesium			S	Unknown			Not Reported	
	Ezetrol			S	Unknown			Not Reported	
	Fluticasone Propionate W/Salmeterol Xinafoate			S	Unknown			Not Reported	
	Hydrochlorothiazide			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Quinapril Hydrochloride			S	Unknown			Not Reported	
	Rhinocort			S	Unknown			Not Reported	
	Ventolin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Ventolin	S	Unknown	Unk, Q Month	Not Reported
	Zantac	S	Unknown		Not Reported
	Zenhale	S	Unknown		Not Reported
	Pantoprazole Sodium Sesquihydrate	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17594275	EXPEDITED (15-DAY)	HO		CN-PFIZER INC-2020126337		41 YR	Male	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chest Pain; Palpitations	Zithromax			S	Oral	2 Df, 1x/Day		Pfizer	
	Niao Su Zhi			C		1 G, 2x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628686	EXPEDITED (15-DAY)	HO, OT		PL-TEVA-2020-PL-1218821		3 YR	Male	POL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Immune Reconstitution	Ethambutol			S	Oral			Barr	
Inflammatory Syndrome;	Azithromycin			S	Oral			Not Reported	
Tuberculosis	Bcg Vaccine			S	Unknown			Not Reported	
Gastrointestinal;	Cefotaxime			S	Oral			Not Reported	
Vaccination Failure	Isoniazid			S	Oral			Not Reported	
	Rifampicin			S	Oral			Not Reported	
	Pyrazinamide			S	Oral			Not Reported	
	Clarithromycin			C	Unknown			Not Reported	
	Amikacin			C	Unknown			Not Reported	
	Prednisone			C	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17628906	EXPEDITED (15-DAY)	HO		FR-TEVA-2020-FR-1218421		66 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Azithromycine Anhydre			S	Oral	500 Mg 1 Days		Not Reported
	Coaprovel 300 Mg/12,5 Mg, Comprimé			S	Oral	1 Dosage Forms 1 Days		Not Reported
	Nebivolol			C				Not Reported
	Amoxicilline			C				Not Reported
	Xarelto 20 Mg, Comprimé Pelliculé			C				Not Reported
	Uvedose			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629392	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217991		40 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Mycobacterium Avium Complex Infection	Ciclosporin			S	Unknown			Ivax
	Prednisone			S	Unknown			Actavis
	Mycophenolate Mofetil			S	Unknown			Teva
	Azithromycin			S	Unknown	625 Milligram Daily;		Not Reported
	Ethambutol			S	Unknown	800 Milligram Daily;		Not Reported
	Rifampin			S	Unknown	300 Milligram Daily;		Not Reported
	Insulin			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629436	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1218648		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Oedema; Weight Increased	Esomeprazole			S	Oral			Teva
	Amlodipine			S	Oral	5mg		Teva
	Aerius (Desloratadine)			S	Oral	5mg		Not Reported
	Novopulmon Novolizer 200 Microgrammes/Dose, Poudre Pour Inhalation			S	Respiratory (inhalation)			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Rhinomaxil 100		S	Nasal					Not Reported
	Microgrammes/Dose, Suspension Pour Pulverisation								
	Nasale								
	Zithromax		S	Oral					Not Reported
	Lantus		C						Not Reported
	Eucreas 50 Mg/1000 Mg, Comprime Pellicule		C						Not Reported
	Novatrex 2,5 Mg, Comprime		C						Not Reported
	Transipeg		C						Not Reported
	Gliclazide		C						Not Reported
	Speciafoldine 5 Mg, Comprime		C						Not Reported
	Kardegic 75 Mg, Poudre Pour Solution Buvable En Sachet- Dose		C						Not Reported
	Inegy 10 Mg/40 Mg, Comprime		C						Not Reported
	Isoptine		C						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629659	NON-EXPEDITED			US-PFIZER INC- 2020137427		12 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17629818	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020136517		94 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Confusional State; Disorientation	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Invanz			S	Intravenous (not otherwise specified)	1 G, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17631235	EXPEDITED (15-DAY)		OT	CA-COVIS PHARMA B.V.-2020COV00140		43 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Bronchiectasis; Cardiac Murmur; Chronic Obstructive Pulmonary Disease; Gastroesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps; Oedema Peripheral; Rhinitis Allergic; Sarcoidosis; Total Lung Capacity Increased; Wheezing	Omnaris			S		Unk		Covis
	Atrovent			S				Not Reported
	Combivent			S		Unk		Not Reported
	Spiriva Respimat			S		18 Mg, 1x/Day		Not Reported
	Inspiolto Respimat			S				Not Reported
	Advair			S				Not Reported
	Avamys			S				Not Reported
	Azithromycin			S				Not Reported
	Breo Ellipta			S				Not Reported
	Ciprofloxacin Hydrochloride			S				Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, 1x/Day		Not Reported
	Moxifloxacin Hydrochloride			S				Not Reported
	Nasonex			S				Not Reported
	Prednisone			S				Not Reported
	Seebri			S				Not Reported
	Singulair			S				Not Reported
	Symbicort			S				Not Reported
	Ultibro Breezhaler			S				Not Reported
	Umeclidinium Bromide			S				Not Reported
	Umeclidinium Bromide; Vilanterol Trifenatate			S				Not Reported
	Ventolin			S		400 Mg, 1x/Day		Not Reported
	Xolair			S				Not Reported
	Zenhale			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17631525	EXPEDITED (15-DAY)		OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis	Spiriva			S	Unknown			Boehringer Ingelheim
	Azithromycin			S	Unknown			Not Reported
	Breo Ellipta			S	Unknown	Form: Inhalation		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Prednisone	S	Unknown					Not Reported	
	Salbutamol Sulfate	S	Unknown					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17631967	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1217475			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Asthenia;	Meloxicam			S	Unknown			Not Reported	
Choking; Cough; Drug	Azithromycin			S	Unknown			Not Reported	
Ineffective; Dry Mouth;	Methotrexate			S	Unknown			Barr	
Finger Deformity;	Etanercept			S	Unknown			Not Reported	
Headache; Malaise; Pain;	Xeljanz			S	Oral	10 Milligram Daily;		Not Reported	
Rheumatoid Arthritis;	Cetirizine			C				Not Reported	
Sinusitis; Skin Reaction	Hydroxychloroquine			C				Not Reported	
	Tylenol			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17632528	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SE47338		43 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma-Chronic	Omnamis			S	Respiratory			Not Reported	
Obstructive Pulmonary					(inhalation)				
Disease Overlap	Symbicort			S	Respiratory			Astrazeneca	
Syndrome; Bronchiectasis;					(inhalation)				
Cardiac Murmur; Chronic	Atrovent			S	Unknown			Not Reported	
Obstructive Pulmonary	Combivent			S	Unknown			Not Reported	
Disease;	Spiriva Respimat			S	Unknown			Not Reported	
Gastrooesophageal Reflux	Inspiolto Respimat			S	Unknown			Not Reported	
Disease; Lung Neoplasm	Advair			S	Unknown			Not Reported	
Malignant; Nasal Polyps;	Avamys			S	Unknown			Not Reported	
Oedema Peripheral;	Azithromycin			S	Unknown			Not Reported	
Rhinitis Allergic;									
Sarcoidosis; Total Lung									
Capacity Increased;									
Wheezing									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Breo Ellipta	S	Unknown	Not Reported
Ciprofloxacin Hydrochloride	S	Unknown	Not Reported
Mepolizumab	S	Unknown	Not Reported
Moxifloxacin Hydrochloride	S	Unknown	Not Reported
Nasonex	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Seebri	S	Unknown	Not Reported
Singulair	S	Unknown	Not Reported
Ultibro Breezhaler	S	Unknown	Not Reported
Umeclidinium Bromide	S	Unknown	Not Reported
Umeclidinium Bromide; Vilanterol	S	Unknown	Not Reported
Ventolin	S	Unknown	Not Reported
Xolair	S	Unknown	Not Reported
Zenhale	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17633313	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA-2020SE47334			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Bronchiectasis; Cardiac Murmur; Chronic Obstructive Pulmonary Disease;	Symbicort			S	Respiratory (inhalation)			Astrazeneca
Gastrooesophageal Reflux Disease; Lung Neoplasm Malignant; Nasal Polyps; Oedema Peripheral; Rhinitis Allergic; Sarcoidosis; Total Lung Capacity Increased; Wheezing	Omnaris			S	Respiratory (inhalation)			Not Reported
	Spiriva Respimat			S	Unknown			Not Reported
	Atrovent			S	Unknown			Not Reported
	Combivent			S	Unknown			Not Reported
	Inspiolto Respimat			S	Unknown			Not Reported
	Advair			S	Unknown			Not Reported
	Avamys			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Breo Ellipta	S	Unknown	Not Reported
Ciprofloxacin	S	Unknown	Not Reported
Mepolizumab	S	Unknown	Not Reported
Moxifloxacin	S	Unknown	Not Reported
Nasonex	S	Unknown	Not Reported
Prednisone	S	Unknown	Not Reported
Seebri	S	Unknown	Not Reported
Singulair	S	Unknown	Not Reported
Ultibro Breezhaler	S	Unknown	Not Reported
Umeclidinium Bromide	S	Unknown	Not Reported
Ventolin	S	Unknown	Not Reported
Xolair	S	Unknown	Not Reported
Zenhale	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17634144	EXPEDITED (15-DAY)		HO, OT	DE-PFIZER INC-2020139033		79 YR	Female	DEU

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Delirium	Azithromycin			S	Oral	500 Mg, Unk		Pfizer
	Edoxaban			S	Oral	30 Mg, Unk		Not Reported
	Ampicillin And Sulbactam			C	Intravenous (not otherwise specified)	3 G, 3x/Day		Not Reported
	Bisoprolol			C	Oral	2.5 Mg, 2x/Day 2,5-0-2,5mg		Not Reported
	Insuman Basal			C	Subcutaneous	4 Iu, 1x/Day 0-0-0-4iu		Not Reported
	Sitagliptin			C	Oral	100 Mg, 1x/Day		Not Reported
	Ceftriaxon			C	Oral	2 G, 1x/Day		Not Reported
	Candesartan			C	Oral	32 Mg, 1x/Day		Not Reported
	Amlodipine			C	Oral	5 Mg, 2x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17635635	EXPEDITED (15-DAY)		OT	CA-ROCHE-2575997			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Lymphoma	Xolair			S	Subcutaneous			Not Reported
	Alendronate Sodium Trihydrate			S	Oral			Not Reported
	Alendronate Sodium Trihydrate			S	Unknown			Not Reported
	Azithromycin			S	Oral			Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	8 Df		Not Reported
	Calcium Carbonate			C	Unknown			Not Reported
	Ciclesonide			C	Unknown			Not Reported
	Montelukast			C	Unknown			Not Reported
	Spiriva			C	Unknown			Not Reported
	Symbicort			C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2020	17635648	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-016886		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Oedema; Weight Increased	Amlodipine			S	Oral	5 Milligram, Once A Day		Aurobindo
	Esomeprazole			S	Oral	Unk		Aurobindo
	Novopulmon			S		Unk		Not Reported
	Rhinomaxil			S	Nasal	Unk		Not Reported
	Aerius (Desloratadine)			S	Oral	5 Milligram, Once A Day		Not Reported
	Novatrex			C	Unknown	Unk		Not Reported
	Zithromax			S	Oral	Unk		Not Reported
	Lantus			C	Unknown	Unk		Not Reported
	Eucreas			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transipeg	C	Unknown	Unk	Not Reported
Gliclazide	C	Unknown	Unk	Not Reported
Speciafoldine	C	Unknown	Unk	Not Reported
Kardegic	C	Unknown	Unk	Not Reported
Inegy	C	Unknown	Unk	Not Reported
Isoptine	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	12460020	NON-EXPEDITED			US-PFIZER INC-2016273157			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Celebrex			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	16976343	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR195163		60 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Asthma-Chronic Obstructive Pulmonary Disease Overlap Syndrome; Breath Sounds Abnormal; Bronchial Hyperreactivity; Bronchitis; Cardiac Disorder; Cardiomyopathy; Drug Ineffective; Drug Intolerance; Dyspnoea; Eosinophilia; Ischaemic Cardiomyopathy; Obstructive Airways Disorder; Pulmonary Function Test Abnormal	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z, Monthly		Glaxosmithkline	
	Advair Inhaler			S	Respiratory (inhalation)	2 Puff(S), Bid		Glaxosmithkline	
	Ventolin Hfa			S		2 Puff(S), Prn		Glaxosmithkline	
	Ventolin Hfa			S		2 Puff(S), Prn		Glaxosmithkline	
	Salbutamol Sulphate Hfa Apotex			S	Respiratory (inhalation)	2 Puff(S), Prn		Glaxosmithkline	
	Salbutamol Sulphate Hfa Apotex			S	Respiratory (inhalation)	2 Puff(S), Prn		Glaxosmithkline	
	Salbutamol Sulphate Hfa Apotex			S	Respiratory (inhalation)	2 Puff(S), Prn		Glaxosmithkline	
	Salbutamol Sulphate Hfa Apotex			S	Respiratory	2 Puff(S), Prn		Glaxosmithkline	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Salbutamol Sulphate Hfa Apotex	S	(inhalation) Respiratory (inhalation)	2 Puff(S), Prn	Glaxosmithkline
Incruse Ellipta	S		1 Puff(S), Qd	Glaxosmithkline
Singulair	S		10 Mg, Qd	Glaxosmithkline
Breo Ellipta	S	Respiratory (inhalation)	1 Df, Qd	Glaxosmithkline
Breo Ellipta	S	Respiratory (inhalation)	1 Df, Qd	Glaxosmithkline
Breo Ellipta	S	Respiratory (inhalation)	1 Df, Qd	Glaxosmithkline
Breo Ellipta	S	Respiratory (inhalation)	1 Df, Qd	Glaxosmithkline
Airomir	S		2 Puff(S), Qid	Glaxosmithkline
Airomir	S	Respiratory (inhalation)	2 Puff(S), Z (Every 4 Hours As Needed)	Glaxosmithkline
Airomir	S		2 Puff(S), Z (Every 4 Hours As Needed)	Glaxosmithkline
Montelukast Sodium	S		10 Mg, Qd	Not Reported
Montelukast Sodium	S		10 Mg, Qd	Not Reported
Montelukast Sodium	S		10 Mg, Qd	Not Reported
Montelukast Sodium	S		10 Mg, Qd	Not Reported
Montelukast Sodium	S		10 Mg, Qd	Not Reported
Montelukast Sodium	S	Oral	10 Mg, Qd	Not Reported
Montelukast Sodium	S	Oral	10 Mg, Qd	Not Reported
Montelukast Sodium	S	Oral	10 Mg, Qd	Not Reported
Montelukast Sodium	S	Oral	10 Mg, Qd	Not Reported
Apo-Doxy-Tabs	S		200 Mg, Qd	Not Reported
Apo-Doxy-Tabs	S		100 Mg, Bid	Not Reported
Spiriva Respimat	S		2 Puff(S), Qd	Not Reported
Alvesco	S		2 Puff(S), Bid	Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Alvesco	S		2 Puff(S), Bid	Not Reported
Alvesco	S		2 Puff(S), Bid	Not Reported
Apo-Furosemide	S		20 Mg, Qd	Not Reported
Apo-Furosemide	S		20 Mg, Qd	Not Reported
Apo-Furosemide	S		20 Mg, Qd	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Entresto	S	Oral	1 Df, Bid	Not Reported
Inspra (Eplerenone)	S		50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S		50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S		50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S		50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S		50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S	Oral	50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S	Oral	50 Mg, Qd	Not Reported
Inspra (Eplerenone)	S	Oral	50 Mg, Qd	Not Reported
Apo-Prednisone	S		50 Mg, Qd	Not Reported
Apo-Prednisone	S		40 Mg, Qd	Not Reported
Apo-Prednisone	S		50 Mg, Qd	Not Reported
Apo-Prednisone	S		5 Mg, Z	Not Reported
Apo-Prednisone	S		5 Mg, Z	Not Reported
Apo-Prednisone	S		5 Mg, Z	Not Reported
Apo-Prednisone	S		25 Mg, Qd	Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Apo-Prednisone	S		25 Mg, Qd	Not Reported
Apo-Prednisone	S		25 Mg, Qd	Not Reported
Apo-Prednisone	S		25 Mg, Qd	Not Reported
Apo-Prednisone	S	Oral	50 Mg, Qd	Not Reported
Apo-Prednisone	S	Oral	50 Mg, Qd	Not Reported
Apo-Prednisone	S		50 Mg, Qd	Not Reported
Apo-Prednisone	S		50 Mg, Qd	Not Reported
Apo-Prednisone	S	Oral	50 Mg, Qd	Not Reported
Pregabalin Sandoz	S	Oral	50 Mg, Bid	Not Reported
Apo-Tramadol/Acet	S	Oral	Unk, 1-2 Tablest Every 4 Hours As Needed	Not Reported
Mar-Ketorolac	S	Oral	10 Mg, Tid	Not Reported
Cyclobenzaprine	S	Oral	10 Mg, Tid	Not Reported
Champix Starter Pack	S		Unk	Not Reported
Seebri Breezhaler	S	Respiratory (inhalation)	1 Df, Qd	Not Reported
Seebri Breezhaler	S	Respiratory (inhalation)	50 Ug, Qd	Not Reported
Seebri Breezhaler	S	Respiratory (inhalation)	50 Ug, Qd	Not Reported
Pms-Azithromycin	S		250 Mg	Not Reported
Act (Amlodipine)	S		2.5 Mg, Qd	Not Reported
Teva-Spironolactone	S		12.5 Mg, Qd	Not Reported
Pms-Carvedilol	S		6.25 Mg, Bid	Not Reported
Coversyl	S		8 Mg, Qd	Not Reported
Coversyl Plus Hd	S		1 Df (Tablet), Qd	Not Reported
Coversyl Plus Hd	S		1 Df (Tablet), Qd	Not Reported
Coversyl Plus Hd	S		1 Df (Tablet), Qd	Not Reported
Coversyl Plus Hd	S		1 Df (Tablet), Qd	Not Reported
Coversyl Plus Hd	S		1 Df (Tablet), Qd	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Coversyl Plus Hd	S		1 Df (Tablet), Qd	Not Reported
Atrovent Hfa	S	Respiratory (inhalation)	20 Ug, Qid	Not Reported
Apo-Bisoprolol	S		2.5 Mg, Qd	Not Reported
Apo-Bisoprolol	S		0.25 Df, Qd, 5 Mg	Not Reported
Teva-Montelukast	S		10 Mg, Qd	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	1 Df, Bid	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	1 Df, Bid	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	1 Df, Bid	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	1 Df, Bid	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	1 Df, Bid	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	1 Df, Bid	Not Reported
Symbicort 200 Turbuhaler	S	Respiratory (inhalation)	2 Df, Qid	Not Reported
Zenhale	S		Unk	Not Reported
Zenhale	S	Respiratory (inhalation)	2 Puff(S), Bid	Not Reported
Ivabradine Hydrochloride	S	Oral	7.5 Mg, Bid	Not Reported
Apo-Doxy	S		100 Mg, Bid	Not Reported
Apo-Doxy	S	Oral	100 Mg, Bid	Not Reported
Apo-Doxy	S		100 Mg, Z	Not Reported
Apo-Doxy	S		100 Mg, Bid	Not Reported
Apo-Doxy	S	Oral	100 Mg, Bid	Not Reported
Apo-Doxy	S	Oral	100 Mg, Bid	Not Reported
Flu Vaccine	C			Glaxosmithkline

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17477701	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1192394		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Rhabdomyolysis	Azithromycine Monohydratée			S	Oral	500 Mg 1 Days		Not Reported	
	Oxomemazine			S	Oral			Not Reported	
	Seretide			C				Not Reported	
	Contraceptif Oestroprogestatif			C				Not Reported	
	Non Precise								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17532751	NON-EXPEDITED			US-PFIZER INC-2020107309		75 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Erythromycin Base			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17557559	EXPEDITED (15-DAY)		OT	CA-JNJFOC-20200318949			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Simponi			S	Subcutaneous	Pms		Janssen	
	Arava			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Benadryl /00000402/			S	Unknown			Not Reported	
	Celebrex			S	Oral			Not Reported	
	Cimzia			S	Subcutaneous			Not Reported	
	Demerol			S	Unknown			Not Reported	
	Enbrel			S	Unknown			Not Reported	
	Humira			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imuran /00001501/	S	Unknown	Not Reported
Levofloxacin	S	Unknown	Not Reported
Methotrexate	S	Unknown	Not Reported
Plaquenil /00072602/	S	Unknown	Not Reported
Procytox	S	Intravenous (not otherwise specified)	Not Reported
Tofacitinib Citrate	S	Oral	Not Reported
Ezetrol	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17580111	NON-EXPEDITED			US-PFIZER INC-2020123676		74 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Zithromax			S		Unk		Pfizer	
	Cetirizine			S		Unk		Not Reported	
	Praluent			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17634310	EXPEDITED (15-DAY)		OT	CA-ROCHE-2577225		54 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthralgia; Back Pain; Blood Pressure Systolic Increased;	Xolair			S	Subcutaneous			Not Reported	
Coccydynia; Contusion;	Pantoprazole			S	Unknown			Not Reported	
Crying; Discomfort;	Montelukast			S	Unknown			Not Reported	
Dizziness Exertional; Dry Skin; Dyspnoea;	Atorvastatin Calcium			S	Unknown			Not Reported	
Dyspnoea Exertional; Ear Pain; Emotional Disorder;	Fentanyl			S	Unknown			Not Reported	
Fall; Fatigue; Feeling Abnormal; Headache;	Azithromycin			S	Unknown			Not Reported	
Heart Rate Increased;	Advair			C	Unknown			Not Reported	
Myalgia; Nausea; Oxygen	Prednisone			C	Unknown			Not Reported	
	Reactine [Cetirizine			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Saturation Decreased; Pain In Extremity; Respiratory Rate Increased; Scratch; Vision Blurred	Hydrochloride] Spiriva Ventolin [Salbutamol]	C	Unknown	Not Reported
		C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17636607	NON-EXPEDITED			US-PFIZER INC- 2020141260		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Vaginal Infection	Zithromax			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17639031	NON-EXPEDITED			US-SLATE RUN PHARMACEUTICALS- SLTR-AE-20-10		83 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Kidney Injury;	Enteric-Coated Aspirin			C				Not Reported
Ascites; Dyspnoea;	Digoxin			C				Not Reported
Ejection Fraction	Donepezil			C				Not Reported
Decreased; Hepatic	Memantine			C				Not Reported
Enzyme Increased;	Fluoxetine			C				Not Reported
Hepatomegaly;	Latanoprost			C				Not Reported
International Normalised	Metformin			C				Not Reported
Ratio Increased; Left	Glipizide			C				Not Reported
Ventricular Failure; Mental	Rivaroxaban			C				Not Reported
Impairment; Oedema	Ceftriaxone			C	Intravenous (not otherwise specified)			Not Reported
Peripheral	Hydrocodone			C	Oral			Not Reported
	Acetaminophen			C	Oral			Not Reported
	Cholecalciferol			C				Not Reported
	Piperacillin-Tazobactam			C	Intravenous (not otherwise specified)	4.5g Iv Loading Dose		Not Reported
	Vancomycin			C	Intravenous (not otherwise specified)	3000 Mg Iv Loading Dose		Not Reported
	Furosemide			C	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

70436-019-82 Azithromycin For Injection Dry Vial Usp 500 Mg S otherwise specified) Intravenous (not otherwise specified) Hainan Poly Pharmaceuticals

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2020	17641490	EXPEDITED (15-DAY)		HO	FR-009507513-2004FRA000607		69 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Generalised Oedema; Weight Increased	Aerius (Desloratadine)			S	Oral	5 Milligram, Qd		Merck
	Novopulmon Novolizer			S	Respiratory (inhalation)	Unk		Not Reported
	Rhinomaxil			S	Nasal	Suspension For Nasal Pulverisation		Not Reported
	Esomeprazole			S	Oral	Unk		Not Reported
	Amlodipine			S	Oral	5 Milligram, Qd		Not Reported
	Zithromax			S	Oral	Unk		Not Reported
	Lantus			C		Unk		Not Reported
	Eucreas			C		Unk		Not Reported
	Novatrex (Methotrexate)			C		Unk		Not Reported
	Transipeg			C		Unk		Not Reported
	Gliclazide			C		Unk		Not Reported
	Speciafoldine			C		Unk		Not Reported
	Kardegic			C		Powder For Oral Solution In Single-Dose Sachet		Not Reported
	Kardegic			C		Powder For Oral Solution In Single-Dose Sachet		Not Reported
	Inegy			C		Unk		Merck
Isoptine			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17640822	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-016731		66 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hyponatraemia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Coaprovel			S	Oral	1 Dosage Form, Once A Day		Not Reported
	Nebivolol			C	Unknown	Unk		Not Reported
	Amoxicillin			C	Unknown	Unk		Not Reported
	Xarelto			C	Unknown	Unk		Not Reported
	Uvedose			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17642163	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS,I NC./RIDGEFIELD-2020- BI-01		74 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Adenocarcinoma; Asthma; Blood Count Abnormal; Breath Sounds Abnormal; Emphysema; Eosinophilia; Gastrooesophageal Reflux Disease; Hypercapnia; Hypertension; Hyperthyroidism; Influenza; Multiple Allergies; Osteoporosis; Pain In Extremity; Pneumonitis; Pneumothorax Spontaneous; Polymyalgia Rheumatica; Productive Cough; Respiratory Tract Infection; Upper Respiratory Tract Infection	Spiriva			S	Unknown			Boehringer Ingelheim
	Azithromycin			S	Unknown			Not Reported
	Calcium			S	Unknown			Not Reported
	Hydrochlorothiazide			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Pantoprazole			S	Unknown			Not Reported
	Potassium Chloride			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Rabeprazole			S	Unknown			Not Reported
	Roflumilast			S	Unknown			Not Reported
	Salbutamol			S	Unknown			Not Reported
	Salbutamol Sulfate			S	Unknown			Not Reported
	Symbicort Turbuhaler			S	Unknown	Dosage Form: Powder		Not Reported
Thyroxine			S	Unknown			Not Reported	
Vitamin D [Vitamin D Nos]			S	Unknown			Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17644271	NON-EXPEDITED			US-PFIZER INC-2020143650		65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Betaine			S		Unk		Not Reported	
	Inositol			S		Unk		Not Reported	
	Inositol Niacinate			S		Unk		Not Reported	
	Niacin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17644417	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002359			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17646286	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002360			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17646292	EXPEDITED (15-DAY)		DE, OT	US-ADVANZ PHARMA-202003002361			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death; Ventricular Fibrillation	Hydroxychloroquine			S		Unk		Concordia	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S		Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17647110	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020140352		38 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Amenorrhoea; Hot Flush; Premature Menopause	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Humira			S	Subcutaneous	24 Mg, Monthly		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17650680	NON-EXPEDITED			US-AKRON, INC.-2082540			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pruritus; Pinguecula	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Apr-2020	17651582	DIRECT	Y	OT			79 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral			Not Reported	
	Amiodarone			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	14585613	NON-EXPEDITED			US-PFIZER INC-2018083742		48 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
	Metformin			S		Unk		Not Reported	
	Victoza			S		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	15255116	NON-EXPEDITED			US-PFIZER INC-2018317770		13 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	16575464	EXPEDITED (15-DAY)		OT	CA-BRISTOL-MYERS SQUIBB COMPANY-BMS-2019-068760			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Kenalog			S	Intra-articular	Unk		Bristol Myers Squibb	
	Amoxicillin Trihydrate			S	Unknown	Unk		Bristol Myers Squibb	
	Triamcinolone Acetonide			S	Intra-articular			Bristol Myers Squibb	
	Paracetamol			S	Unknown	Unk		Bristol Myers Squibb	
	Atorvastatin			S	Unknown			Not Reported	
	Atropine Sulfate;Diphenoxylate Hydrochloride			S	Oral			Not Reported	
	Acetaminophene			S	Unknown	Unk		Not Reported	
	Morphine Sulphate			S	Unknown			Not Reported	
	Alprazolam			S	Unknown	Unk		Not Reported	
	Apo Hydro			S	Unknown	Unk		Not Reported	
	Atorvastatin Calcium			S	Unknown	Unk		Not Reported	
	Avamys			S	Unknown	Unk		Not Reported	
	Ascorbic Acid;Copper;Tocopherol;Xantofy I;Zeaxanthin;Zinc			S	Unknown			Not Reported	
	Azithromycin Dihydrate			S	Unknown	Unk		Not Reported	
	Bactroban [Mupirocin]			S	Unknown	Unk		Not Reported	
	Betaderm [Betamethasone]			S	Unknown	Unk		Not Reported	
	Betamethasone Dipropionate			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Biacin XL	S	Unknown	Unk	Not Reported
Bisacodyl	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Magnesium Sulfate	S	Unknown	Unk	Not Reported
Vitamin D3	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Clotrimazole	S	Unknown	Unk	Not Reported
Cupric Oxide	S	Unknown	Unk	Not Reported
DL-Alpha Tocopheryl Acetate	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	S	Unknown	Unk	Not Reported
Zeaxanthin	S	Unknown	Unk	Not Reported
Zinc Oxide	S	Unknown	Unk	Not Reported
Desonide	S	Unknown	Unk	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	S	Unknown	Unk	Not Reported
Entocort	S	Unknown	Unk	Not Reported
Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk	Not Reported
Glycerine	S	Oral	Unk	Not Reported
Gramicidin;Neomycin Sulfate;Polymyxin B Sulfate	S	Unknown	Unk	Not Reported
Nicotine	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous		Not Reported
Lomotil [Atropine Sulfate;Diphenoxylate Hydrochloride]	S	Oral	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride;So	S	Unknown	Unk	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ms Ir	S	Unknown		Not Reported
Mupirocin	S	Topical	Unk	Not Reported
Nadolol	S	Unknown		Not Reported
Nicoderm	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	S	Unknown		Not Reported
Pantoprazole	S	Unknown		Not Reported
Pentasa	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown		Not Reported
Pulmicort	S	Unknown	Unk	Not Reported
Refresh Tears	S	Ophthalmic		Not Reported
Salinex [Sodium Chloride]	S	Nasal		Not Reported
Sinus Rinse	S	Nasal	Unk	Not Reported
Statex [Morphine Sulfate]	S	Unknown		Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown		Not Reported
Habitrol [Nicotine]	S	Unknown	Unk	Not Reported
Cetirizine Dihydrochloride	S	Unknown		Not Reported
Bactrim	S	Unknown		Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	S	Oral		Not Reported
Calcium Carbonate/Vitamin D3	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown		Not Reported
Mupirocin Calcium	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	16918267	EXPEDITED (15-DAY)		DE, LT, OT	IT-AUROBINDO-AUR-APL-2019-066585		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister;	Allopurinol			S	Unknown	150 Milligram, Once A Day		Not Reported	
Conjunctivitis;	Azithromycin			S	Unknown	Unk		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Epidermolysis; Mucosal
Inflammation;
Oropharyngeal Pain;
Pyrexia; Toxic Epidermal
Necrolysis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17024583	EXPEDITED (15-DAY)		HO, LT, OT	PT-AUROBINDO-AUR- APL-2019-070240		72 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Dermatitis; Erythema; Hypersensitivity; Malaise; Pharyngeal Enanthema; Pruritus; Stevens-Johnson Syndrome; Transaminases Increased	Azithromycin			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17041740	EXPEDITED (15-DAY)		HO	PT-AUROBINDO-AUR- APL-2019-073330		78 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Infection; Pyrexia; Sepsis; Uterine Prolapse; Vulvovaginal Candidiasis	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S				Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Aurobindo	
	Ceftriaxone			S				Aurobindo	
	Ceftriaxone			S				Aurobindo	
	Econazole			C	Unknown	Unk		Not Reported	
	Fluconazole			C	Oral	300 Milligram, 3 Times A Day(2 Doses Of 150 Mg Every 72 Hours)		Not Reported	
	Fluconazole			C	Oral	2 Dosage Form, 72 Hourly(2 Doses Of 150 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Every 72 Hours)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17492535	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR- APL-2020-010283		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anuria; Decreased Appetite; General Physical Health Deterioration; Myalgia; Rhabdomyolysis; Transaminases Increased; Vomiting	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Oxomemazine			S	Oral	Unk		Not Reported	
	Seretide			C	Unknown	Unk		Not Reported	
	Progesterone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17511447	EXPEDITED (15-DAY)		HO, OT	FR-PFIZER INC- 2020096898		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anuria; Decreased Appetite; General Physical Health Deterioration; Myalgia; Rhabdomyolysis; Transaminases Increased; Vomiting	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Oxomemazine			S	Oral	Unk		Not Reported	
	Seretide			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17647625	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-243269		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
	Coaprovel 300 Mg/12,5 Mg, Comprime			S	Oral	1 Dosage Form, Daily		Not Reported	
	Nebivolol			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Amoxicilline	C	Unknown	Unk	Not Reported
Xarelto 20 Mg, Comprime Pellicule	C	Unknown	Unk	Not Reported
Uvedose	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17647770	EXPEDITED (15-DAY)		OT	CA-SAMSUNG BIOEPIS-SB-2020-11139			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Asthenia; Choking; Cough; Drug Ineffective; Dry Mouth; Finger Deformity; Headache; Malaise; Pain; Rheumatoid Arthritis; Sinusitis; Skin Reaction	Etanercept			S	Unknown	Unknown		Not Reported
	Azithromycin			S	Unknown	Unknown		Not Reported
	Meloxicam			S	Unknown	Unknown		Not Reported
	Methotrexate			S	Unknown	Unknown		Not Reported
	Xeljanz			S	Oral			Not Reported
	Cetirizine			C	Unknown	Unknown		Not Reported
	Hydroxychloroquine			C	Unknown	Unknown		Not Reported
	Tylenol			C	Unknown	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17647958	EXPEDITED (15-DAY)		HO	CA-ROCHE-2578691		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anaemia; Aspiration; Asthenia; Asthma; Blood Calcium Increased; Blood Creatinine Increased; Bronchiectasis; Bronchopulmonary Aspergillosis Allergic; Constipation; Cough; Drug Hypersensitivity; Drug Ineffective; Dyspnoea;	Xolair			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Candesartan			S	Oral	8 Mg, Qd		Not Reported
	Lansoprazole			S	Unknown	Unk		Not Reported
	Montelukast			S	Oral	10 Mg, Qd		Not Reported
	Morphine			S	Unknown	10 Mg		Not Reported
	Nitroglicerina			S	Unknown	Unk		Not Reported
	Pramipexole			S	Oral	0.5 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fatigue;	Pramipexole	S	Oral	0.25 Mg	Not Reported
Gastroesophageal Reflux Disease; Haemoptysis;	Pregabalin	S	Oral	75 Mg	Not Reported
Headache; Hypoxia; Liver Function Test Increased;	Quetiapine	S	Unknown	Unk	Not Reported
Lower Respiratory Tract Infection; Lung Opacity;	Ranitidine	S	Unknown	Unk	Not Reported
Musculoskeletal Stiffness; Obstructive Airways Disorder; Oedema	Risedronate	S	Unknown	Unk	Not Reported
Peripheral; Pain; Pleural Effusion; Pneumonia;	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
Pulmonary Fibrosis;	Sennosides	S	Unknown	Unk	Not Reported
Pyrexia; Rales; Sputum Discoloured; Total Lung Capacity Decreased;	Zopiclone	S	Unknown	Unk	Not Reported
Transaminases Increased;	Acetaminophen	S	Unknown	1000 Mg	Not Reported
Tremor; Upper Respiratory Tract Infection; Wheezing	Prevnar	S	Unknown	Unk	Not Reported
	Budesonide	S	Unknown	Unk	Not Reported
	Dexilant	S	Unknown	Unk	Not Reported
	Domperidone	S	Unknown	Unk	Not Reported
	Efinaconazole	S	Unknown	Unk	Not Reported
	Influenza Vaccine	S	Unknown	Unk	Not Reported
	Levothyroxine Sodium	S	Unknown	Unk	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Nasonex	S	Unknown	Unk	Not Reported
	Pantoloc [Pantoprazole]	S	Unknown	Unk	Not Reported
	Senokot	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	1 Df, Qd	Not Reported
	Statex [Morphine Sulfate]	S	Oral	10 Mg	Not Reported
	Symbicort	S	Unknown	2 Df, Bid	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Trazodone	S	Unknown	10 Mg	Not Reported
	Trazodone	S	Unknown	12.5 Mg	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ventolin [Salbutamol]			S	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17648526	EXPEDITED (15-DAY)	HO		SK-TEVA-2020-SK-1220114		74 YR	Female	SVK
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Frequent Bowel Movements	Azithromycin			S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17650468	EXPEDITED (15-DAY)	HO		FR-PFIZER INC-2020142584		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Oedema; Weight Increased	Esomeprazole Magnesium			S	Oral	Unk			Pfizer
	Amlodipine Besilate			S	Oral	5 Mg, 1x/Day			Pfizer
	Zithromax			S	Oral	Unk			Pfizer
	Aerius [Desloratadine]			S	Oral	5 Mg, 1x/Day			Not Reported
	Novopulmon			S	Respiratory (inhalation)	Unk			Not Reported
	Rhinomaxil			S	Nasal	Unk			Not Reported
	Lantus			C		Unk			Not Reported
	Eucreas			C		Unk			Not Reported
	Novatrex [Methotrexate]			C		Unk			Not Reported
	Transipeg [Macrogol]			C		Unk			Not Reported
	Gliclazide			C		Unk			Not Reported
	Speciafoldine			C					Not Reported
	Kardegic			C		Unk			Not Reported
	Inegy			C		Unk			Not Reported
	Isoptine			C		Unk			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652024	EXPEDITED (15-DAY)		HO	IT-PFIZER INC-2020142626		57 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Shock; Chills; Nausea; Rash Pruritic; Syncope; Vomiting	Zitromax			S	Oral	Unk		Pfizer	
	Tachidol			S	Oral	Unk		Not Reported	
	Zelitrex			S	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652790	NON-EXPEDITED			US-GILEAD-2020-0458399		27 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bowel Movement Irregularity; Weight Increased	Cayston			S	Respiratory (inhalation)	75 Mg, Tid		Gilead	
	Cayston			S				Gilead	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Apr-2020	17652981	EXPEDITED (15-DAY)		HO, OT	CA-B.I. PHARMACEUTICALS, I NC./RIDGEFIELD-2020- BI-01		24 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ankle Fracture; Asthma; Condition Aggravated; Ligament Sprain; Osteonecrosis	Spiriva			S	Unknown			Boehringer Ingelheim	
	Advair			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Mepolizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Mepolizumab			S				Not Reported	
	Prednisone			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Singulair	S	Unknown	Not Reported
Ventolin [Salbutamol]	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	16988218	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2019-070763		77 YR	Female	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Bullous; Drug Ineffective; Erythema; Genital Ulceration; Pemphigoid; Pharyngeal Ulceration	Azithromycin			S	Unknown	Unk		Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17560114	NON-EXPEDITED			US-PFIZER INC- 2020119016		86 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Zithromax			S		Unk		Pfizer
	Methylprednisolone			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17654666	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR- 1221569			Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycine Dihydratee			S	Oral	500 Mg		Not Reported
	Plaquenil 200 Mg, Comprime Enrobe			S	Oral	600 Mg		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17655524	NON-EXPEDITED			US-PFIZER INC- 2020147352			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cough; Fatigue	Azithromycin			S		Unk		Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
	Azithromycin			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17655601	NON-EXPEDITED			NVSC2020US096505		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Maternal Exposure During Pregnancy; Premature Delivery	Azithromycin			S	Unknown	Unk		Novartis	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656611	DIRECT	Y	OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine 400 Mg			C				Not Reported	
	Hydroxychloroquine 200 Mg			C				Not Reported	
	Lopinavir-Ritonavir 400 Mg-100 Mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656625	DIRECT	Y	OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronavirus Test Positive; Electrocardiogram Abnormal; Sinus Tachycardia	Azithromycin			S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine 400 Mg			C				Not Reported	
	Hydroxychloroquine 200 Mg			C				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656705	NON-EXPEDITED			NVSC2020US097495		5 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Product Use In Unapproved Indication	Clofazimine			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Rifampicin			S	Unknown	Unk		Not Reported	
	Amikacin			S	Unknown	Unk		Not Reported	
	Ethambutol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17656954	NON-EXPEDITED			US-PFIZER INC-2020148468			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Tramadol			S		Unk		Not Reported	
	Budesonide			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2020	17657199	EXPEDITED (15-DAY)		OT	US-PFIZER INC-2020150173			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diabetes Mellitus	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Apr-2020	15100757	EXPEDITED (15-DAY)		OT	CA-ROCHE-1813565		41 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Arthropathy; Blood Pressure Increased;	Xolair			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Burning Sensation; Chest	Xolair	S	Subcutaneous	Not Reported
Pain; Cough; Cystitis;	Xolair	S	Subcutaneous	Not Reported
Dizziness; Drug	Xolair	S	Subcutaneous	Not Reported
Ineffective; Erythema; Fall;	Xolair	S	Subcutaneous	Not Reported
Fatigue; Feeling	Xolair	S	Subcutaneous	Not Reported
Abnormal; Gait Inability;	Xolair	S	Subcutaneous	Not Reported
Hangover; Heart Rate	Xolair	S	Subcutaneous	Not Reported
Increased; Histamine	Xolair	S	Subcutaneous	Not Reported
Level Increased; Incorrect	Xolair	S	Subcutaneous	Not Reported
Dose Administered;	Xolair	S	Subcutaneous	Not Reported
Influenza Like Illness;	Xolair	S	Subcutaneous	Not Reported
Injection Site Dryness;	Xolair	S	Subcutaneous	Not Reported
Injection Site Pain; Lip	Xolair	S	Subcutaneous	Not Reported
Swelling; Middle Insomnia;	Xolair	S	Subcutaneous	Not Reported
Mobility Decreased;	Xolair	S	Subcutaneous	Not Reported
Muscular Weakness;	Xolair	S	Subcutaneous	Not Reported
Myalgia; Nasopharyngitis;	Xolair	S	Subcutaneous	Not Reported
Pain; Pain In Extremity;	Xolair	S	Subcutaneous	Not Reported
Painful Respiration;	Xolair	S	Subcutaneous	Not Reported
Peripheral Swelling;	Xolair	S	Subcutaneous	Not Reported
Product Storage Error;	Xolair	S	Subcutaneous	Not Reported
Pruritus; Rash;	Xolair	S	Subcutaneous	Not Reported
Respiratory Tract	Xolair	S	Subcutaneous	Not Reported
Infection; Scratch;	Xolair	S	Subcutaneous	Not Reported
Sensation Of Foreign	Xolair	S	Subcutaneous	Not Reported
Body; Stress; Swelling;	Xolair	S	Subcutaneous	Not Reported
Thyroid Hormones	Xolair	S	Subcutaneous	Not Reported
Increased; Thyroid Mass;	Xolair	S	Subcutaneous	Not Reported
Tooth Fracture; Urticaria;	Xolair	S	Subcutaneous	Not Reported
Urticaria; Urticaria	Xolair	S	Subcutaneous	Not Reported
Vesiculosa	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Xolair	S	Subcutaneous	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Azithromycin	S		Not Reported
	Azithromycin	S		Not Reported
	Azithromycin	S		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pantoprazole	C	Unknown	40 Mg, Qd	Not Reported
Hydroxyzine	C	Unknown	40 Mg, Qd	Not Reported
Reactine [Cetirizine Hydrochloride]	C	Unknown	2 Df, Qd	Not Reported
Prednisone	C	Unknown	1 Df, Other	Not Reported
Cetirizine	C	Unknown	2 Df, Qd	Not Reported
Nystatin	C	Unknown	40 Mg, Qd	Not Reported
Pepcid [Famotidine]	C	Unknown	40 Mg, Qd	Not Reported
Ventolin [Salbutamol]	C	Unknown	40 Mg, Qd	Not Reported
Metronidazole	C	Unknown	70 Mg	Not Reported
Fucidin [Fusidic Acid]	C	Unknown	Unk	Not Reported
Demulen-28	C	Unknown	Unk	Not Reported
Zoloft	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Apr-2020	15491462	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2018-049503		85 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anticoagulation Drug	Azithromycin			S	Unknown	Unk		Aurobindo
Level Above Therapeutic;	Cefuroxime			S	Unknown	Unk		Aurobindo
Drug Interaction; Labelled	Warfarin			S	Unknown	Unk		Not Reported
Drug-Drug Interaction								
Medication Error;								
Peripheral Swelling;								
Toxicity To Various Agents								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17371908	EXPEDITED (15-DAY)		LT, OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-235720		74 YR	Male	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pneumonia Necrotising; Pneumothorax; Pulmonary	Azithromycin			S	Unknown	Unk		Sun

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Fistula; Subcutaneous	Cefepime	S	Unknown	Unk	Not Reported
Emphysema; Treatment Failure	Vancomycin Hydrochloride	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17658773	EXPEDITED (15-DAY)		HO, OT	CA-TAKEDA-2020TJP006975		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Risedronate Sodium			S	Unknown	Unk		Not Reported
Anaemia; Aspiration;	Fluvaccin			S	Unknown	Unk		Not Reported
Asthenia; Asthma; Blood	Lansoprazole			S	Unknown	Unk		Takeda
Calcium Increased; Blood	Morphine			S	Unknown	10 Milligram		Not Reported
Creatinine Increased;	Acetaminophen			S	Unknown	1000 Milligram		Not Reported
Blood Test Abnormal;	Atrovent			S	Unknown	Unk		Not Reported
Bronchiectasis;	Azithromycin			S	Unknown	Unk		Not Reported
Bronchopulmonary	Budesonide			S	Unknown	Unk		Not Reported
Aspergillosis Allergic;	Candesartan			S	Oral	8 Milligram, Qd		Not Reported
Constipation; Cough; Drug	Dexilant			S	Unknown	Unk		Takeda
Hypersensitivity; Drug	Domperidone			S	Unknown	Unk		Not Reported
Ineffective; Dyspnoea;	Efinaconazole			S	Unknown	Unk		Not Reported
Fatigue;	Levothyroxine Sodium			S	Unknown	Unk		Not Reported
Gastrooesophageal Reflux	Mepolizumab			S	Unknown	100 Milligram		Not Reported
Disease; Haemoptysis;	Mepolizumab			S	Unknown	100 Milligram		Not Reported
Headache; Hypoxia; Liver	Montelukast			S	Oral	10 Milligram, Qd		Not Reported
Function Test Increased;	Nasonex			S	Unknown	Unk		Not Reported
Lower Respiratory Tract	Nitroglycerin			S	Unknown	Unk		Not Reported
Infection; Lung Opacity;	Pantoloc			S	Unknown	Unk		Not Reported
Musculoskeletal Stiffness;	Pantoloc			S	Unknown	Unk		Not Reported
Obstructive Airways	Pramipexole			S	Oral	0.25 Milligram		Not Reported
Disorder; Oedema	Pramipexole			S	Oral	0.5 Milligram		Not Reported
Peripheral; Pain; Pleural								
Effusion; Pneumonia;								
Pulmonary Fibrosis;								
Pyrexia; Rales; Sputum								
Discoloured; Total Lung								
Capacity Decreased;								
Transaminases Increased;								
Tremor; Upper Respiratory								
Tract Infection; Wheezing								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pregabalin	S	Oral	75 Milligram	Not Reported
Prevnar	S	Unknown	Unk	Not Reported
Quetiapine	S	Unknown	Unk	Not Reported
Ranitidine	S		Unk	Not Reported
Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
Sennoside A+B	S	Unknown	Unk	Not Reported
Senokot /00142201/	S	Unknown	Unk	Not Reported
Singulair	S	Unknown	Unk	Not Reported
Spiriva	S	Unknown	1 Dosage Form, Qd	Not Reported
Statex (Morphine Sulfate)	S	Oral	10 Milligram	Not Reported
Symbicort	S	Unknown	2 Dosage Form, Bid	Not Reported
Synthroid	S	Unknown	Unk	Not Reported
Trazodone	S	Unknown	10 Milligram	Not Reported
Trazodone	S	Unknown	10 Milligram	Not Reported
Ventolin /00139501/	S	Unknown	Unk	Not Reported
Vitamin D Nos	S	Oral	Unk	Not Reported
Xolair	S	Unknown		Not Reported
Zopiclone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17660317	NON-EXPEDITED			US-PFIZER INC-2020147388		38 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication; Therapeutic Response Unexpected	Azithromycin			S		Unk		Pfizer	
	Hydroxychloroquine Sulfate			S		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17661808	EXPEDITED (15-DAY)		OT	NL-MYLANLABS-2020M1035752		52 YR	Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Diarrhoea; Dysgeusia; Haematochezia; Vomiting	Azithromycine Mylan 200 Mg/5 MI, Poeder Voor Orale Suspensie			S	Oral	1 Dosage Form, Qd(1x Per Day One Bottle)		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662053	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1223033		54 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Azithromycine Anhydre			S	Oral	Unknown Dosage		Not Reported	
	Plaquenil			S	Oral	800 Mg		Not Reported	
	Augmentin			C	Oral	Unknown Dosage		Not Reported	
	Hypnovel			C				Not Reported	
	Sufentanil			C				Not Reported	
	Etomidate			C				Not Reported	
	Tracrium			C				Not Reported	
	Esmeron			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662417	EXPEDITED (15-DAY)		OT	US-ADVANSZ PHARMA-202003003386			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Zinc Salt Nos			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662455	EXPEDITED (15-DAY)		OT	NVSC2020US097523			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Foetal Exposure During Pregnancy; Low Birth Weight Baby; Premature Baby	Azithromycin			S	Transplacental	Unk (Maternal Dose)		Novartis	
	Ceftriaxone			S	Transplacental	Unk (Maternal Dose)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17662561	EXPEDITED (15-DAY)		HO	NVSC2020CZ097131		71 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Eosinophil Count Decreased	Azithromycin			S	Unknown	Unk		Novartis	
	Roflumilast			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17663379	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-018198			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo	
	Ibuprofen			S	Unknown	Unk		Aurobindo	
	Paracetamol			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Apr-2020	17664526	DIRECT	Y	HO, LT			81 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaphylactic Reaction; Pharyngeal Swelling; Respiratory Distress; Stridor	Azithromycin (Azithromycin 250mg Tab)			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	12949488	NON-EXPEDITED			US-PFIZER INC-2016528224		50 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Lovenox			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17523799	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-240048		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anuria; Decreased Appetite; General Physical Health Deterioration; Myalgia; Rhabdomyolysis; Transaminases Increased; Vomiting	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Oxomemazine			S	Oral	Unk		Not Reported	
	Seretide			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17640603	EXPEDITED (15-DAY)		OT	GB-AUROBINDO-AUR- APL-2020-016783			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	1 Gram Once Total		Aurobindo	
	Azithromycin			S	Oral	2 Gram Once Total		Aurobindo	
	Ceftriaxone Sodium			S	Intramuscular	500 Milligram Once Total		Not Reported	
	Ceftriaxone Sodium			S	Intramuscular	1 Gram Once Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17656876	EXPEDITED (15-DAY)		LT	US-PFIZER INC- 2020148479		70 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Electrocardiogram Qt	Azithromycin			S	Oral	500 Mg, Daily (500 Mg On Day 1)		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prolonged; Ventricular Fibrillation	Azithromycin	S	Oral	250 Mg, Daily (Followed By 250 Mg Daily For 4 Days)	Pfizer
	Hydroxychloroquine	S	Oral	400 Mg, 2x/Day (400 Mg Twice Daily On Day 1)	Not Reported
	Hydroxychloroquine	S	Oral	400 Mg, 1x/Day (Followed By 400 Mg Daily For 4 Days)	Not Reported
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17663632	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018207		52 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo
	Azithromycin			S				Aurobindo
	Paracetamol			S	Oral	1 Gram, 3 Times A Day (1gr Cada 8 Horas)		Aurobindo
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day (Dia)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day (Dia)		Not Reported
	Dolquine			S				Not Reported
	Simvastatina Alter			S	Oral	0-0-1		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17666021	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020147311		17 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug-Induced Liver Injury; Hepatic Encephalopathy; Hepatic Failure; Hepatitis	Zithromax			S		1 Df, Daily (Every 24 Hours)		Pfizer

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Acute; Hepatitis Viral

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17666662	NON-EXPEDITED			NVSC2020US098801			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Inappropriate Schedule Of Product Administration	Azithromycin			S	Unknown	250 Mg		Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17667062	EXPEDITED (15-DAY)		HO, OT	CA-ASTRAZENECA-2020SE49789		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper;	Budesonide			S	Respiratory (inhalation)			Not Reported
Anaemia; Aspiration;								
Asthenia; Asthma; Blood Calcium Increased; Blood Creatinine Increased;	Symbicort			S	Respiratory (inhalation)	2 Dosage Form, Two Times A Day		Astrazeneca
Blood Test Abnormal;	Candesartan			S	Oral			Not Reported
Bronchiectasis;	Quetiapine			S	Oral			Not Reported
Bronchopulmonary Aspergillosis Allergic;	Rosuvastatin Calcium			S	Oral			Not Reported
Constipation; Cough; Drug Hypersensitivity; Drug Ineffective; Dyspnoea;	Azithromycin			S	Unknown			Not Reported
Fatigue;	Dexilant			S	Unknown			Not Reported
Gastrooesophageal Reflux Disease; Haemoptysis;	Domperidone			S	Unknown			Not Reported
Headache; Hypoxia; Liver Function Test Increased;	Efinaconazole			S	Unknown			Not Reported
Lower Respiratory Tract Infection; Lung Opacity;	Nitroglycerin			S	Unknown			Not Reported
Musculoskeletal Stiffness; Obstructive Airways Disorder; Oedema	Fluvaccin			S	Unknown			Not Reported
Peripheral; Pain; Pleural Effusion; Pneumonia;	Atrovent			S	Unknown			Not Reported
Pulmonary Fibrosis;	Lansoprazole			S	Unknown			Not Reported
	Levothyroxine Sodium			S	Unknown			Not Reported
	Synthroid			S	Unknown			Not Reported
	Mepolizumab			S	Intravenous (not	First Dose100.0mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Pyrexia; Rales; Sputum Discoloured; Total Lung Capacity Decreased; Transaminases Increased; Tremor; Upper Respiratory Tract Infection; Wheezing	Mepolizumab	S	otherwise specified)	Unknown	
	Nasonex	S	Intravenous (not otherwise specified)	Second Dose100.0mg	Not Reported
	Montelukast	S	Unknown	Unknown	Not Reported
	Singulair	S	Oral		Not Reported
	Morphine	S	Unknown	10.0mg Unknown	Not Reported
	Statex (Morphine Sulfate)	S	Oral	10.0mg Unknown	Not Reported
	Xolair	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Pantoloc	S	Unknown		Not Reported
	Acetaminophen	S	Unknown	1000.0mg Unknown	Not Reported
	Prevnar	S	Unknown		Not Reported
	Pramipexole	S	Oral	First Dose0.25mg Unknown	Not Reported
	Pramipexole	S	Oral	Second Dose0.5mg Unknown	Not Reported
	Pregabalin	S	Oral	75.0mg Unknown	Not Reported
	Ranitidine	S	Unknown		Not Reported
	Risedronate Sodium	S	Unknown		Not Reported
	Ventolin	S	Unknown		Not Reported
	Senokot	S	Unknown		Not Reported
	Sennoside A+B	S	Unknown		Not Reported
	Spiriva	S	Unknown		Not Reported
	Trazodone	S	Unknown	First Dose12.5mg Unknown	Not Reported
	Trazodone	S	Unknown	Second Dose10.0mg Unknown	Not Reported
	Vitamin D Nos	S	Oral		Not Reported
	Zopiclone	S	Unknown		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Apr-2020	17668265	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-017705			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	10225004	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2014153075		56 DAY	Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Low Birth Weight Baby; Maternal Exposure During Pregnancy; Toxicity To Various Agents	Azithromycin			S	Transplacental	2 Df, Daily		Pfizer	
	Aciclovir			S	Transplacental	Unk		Pfizer	
	Abacavir			S	Transplacental	300 Mg, 2x/Day		Not Reported	
	Bactrim			S	Transplacental	400 Mg, 2x/Day		Not Reported	
	Intelence			S	Transplacental	200 Mg, 2x/Day		Not Reported	
	Isentress			S	Transplacental	400 Mg, 2x/Day		Not Reported	
	Lamivudine			S	Transplacental	150 Mg, 2x/Day		Not Reported	
	Prezista			S	Transplacental	600 Mg, 2x/Day		Not Reported	
	Ritonavir			S	Transplacental	100 Mg, 2x/Day		Not Reported	
	Tenofovir			S	Transplacental	300 Mg, 1x/Day		Not Reported	
	Zidovudine			S	Transplacental	300 Mg, 2x/Day		Not Reported	
	Folic Acid			C		Unk		Not Reported	
	Iron			C		Unk		Not Reported	
	Magnesium Gluconate			C		Unk		Not Reported	
	Prenatal Vitamins			C		Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	15752717	EXPEDITED (15-DAY)		OT	CA- GLAXOSMITHKLINE- CA2018GSK229409		67 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anaemia; Aphonia; Arthralgia; Arthritis; Arthropathy; Asthma; Breath Sounds; Chest Discomfort; Chest Pain; Cough; Deafness; Drug Ineffective; Dyspepsia; Dyspnoea; Ear Discomfort; Ear Disorder; Ear Infection; Eosinophil Count Increased; Fatigue; Headache; Loss Of Personal Independence In Daily Activities; Malaise; Nasal Polyps; Nasopharyngitis; Oral Candidiasis; Oropharyngeal Pain; Pain In Extremity; Productive Cough; Pyrexia; Rhinorrhoea; Sleep Disorder Due To A General Medical Condition; Sputum Discoloured; Tympanic Membrane Perforation; Wheezing	Fluticasone Propionate+Salmeterol Xinafoate Ventolin Flovent Albuterol Avelox Prednisone Nasonex Nasonex Zithromax Spiriva Respimat			S S S S S S S S S		Unk Unk, Bid Unk 250 Mg, Bid Unk Unk Unk Unk Unk		Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Glaxosmithkline Not Reported Not Reported Not Reported Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	16216073	EXPEDITED (15-DAY)		HO, OT	CA- GLAXOSMITHKLINE- CA2019GSK068105			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Adenocarcinoma; Asthma;	Salbutamol Sulphate	S		Unk Unk, Prn (1-2 Puffs)	Glaxosmithkline
Asthma; Blood Count	Pantoprazole	S		Unk	Glaxosmithkline
Abnormal; Breath Sounds	Calcium	S		Unk	Glaxosmithkline
Abnormal; Dyspnoea;	Vitamin D	S		Unk	Glaxosmithkline
Emphysema; Eosinophilia;	Potassium Chloride	S		Unk	Glaxosmithkline
Gastrooesophageal Reflux	Salbutamol	S		Unk	Glaxosmithkline
Disease; Hypercapnia;	Thyroxine	S		Unk	Glaxosmithkline
Hypertension;	Nucala	S	Intravenous (not otherwise specified)	100 Mg, Z(Monthly)	Glaxosmithkline
Hyperthyroidism;					
Influenza; Loss Of					
Personal Independence In					
Daily Activities; Multiple	Nucala	S	Intravenous (not otherwise specified)	100 Mg, Z(Monthly)	Glaxosmithkline
Allergies; Osteoporosis;					
Pain In Extremity;	Spiriva Respimat	S		Unk	Not Reported
Pneumonitis;	Symbicort	S		2 Puff(S), Bid	Not Reported
Pneumothorax	Hydrochlorothiazide	S		Unk	Not Reported
Spontaneous; Polymyalgia	Prednisone	S		10 Mg, Qd	Not Reported
Rheumatica; Productive	Metoprolol	S		Unk	Not Reported
Cough; Respiratory Tract	Azithromycin	S		Unk	Not Reported
Infection; Sleep Disorder	Roflumilast	S		Unk	Not Reported
Due To A General Medical	Rabeprazole	S		Unk	Not Reported
Condition; Therapeutic	Tudorza	S		1 Puff(S), Qd (400ug)	Not Reported
Product Effect Incomplete;					
Upper Respiratory Tract					
Infection; Wheezing					

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	16907063	EXPEDITED (15-DAY)		HO	CA- GLAXOSMITHKLINE- CA2019GSK093322			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Back Pain; Chest	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z, Monthly		Glaxosmithkline	
Discomfort; Dyspnoea	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Z (Monthly)		Glaxosmithkline	
Exertional; Hepatic	Mepolizumab			S		100 Mg, Z (Monthly)		Glaxosmithkline	
Enzyme Increased;									
Palpitations; Productive									
Cough; Sputum									
Discoloured									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg, Z,Monthly	Glaxosmithkline
Zithromax	S		Unk	Not Reported
Trikafta	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17643631	EXPEDITED (15-DAY)	HO, OT		IT-AUROBINDO-AUR-APL-2020-015943			Unknown	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Generalised Exanthematous Pustulosis; Dermatitis Bullous; Drug Reaction With Eosinophilia And Systemic Symptoms; Pemphigus; Stevens-Johnson Syndrome; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Aciclovir			S	Unknown	Unk		Aurobindo
	Cefixime			S	Unknown	Unk		Aurobindo
	Ceftriaxone			S	Unknown	Unk		Aurobindo
	Fluconazole			S	Unknown	Unk		Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Lamotrigine			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Paracetamol			S	Unknown	Unk		Aurobindo
	Risperidone			S		Unk		Aurobindo
	Terbinafine			S	Unknown	Unk		Aurobindo
	Ampicillin;Sulbactam			S	Unknown	Unk		Not Reported
	Ketoprofen			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Aspirin			S	Unknown	Unk		Not Reported
	Hydroxychloroquine			S	Unknown	Unk		Not Reported
	Vancomycin			S	Unknown	Unk		Not Reported
	Enoxaparin			S	Unknown	Unk		Not Reported
	Ceftazidime			S	Unknown	Unk		Not Reported
	Oxacillin			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clindamycin	S	Unknown	Unk	Not Reported
Carbamazepine	S	Unknown	Unk	Not Reported
Phenytoin	S	Unknown	Unk	Not Reported
Phenobarbital	S	Unknown	Unk	Not Reported
Teicoplanin	S	Unknown	Unk	Not Reported
Rufinamide	S	Unknown	Unk	Not Reported
Cotrimoxazole	S	Unknown	Unk	Not Reported
Cisplatin	S	Unknown	Unk	Not Reported
Fluorouracil	S	Unknown	Unk	Not Reported
Asa	S	Unknown	Unk	Not Reported
Lithium	S	Unknown	Unk	Not Reported
Methylphenidate	S	Unknown	Unk	Not Reported
Acetylcysteine	S	Unknown	Unk	Not Reported
Ibuprofen	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669433	NON-EXPEDITED			US-GW PHARMA-202004USGW01390			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Urticaria	Epidiolex			S	Oral	400 Milligram, Bid		Gw Pharma	
	Azithromycin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17669916	DIRECT		DE				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Arrest; Torsade De Pointes	Hydroxychloroquine			S				Not Reported	
	Hydroxychloroquine			S			1 DAY	Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin			S			2 DAY			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670319	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI-FK202003746		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Levofloxacin (Manufacturer Unknown)			S	Unknown			Fresenius Medical Care	
	Hydroxychloroquine Sulfate			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Ritonavir/Lopinavir			S	Oral			Not Reported	
	Enoxaparin Sodium			C	Subcutaneous			Not Reported	
	Prednisone			C	Oral			Not Reported	
	Ceftriaxone			C	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670400	DIRECT		OT			45 YR	Male	ECU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Asthenia; Dyspnoea; Headache; Heart Rate Irregular; Leukopenia; Nervousness; Neutropenia; Pain In Extremity; Pruritus; Salmonella Test Positive; Tremor	Coartem 80/480			S	Oral			Novartis	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670428	EXPEDITED (15-DAY)		HO	FR-ACCORD-178669		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Oedema;	Amlodipine			S	Oral			Accord	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Weight Increased	Esomeprazole/Esomeprazole	S	Oral		Not Reported
	Magnesium/Esomeprazole				
	Sodium				
	Aerius (Desloratadine)	S	Oral		Not Reported
	Novopulmon Novolizer	S	Respiratory (inhalation)	200 Micrograms / Dose, Powder For Inhalation	Not Reported
	Rhinomaxil	S	Nasal	100 Micrograms / Dose, Suspension For Nasal Spray	Not Reported
	Zithromax	S	Oral		Not Reported
	Lantus	C			Not Reported
	Eucreas	C		50 Mg / 1000 Mg	Not Reported
	Novatrex	C		2.5 Mg	Not Reported
	Transipeg	C			Not Reported
	Gliclazide	C			Not Reported
	Speciafoldine	C		5 Mg,	Not Reported
	Kardegic	C		75 Mg, Powder For Oral Solution In Sachet-Dose	Not Reported
	Inegy	C		10 Mg / 40 Mg	Not Reported
	Isoptine	C			Not Reported
	Kardegic	C		75 Mg, Powder For Oral Solution In Sachet-Dose	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670440	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1223401		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sudden Death	Levofloxacin (2791a)			S	Unknown			Teva	
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Mg		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Lopinavir+Ritonavir			S	Oral	4 Dosage Forms Daily;		Not Reported	
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Mg		Not Reported	
	Prednisona (886a)			C	Oral	20 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxona (501a)			C		Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670568	EXPEDITED (15-DAY)		HO	NVSC2020ES099621		26 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azitromicina Sandoz			S	Oral	500 Mg Dia		Novartis	
	Ibuprofeno Sandoz			S	Oral	1-1-1-1		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670879	DIRECT		OT			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperbilirubinaemia; Liver Function Test Increased	Azithromycin 250 Mg			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17670925	EXPEDITED (15-DAY)		DE, OT	ES-CIPLA LTD.-2020ES02594			Unknown	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Levofloxacin			S	Unknown	Unk		Cipla	
	Hidroxicloroquina Sulfato			S	Oral	200 Milligram, Per Day		Not Reported	
	Azitromicina			S	Oral	500 Milligram, Per Day		Not Reported	
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported	
	Ceftriaxona [Ceftriaxone]			C	Unknown	Unk		Not Reported	
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Per Day		Not Reported	
	Prednisona			C	Oral	20 Milligram, Per Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671006	EXPEDITED (15-DAY)		HO	NVSC2020IT100054		15 YR	Female	ITA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Medication Error	Azithromycin			S	Oral	1.5 G, Qd		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671059	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020133540		78 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper;	Prevnar			S		Single Dose		Pfizer	
Anaemia; Aspiration;	Azithromycin			S		Unk		Pfizer	
Asthenia; Asthma; Blood	Morphine Sulfate			S		10 Mg, Unk		Pfizer	
Calcium Increased; Blood	Nitroglycerin			S		Unk		Pfizer	
Creatinine Increased;	Pregabalin			S	Oral	75 Mg, Unk		Pfizer	
Blood Test Abnormal;	Lansoprazole			S	Unknown	Unk		Pfizer	
Bronchiectasis;	Pantoloc			S	Unknown	Unk		Pfizer	
Bronchopulmonary	Pantoloc			S		Unk		Pfizer	
Aspergillosis Allergic;	Fluvaccin			S		Single Dose		Not Reported	
Constipation; Cough; Drug	Fluvaccin			S				Not Reported	
Hypersensitivity; Drug	Acetaminophen			S		1000 Mg, Unk		Not Reported	
Ineffective; Dyspnoea;	Atrovent			S		Unk		Not Reported	
Fatigue;	Budesonide			S		Unk		Not Reported	
Gastrooesophageal Reflux	Candesartan			S	Oral	8 Mg, 1x/Day		Not Reported	
Disease; Haemoptysis;	Dexilant			S		Unk		Not Reported	
Headache; Hypoxia; Liver	Domperidone			S		Unk		Not Reported	
Function Test Increased;	Efinaconazole			S		Unk		Not Reported	
Lower Respiratory Tract	Levothyroxine Sodium			S		Unk		Not Reported	
Infection; Lung Opacity;	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported	
Musculoskeletal Stiffness;	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg, Unk		Not Reported	
Obstructive Airways									
Disorder; Oedema									
Peripheral; Pain; Pleural									
Effusion; Pneumonia;									
Pulmonary Fibrosis;									
Pyrexia; Rales; Sputum									
Discoloured; Total Lung									
Capacity Decreased;									
Transaminases Increased;									
Tremor; Upper Respiratory									
Tract Infection; Wheezing									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Montelukast	S	Oral	10 Mg, 1x/Day	Not Reported
Nasonex	S		Unk	Not Reported
Pramipexole	S	Oral	0.5 Mg, Unk	Not Reported
Pramipexole	S	Oral	0.25 Mg, Unk	Not Reported
Quetiapine	S		Unk	Not Reported
Ranitidine	S		Unk	Not Reported
Risedronate	S		Unk	Not Reported
Rosuvastatin Calcium	S		Unk	Not Reported
Sennosides	S		Unk	Not Reported
Senokot	S		Unk	Not Reported
Singulair	S		Unk	Not Reported
Spiriva	S		1 Df, 1x/Day	Not Reported
Statex [Morphine Sulfate]	S	Oral	10 Mg, Unk	Not Reported
Symbicort	S		2 Df, 2x/Day	Not Reported
Synthroid	S		Unk	Not Reported
Trazodone	S		10 Mg, Unk	Not Reported
Trazodone	S		12.5 Mg, Unk	Not Reported
Ventolin [Salbutamol]	S		Unk	Not Reported
Vitamin D [Colecalciferol]	S	Oral	Unk	Not Reported
Xolair	S		Unk	Not Reported
Zopiclone	S		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671153	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1223386		68 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Hidroxicloroquina (2143a)			S	Oral	200mg/12h		Teva
	Hidroxicloroquina (2143a)			S				Teva
	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500mg/24h		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Azitromicina (7019a)		S						Not Reported
	Ceftriaxona (501a)		S		Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h			Not Reported
	Ceftriaxona (501a)		S						Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17671321	EXPEDITED (15-DAY)		DE	CN-PFIZER INC-2020145116		1 YR	Unknown	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use; Product Use Issue	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17672283	NON-EXPEDITED			US-PFIZER INC-2020152867			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Zithromax			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17673397	EXPEDITED (15-DAY)		OT	NVSC2020AU097773			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Graft Versus Host Disease In Lung; Non-Hodgkin'S Lymphoma; Scleroderma; Therapy Partial Responder	Jakavi			S	Oral	5 Mg, Bid		Not Reported	
	Methotrexate			S	Unknown			Novartis	
	Mycophenolate Mofetil			S	Unknown			Not Reported	
	Rituximab			S	Unknown	5 Mg, Bid		Not Reported	
	Rituximab			S	Unknown	10 Mg, Bid		Not Reported	
	Imatinib			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Montelukast			S	Unknown			Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Etoposide		S	Unknown	Unk			Not Reported	
	Ibrutinib		S	Unknown	Unk			Not Reported	
	Prednisone		S	Unknown	Unk			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674032	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-018904		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Tachyarrhythmia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported	
	Ceftriaxone			C	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported	
	Tocilizumab			C	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674037	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018903		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674055	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018905		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Dolquine			S	Other	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17674075	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2020-018907		28 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Aurobindo	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Azithromycin			S	Oral	500 Milligram, Once A Day		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17675087	DIRECT	Y	OT			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperbilirubinaemia; Jaundice	Azithromycin 250mg			S	Oral			Not Reported	
	Metformin			C				Not Reported	
	Losaran			C				Not Reported	
	Ozempic			C				Not Reported	
	Rosuvastatin			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Apr-2020	17675807	DIRECT	Y	HO			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema	Lisinopril (Lisinopril 40mg Tab)			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	15370006	EXPEDITED (15-DAY)		OT	CA-APOTEX-2018AP020138		66 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Count Abnormal;	Azithromycin			S	Oral	250 Mg, Qd		Apotex
Blood Pressure Increased;	Prednisone			S	Oral	8 Mg, Qd		Not Reported
Body Temperature Increased; Cataract;	Salbutamol			S	Unknown	Unk		Apotex
Cough; Drug Dependence;	Spiriva			S	Unknown	18 Mg, Qd		Not Reported
Heart Rate Increased;	Zenhale			S	Unknown	2 Df, Bid		Not Reported
Lung Diffusion Test Decreased; Lung Diffusion Test Decreased; Nasal	Zenhale			S	Unknown	1 Df, Bid		Not Reported
Disorder; Nasopharyngitis;	Advair			S	Unknown	1 Df, Bid		Not Reported
Obstructive Airways Disorder; Pyrexia;	Cetirizine			C	Unknown	20 Mg, Qd		Not Reported
Restrictive Pulmonary Disease; Therapeutic Response Decreased;	Pariet			C	Unknown	Unk		Not Reported
Type 2 Diabetes Mellitus	Rosuvastatin Calcium			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	16599628	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR-APL-2019-040214			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Amoxicillin			S	Unknown	Unk		Aurobindo
	Atorvastatin Tablets			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Aurobindo
	Metronidazole			S	Unknown	Unk		Aurobindo
	Pregabalin Capsules			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Aurobindo
	Avamys			S	Unknown	Unk		Not Reported
	Acetaminophen			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Apo Hydro	S	Endocervical	Unk	Not Reported
Ascorbic Acid;Copper;Tocopherol;Xantofy I;Zeaxanthin;Zinc	S	Unknown	Unk	Not Reported
Bactroban	S	Unknown	Unk	Not Reported
Betaderm	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	S	Unknown	Unk	Not Reported
Biaxin XI	S	Unknown	Unk	Not Reported
Bisacodyl	S	Unknown	Unk	Not Reported
Calcium Carbonate;Vitamin D Nos	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Clotrimazole	S	Unknown	Unk	Not Reported
Desonide	S	Unknown	Unk	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Diphenhydramine	S	Unknown	Unk	Not Reported
Entocort	S	Unknown	Unk	Not Reported
Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk	Not Reported
Glycerine	S	Oral	Unk	Not Reported
Gramicidin;Neomycin Sulfate;Polymyxin B Sulfate	S	Unknown	Unk	Not Reported
Habitrol	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog	S	Intra-articular	Unk	Not Reported
Lomotil	S	Oral	Unk Unk, Four Times/Day	Not Reported
Ms Ir	S	Unknown	Unk	Not Reported
Mupirocin	S	Topical	Unk	Not Reported
Mupirocin	S	Unknown	Unk	Not Reported
Mupirocin Calcium	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Nadolol	S	Unknown	Unk	Not Reported
Nicoderm	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	S	Unknown	Unk	Not Reported
Pentasa	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pulmicort	S	Unknown	Unk	Not Reported
Refresh Tears	S	Ophthalmic	Unk	Not Reported
Salinex [Sodium Chloride]	S	Nasal	Unk	Not Reported
Sinus Rinse	S	Nasal	Unk	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Unk	Not Reported
Bactrim	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	S	Intra-articular	Unk	Not Reported
Vitamin D3	S	Unknown	Unk	Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Calcium;Magnesium;Vitamin D	S	Unknown	Unk	Not Reported
Cupric Oxide	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	S	Unknown	Unk	Not Reported
Magnesium Sulfate	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	S	Unknown	Unk	Not Reported
Zeaxanthin	S	Unknown	Unk	Not Reported
Zinc Oxide	S	Unknown	Unk	Not Reported
Betamethasone Valerate	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Unk	Not Reported
Pms Azithromycin	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride	S	Unknown	Unk	Not Reported
Paracetamol	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Valsartan	C	Unknown	Unk	Not Reported
Calcium Carbonate;Vitamin D Nos	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17652678	EXPEDITED (15-DAY)		DE, OT	NVSC2020AU096495		45 YR	Female	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Deafness; Obstructive Airways Disorder; Product Use In Unapproved Indication; Respiratory Failure	Azithromycin			S	Oral	250 Mg, Q3w		Novartis
	Azithromycin			S				Novartis
	Prednisone			S	Unknown			Not Reported
	Ultibro Breezhaler			C	Respiratory (inhalation)	Unk, Daily		Not Reported
	Alvesco			C	Respiratory (inhalation)	160, 2 Df, Bid		Not Reported
	Salbutamol			C	Respiratory (inhalation)	Unk,Prn		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17663375	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-018165		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lasilix			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Perfalgan			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Noradrenaline Tartrate Renaudin			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tazocilline	C	otherwise specified)	Unk	Not Reported
Transipeg	C	Intravenous (not otherwise specified)	Unk	Not Reported
Potassium Chloride	C	Oral	Unk	Not Reported
Nimbex	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17673245	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018502		53 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Azithromycin			S				Aurobindo
	Propofol			S	Intravenous (not otherwise specified)	6.6 Milligram/Kilogram, 1 In Hour, (Sedation)		Not Reported
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported
	Dolquine			S				Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Milligram, Once A Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17673548	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-017887		74 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Levofloxacin Arrow Film-Coated Tablets 500mg			S	Oral	2 Dosage Form, Once A Day		Aurobindo
	Sandoz Co Amoxyclav [Amoxicillin Trihydrate;Clavulanate Potassium]			S	Oral	3 Dosage Form, Once A Day		Not Reported
	Lovenox			S	Subcutaneous	1 Dosage Form, Once A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Primperan	S	Oral	1 Dosage Form	Not Reported
Ritonavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
Azithromycine Sandoz [Azithromycin]	S	Oral	4 Dosage Form, Once A Day	Not Reported
Doliprane	S	Oral	1 Dosage Form	Not Reported
Plaquenil	S	Oral	3 Dosage Form, Once A Day	Not Reported
Darunavir Mylan	S	Oral	1 Dosage Form, Once A Day	Not Reported
Ceftriaxone	S	Intravenous (not otherwise specified)	1 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17673805	EXPEDITED (15-DAY)		OT	AU-TEVA-2020-AU-1224015			Male	AUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Graft Versus Host Disease; Drug Ineffective; Respiratory Disorder; Scleroderma	Imatinib Mesylate			S	Unknown			Teva
	Methotrexate			S	Unknown			Barr
	Tacrolimus			S	Unknown			Not Reported
	Mycophenolate			S	Unknown			Not Reported
	Ibrutinib			S	Unknown			Not Reported
	Rituximab			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Montelukast			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17674454	EXPEDITED (15-DAY)		HO	ES-ABBVIE-20K-144-3365014-00		36 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Kaletra 200/50			S	Oral			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Kaletra 200/50	S			Not Reported
Azitromicina	S	Oral		Not Reported
Azitromicina	S			Not Reported
Dolquine	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675050	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1223986		41 YR	Female	ITA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain; Haematochezia	Azithromycin			S	Oral	500 Mg 1 Cyclical		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675164	EXPEDITED (15-DAY)		OT	CA-ABBVIE-18K-028-2607481-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Dizziness; Drug Ineffective; Impaired Work Ability; Joint Stiffness; Joint Swelling; Musculoskeletal Pain; Musculoskeletal Stiffness; Musculoskeletal Stiffness; Nausea; Pain; Pain In Extremity; Peripheral Swelling; Rheumatoid Arthritis; Swelling	Humira			S	Subcutaneous			Not Reported
	Methotrexate			S	Unknown			Not Reported
	Sulfasalazine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Azathioprine			S	Unknown			Not Reported
	Plaquenil			S	Unknown			Not Reported
	Naproxen			S	Unknown			Not Reported
	Metoprolol			S	Unknown			Not Reported
	Xeljanz			S	Unknown			Not Reported
	Hydroxychloroquine Sulfate			S	Unknown			Not Reported
	Pms Azithromycin			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675643	EXPEDITED (15-DAY)		DE, OT	ES-HETERO- HET2020ES00415		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Levofloxacin			S	Unknown	Unk		Hetero	
	Hydroxychloroquine			S	Oral	200 Mg, Qd		Not Reported	
	Azitromicina			S	Oral	500 Mg, Qd		Not Reported	
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported	
	Ceftriaxone			C	Unknown	Unk		Not Reported	
	Enoxaparin Sodium			C	Unknown	Unk		Not Reported	
	Prednisona			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17675750	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP009990		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mental Status Changes	Azithromycin			S	Unknown	Unk		Apotex	
	Minocycline			S	Unknown			Not Reported	
	Tigecycline			S	Unknown	Unk		Apotex	
	Cilastatin Sodium W/Imipenem			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676221	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1223885		43 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily; 200mg/12h		Teva	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hidroxyclozoquina (2143a)	S								Teva
Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr/24h						Not Reported
Ceftriaxona (501a)	S								Not Reported
Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	2 Doses In Total						Not Reported
Tocilizumab (8289a)	S								Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676462	EXPEDITED (15-DAY)		HO, OT	CZ-TEVA-2020-CZ-1224063		71 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Chronic Obstructive Pulmonary Disease; Sputum Increased; Treatment Noncompliance	Azithromycin			S	Unknown				Not Reported
	Roflumilast			S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17676812	EXPEDITED (15-DAY)		OT	FR-TEVA-2020-FR-1224309		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycine Anhydre			S	Oral	500 Mg			Not Reported
	Plaquenil			S	Oral	600 Mg			Not Reported
	Ceftriaxone Base			C	Unknown				Not Reported
	Inipomp			C	Unknown				Not Reported
	Rovamycine			C	Unknown				Not Reported
	Paracetamol			C	Unknown				Not Reported
	Xarelto 10 Mg, Comprimé Pelliculé			C	Oral				Not Reported
	Diffu K			C	Oral				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677649	EXPEDITED (15-DAY)		OT	JP-PFIZER INC-2020154246		65 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rhabdomyolysis	Zithromac 250mg			S	Oral			Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17677781	EXPEDITED (15-DAY)		OT	AU-INCYTE CORPORATION-2020IN003495			Unknown	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Respiratory Failure; Graft Versus Host Disease In Lung; Non-Hodgkin'S Lymphoma; Scleroderma; Therapy Partial Responder	Jakavi			S	Oral	5 Mg, Bid		Incyte	
	Methotrexate			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported	
	Rituximab			S	Unknown	5 Mg, Bid		Not Reported	
	Rituximab			S	Unknown	10 Mg, Bid		Not Reported	
	Imatinib			S	Unknown	Unk		Not Reported	
	Tacrolimus			S	Unknown	Unk		Not Reported	
	Montelukast			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Etoposide			S	Unknown	Unk		Not Reported	
	Ibrutinib			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Apr-2020	17678014	EXPEDITED (15-DAY)		DE, HO, OT	US-SUN PHARMACEUTICAL INDUSTRIES LTD-2020R1-244182		26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dyspnoea; Exposure	Azithromycin			S	Unknown	Unk		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

During Pregnancy; Hypotension; Hypoxia; Live Birth; Multiple Organ Dysfunction Syndrome; Postpartum Haemorrhage; Pre-Eclampsia; Signet- Ring Cell Carcinoma; Tachypnoea; Uterine Atony	Ceftriaxone	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17614338	EXPEDITED (15-DAY)		OT	CA-APOTEX- 2020AP009150			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity; Drug Ineffective; Drug Intolerance; Interstitial Lung Disease; Rheumatoid Arthritis; Treatment Failure	Levofloxacin			S	Unknown	Unk		Apotex
	Arava			S	Unknown	Unk		Not Reported
	Benadryl /00000402/			S	Unknown	Unk		Not Reported
	Celebrex			S	Oral	Unk		Not Reported
	Cimzia			S	Unknown	Unk		Not Reported
	Demerol			S	Unknown	Unk		Not Reported
	Enbrel			S	Unknown	Unk		Not Reported
	Humira			S	Unknown	Unk		Not Reported
	Imuran /00001501/			S	Unknown	Unk		Not Reported
	Methotrexate			S	Unknown	Unk		Not Reported
	Plaquenil /00072602/			S	Unknown	Unk		Not Reported
	Pms Azithromycin			S	Unknown	250 Mg, Qd		Not Reported
	Procytox			S	Unknown	Unk		Not Reported
	Simponi			S	Unknown	Unk		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported
	Xeljanz			S	Oral	5 Mg, Bid		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ezetrol			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17655678	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1221608		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Ventricular Tachycardia	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported	
	Lasilix 20 Mg/2 ML, Solution Injectable En Ampoule			S	Intravenous (not otherwise specified)	2 Dosage Forms		Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Sufentanil			C	Intravenous (not otherwise specified)			Not Reported	
	Perfalgan 10 Mg/ML, Solution Pour Perfusion			C	Intravenous (not otherwise specified)			Not Reported	
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)			Not Reported	
	Midazolam			C	Intravenous (not otherwise specified)			Not Reported	
	Tazocilline 4 G/500 Mg, Poudre Pour Solution Pour Perfusion			C	Intravenous (not otherwise specified)	4 Dosage Forms		Not Reported	
	Transipeg			C	Oral			Not Reported	
	Potassium (Chlorure De)			C	Intravenous (not otherwise specified)			Not Reported	
	Nimbex			C	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678265	EXPEDITED (15-DAY)		OT	US-ADVANZ PHARMA-202004002747			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Atrial Fibrillation; Electrocardiogram Qrs	Hydroxychloroquine			S	Unknown	400 Mg, Bid (For One Day Followed By 200mg Twice Daily For Four Days)		Concordia	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Complex Prolonged; Electrocardiogram Qt Prolonged; Off Label Use	Hydroxychloroquine	S	Unknown	200 Mg, Bid (For One Day Followed By 200mg Twice Daily For Four Days)	Concordia
	Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, Qd	Not Reported
	Apixaban	C		5 Mg, Bid	Not Reported
	Metoprolol Succinate	C		25 Mg, Qd	Not Reported
	Flecainide	C		50 Mg, Bid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678592	EXPEDITED (15-DAY)		OT	CA-009507513- 2004CAN002962			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Foetal Exposure During Pregnancy	Isentress			S	Transplacental	400 Milligram, Unk		Merck	
	Abacavir			S	Transplacental	300 Milligram, 1 Every 1 Days		Not Reported	
	Acyclovir			S	Transplacental	Unk		Not Reported	
	Intelence			S	Transplacental	200 Milligram, 1 Every 1 Days		Not Reported	
	Lamivudine			S	Transplacental	150 Milligram, Unk		Not Reported	
	Prezista			S	Transplacental	600 Milligram, Unk		Not Reported	
	Ritonavir			S	Transplacental	100 Milligram, Unk		Not Reported	
	Viread			S	Transdermal	200 Milligram, 1 Every 1 Days		Not Reported	
	Zidovudine			S	Transplacental	300 Milligram, Unk		Not Reported	
	Bactrim			S	Transplacental	Unk		Not Reported	
	Pms-Azithromycin			S	Transplacental	Unk		Not Reported	
	Folic Acid			C	Transplacental	Unk		Not Reported	
	Iron (Unspecified)			C	Transplacental	Unk		Not Reported	
	Magnesium Gluconate			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17678744	EXPEDITED (15-DAY)		HO, LT	FR-TEVA-2020-FR-1224307		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycine Dihydratee			S	Oral	500 Mg D1 Then 250 Mg Per Day		Not Reported	
	Plaquenil			S	Oral	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679307	EXPEDITED (15-DAY)		DE, HO	US-INSMED, INC.-US-INS-19-02367		72 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Asthenia; Chronic Obstructive Pulmonary Disease;	Arikayce			S	Respiratory (inhalation)			Insmed	
Cough; Death; Decreased Appetite; Dehydration; Dyspnoea; Glossitis;	Arikayce			S	Respiratory (inhalation)			Insmed	
Glossodynia; Myalgia; Nausea; Product Dose Omission; Productive Cough; Sputum Increased; Weight Decreased	Lamira Nebulizer System			S				Insmed	
	Azithromycin			S				Not Reported	
	Ethambutol			S				Not Reported	
	Rifampin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679380	EXPEDITED (15-DAY)		HO, LT	NL-TEVA-2020-NL-1223674		55 YR	Female	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatic Enzyme Abnormal; Thrombocytopenia	Azithromycine			S		500 Milligram Daily; 1 Piece Once A Day		Not Reported	
	Azithromycine			S				Not Reported	
	Loperamide			C		Capsule, 2 Mg (Milligram)		Not Reported	
	Prednisolon			C		Capsule, 15 Mg (Milligram)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novorapid (Insuline Aspart)	C	Injection Liquid, 100 Units / MI (Units Per Milliliter)	Not Reported
Furosemide	C	40 Mg (Milligram)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17679870	NON-EXPEDITED			US-EPIC PHARMA LLC-2020EPC00066		4 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Behaviour; Aggression; Agitation; Crying; Irritability; Reaction To Excipient; Unevaluable Event; Urticaria	Azithromycin			S		Unk		Epic Pharm	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680068	EXPEDITED (15-DAY)		DS	US-009507513-2004USA002545		80 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Toxicity To Various Agents	Primaxin I.V.			S		Unk		Merck	
	Linezolid			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Tigecycline			S		Unk		Not Reported	
	Prednisone			C		60 Milligram, Daily		Not Reported	
	Prednisone			C		40 Milligram, Daily		Not Reported	
	Prednisone			C		30 Mg, Daily		Not Reported	
	Prednisone			C		20 Mg, Daily		Not Reported	
	Aspirin			C		Unk		Not Reported	
	Atovaquone			C		Unk		Not Reported	
	Prinivil			C		Unk		Merck	
	Omeprazole			C		Unk		Not Reported	
	Quetiapine Fumarate			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Thiamine	C	Unk	Not Reported
Naproxen	C	Unk	Not Reported
Polyethylene Glycol	C	Unk	Not Reported
Senna	C	Unk	Not Reported
Calcium Carbonate (+) Cholecalciferol	C	Unk	Not Reported
Melatonin	C	Unk	Not Reported
Nystatin	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680354	EXPEDITED (15-DAY)		OT	CA-SHIRE- CA202013392			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis Acute	Mezavant			S	Unknown	Unk		Shire
	5-Asa			S	Unknown	Unk		Not Reported
	Asacol			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	Azithromycin			S	Unknown	Unk		Not Reported
	Levonorgestrel And Ethinyl Estradiol			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Mercaptopurine			S	Unknown	Unk		Not Reported
	Para-Aminosalicylic Acid			S	Unknown	Unk		Not Reported
	Prednisone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680740	EXPEDITED (15-DAY)		HO	CA-ANIPHARMA-2020- CA-000419		78 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain Upper; Anaemia; Aspiration;	Candesartan Cilexetil			S	Oral	8 Mg Qd		Ani

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Asthma; Blood	Nitroglycerin	S	Unknown	Unk	Not Reported
Calcium Increased; Blood	Fluvaccin	S	Unknown	Unk	Not Reported
Creatinine Increased;	Atrovent	S	Unknown	Unk	Not Reported
Blood Test Abnormal;	Lansoprazole	S	Unknown	Unk	Not Reported
Bronchiectasis;	Levothyroxine Sodium	S	Unknown	Unk	Not Reported
Bronchopulmonary	Synthroid	S	Unknown	Unk	Not Reported
Aspergillosis Allergic;	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg Unk / 100 Mg Unk	Not Reported
Constipation; Cough; Drug	Nasonex	S	Unknown	Unk	Not Reported
Hypersensitivity; Drug	Montelukast	S	Unknown	10 Mg Qd	Not Reported
Ineffective; Dyspnoea;	Singulair	S	Unknown	Unk	Not Reported
Fatigue;	Budesonide	S	Respiratory (inhalation)	Unk	Not Reported
Gastroesophageal Reflux	Morphine	S	Unknown	10 Mg Unk	Not Reported
Disease; Haemoptysis;	Statex (Morphine Sulfate)	S	Oral	10 Mg Unk	Not Reported
Headache; Hypoxia; Liver	Xolair	S	Unknown	Unk	Not Reported
Function Test Increased;	Pantoloc	S	Unknown	Unk	Not Reported
Lower Respiratory Tract	Acetaminophen	S	Unknown	1000 Mg Unk	Not Reported
Infection; Lung Opacity;	Prevnar	S	Unknown	Unk	Not Reported
Musculoskeletal Stiffness;	Pramipexole	S	Oral	.25 Mg Unk / .5 Mg Unk	Not Reported
Obstructive Airways	Pregabalin	S	Oral	75 Mg Unk	Not Reported
Disorder; Oedema	Ranitidine	S	Unknown	Unk	Not Reported
Peripheral; Pain; Pleural	Risedronate Sodium	S	Unknown	Unk	Not Reported
Effusion; Pneumonia;	Symbicort	S	Respiratory (inhalation)	2 Dosage Form, Two Times A Day	Not Reported
Pulmonary Fibrosis;	Ventolin	S	Unknown	Unk	Not Reported
Pyrexia; Rales; Sputum	Senokot	S	Unknown	Unk	Not Reported
Discoloured; Total Lung	Sennoside A+B	S	Unknown	Unk	Not Reported
Capacity Decreased;	Spiriva	S	Unknown	1 Df Qd	Not Reported
Transaminases Increased;	Trazodone	S	Unknown	12.5 Mg Unk / 10 Mg Unk	Not Reported
Tremor; Upper Respiratory					
Tract Infection; Wheezing					

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D Nos	S	Oral	Unk	Not Reported
Zopiclone	S	Unknown	Unk	Not Reported
Quetiapine	S	Oral	Unk	Not Reported
Rosuvastatin Calcium	S	Oral	Unk	Not Reported
Azithromycin	S	Unknown	Unk	Not Reported
Dexilant	S	Unknown	Unk	Not Reported
Domperidone	S	Unknown	Unk	Not Reported
Efinaconazole	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17680902	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224376		46 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg Day		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 400 Mg Day		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily; 2 Gr Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681212	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US-1226055			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chills; Tremor	Azithromycin			S	Unknown	Took Two Tablets Total		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681290	EXPEDITED (15-DAY)		HO	NVSC2020HU102416		12 YR	Male	HUN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Aphthous Ulcer; Conjunctivitis; Mouth Swelling; Skin Lesion; Swelling Of Eyelid	Azithromycin			S	Unknown	Unk		Novartis	
	Amoxicillin,Clavulanic Acid			S	Intravenous (not otherwise specified)	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681817	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR- APL-2020-019821		20 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Azithromycin			S	Oral	500 Milligram, Once A Day (Dia)		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681818	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR- APL-2020-019820		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Ertapenem			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Aurobindo	
	Piperacillin+Tazobactam 4/0.5g Powderforsolutionforinfusion			S	Intravenous (not otherwise specified)	Unk Unk, Once A Day		Aurobindo	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681820	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR- APL-2020-019814		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			S	Intravenous (not	2 Gram, Once A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

					otherwise specified)				
		Ceftriaxone		S					Not Reported
		Hydroxychloroquine		S	Oral	200 Milligram, Two Times A Day			Not Reported
		Hydroxychloroquine		S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681821	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-019810		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Dolquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17681826	EXPEDITED (15-DAY)		HO, OT	RU-AUROBINDO-AUR-APL-2020-019554		48 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Accidental Overdose; Dysgeusia; Hepatotoxicity	Amoxicillin And Clavulanic Potassium			S	Oral	1000 Milligram (875!125mg), Two Times A Day		Aurobindo	
	Azithromycin			S	Unknown	1 Gram, Two Times A Day		Not Reported	
	Cefazolin			C	Unknown	Unk		Not Reported	
	Novorapid			C	Unknown	Unk		Not Reported	
	Insulin Aspart;Insulin Degludec			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17684210	DIRECT	Y	HO			89 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Choking Sensation; Drug-Disease Interaction; Dysphagia; Myasthenia Gravis	Azithromycin			S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Apr-2020	17687783	DIRECT	Y	HO			52 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Myasthenia Gravis Crisis	Azithromycin (Azithromycin 250mg Cap)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	16038950	EXPEDITED (15-DAY)		OT	CA-ABBVIE-19K-028-2688707-00			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Ineffective; Macular Degeneration	Humira			S	Subcutaneous			Not Reported	
	Lomotil			S	Oral	0.025 + 2.5 Mg/ 1 Tablet Times A Day Or As Needed Every 6 Hours		Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	Clotrimaderm			S	Unknown			Not Reported	
	Apo Sulfatrim			S	Unknown			Not Reported	
	Invanz			S	Unknown			Not Reported	
	Apo Amoxi			S	Unknown			Not Reported	
	Statex [Morphine Sulfate]			S	Unknown			Not Reported	
	Apo Nadol			S	Unknown			Not Reported	
	Atorvastatine			S	Unknown			Not Reported	
	Pantoprazole			S	Unknown			Not Reported	
	Pms Pregabalin			S	Unknown			Not Reported	
	Oracort [Triamcinolone			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Acetonide] M Cal [Calcium Carbonate/Cholecalciferol/Magn esium Sulfate]	S	Unknown		Not Reported
Jamp Azithromycin	S	Unknown		Not Reported
Act Clarithromycin	S	Unknown		Not Reported
Avamys	S	Unknown		Not Reported
Prednisone	S	Unknown		Not Reported
Salinex [Sodium Chloride]	S	Unknown		Not Reported
Ms Ir	S	Unknown		Not Reported
Apo Hydro	S	Unknown		Not Reported
Pms-Desonide	S	Unknown		Not Reported
Pentasa	S	Unknown		Not Reported
Entocort	S	Unknown		Not Reported
Bisacodyl	S	Unknown		Not Reported
Peglyte	S	Unknown		Not Reported
Polysporin	S	Unknown		Not Reported
D-Tabs	S	Unknown		Not Reported
Eurocal	S	Unknown		Not Reported
Acetaminophene	S	Unknown		Not Reported
Kenalog	S	Intra-articular		Not Reported
Habitrol	S	Unknown		Not Reported
Thrive	S	Unknown		Not Reported
Taro-Mupirocin	S	Unknown		Not Reported
Metronidazole	S	Unknown		Not Reported
Ratio-Topisone	S	Unknown		Not Reported
Flovent	S	Unknown		Not Reported
Nicoderm	S	Unknown	Patch	Not Reported
Betaderm	S	Unknown		Not Reported
Alrex	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Refresh Tears	S	Ophthalmic	Not Reported
Glycerine	S	Unknown	Not Reported
Biaxin XL	S	Unknown	Not Reported
Preservision Areds 2	S	Unknown	Not Reported
Dilaudid	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Sinus Rinse	S	Nasal	Not Reported
Cetirizine	S	Unknown	Not Reported
Bactroban	S	Unknown	Not Reported
Sulfamethoxazole	S	Unknown	Not Reported
Trimethoprim	S	Unknown	Not Reported
Morphine Sulfate	S	Unknown	Not Reported
Sodium Chloride	S	Nasal	Not Reported
Nicotine Polacrilex	S	Unknown	Not Reported
Mupirocin	S	Topical	Not Reported
Macrogol 3350	S	Unknown	Not Reported
Potassium Chloride	S	Unknown	Not Reported
Sodium Bicarbonate	S	Unknown	Not Reported
Chloride	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Atropine Sulfate	S	Oral	Not Reported
W/Diphenoxylate Hydrochloride			
Diphenoxylate Hydrochloride	S	Oral	Not Reported
Nicotine	S	Unknown	Not Reported
Gramicidin	S	Unknown	Not Reported
Neomycin Sulfate	S	Unknown	Not Reported
Polymyxin B Sulfate	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Amoxicillin	S	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Zinc Oxide	S	Unknown	Not Reported
Zeaxanthin	S	Unknown	Not Reported
Xantofyl Palmitate	S	Unknown	Not Reported
DI-Alpha Tocopheryl Acetate	S	Unknown	Not Reported
Cupric Oxide	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Vitamin D3	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Magnesium Sulfate	S	Unknown	Not Reported
Calcium Carbonate	S	Unknown	Not Reported
Betamethasone Dipropionate	S	Unknown	Not Reported
Betamethasone	S	Unknown	Not Reported
Azithromycin Dihydrate	S	Unknown	Not Reported
Alprazolam	S	Unknown	Not Reported
Prednisone Teva	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
Betamethasone Valerate	S	Unknown	Not Reported
Cetirizine Hydrochloride	S	Oral	Not Reported
Paracetamol	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	S	Unknown	Not Reported
Amoxicillin Trihydrate	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Bactrim	S	Unknown	Not Reported
Pms Azithromycin	S	Unknown	Not Reported
Atorvastatin Calcium	S	Unknown	Not Reported
Calcium + Vitamin D	C		Not Reported
Valsartan	C		Not Reported
Pantoprazole	C		Not Reported
Inflectra	C	Intravenous (not otherwise specified)	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17530937	EXPEDITED (15-DAY)		HO, OT	PL-AUROBINDO-AUR-APL-2020-012157		3 YR	Male	POL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cachexia; Decreased Appetite; Drug Ineffective; Gastrointestinal Obstruction; Immune Reconstitution Inflammatory Syndrome; Tuberculosis; Gastrointestinal; Vaccination Failure	Amoxicillin			S	Unknown	Unk		Aurobindo
	Amoxicillin			S				Aurobindo
	Azithromycin			S	Oral	Unk		Aurobindo
	Cefuroxime			S	Unknown	Unk		Aurobindo
	Levofloxacin			S	Intravenous (not otherwise specified)	8.5 Milligram/Kilogram		Aurobindo
	Amikacin			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Clarithromycin			S				Not Reported
	Ethambutol			S	Oral	20 Milligram/Kilogram		Not Reported
	Isoniazid			S	Oral	10 Milligram/Kilogram		Not Reported
	Prednisone			S	Unknown	1.5 Milligram/Kilogram		Not Reported
	Pyrazinamide			S	Oral	35 Milligram/Kilogram		Not Reported
	Rifampicin			S	Oral	15 Milligram/Kilogram		Not Reported
	Rifampicin			S	Intravenous (not otherwise specified)	16 Milligram/Kilogram		Not Reported
	Streptomycin			S	Intramuscular	16 Milligram/Kilogram		Not Reported
	Cefotaxime Sodium			S	Oral	Unk		Not Reported
	Cefotaxime Sodium			S				Not Reported
	Bcg Vaccine			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17681996	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR-APL-2020-018379			Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hyperkeratosis;	Azithromycin			S	Oral	Unk		Aurobindo

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperplasia; Limb Discomfort; Mass; Product Use In Unapproved Indication; Pyoderma Gangrenosum; Vasculitis	Doxyhexal	S	Oral	100 Milligram, Two Times A Day, (200 Mg, Daily)	Not Reported
	Doxyhexal	S	Oral	Unk	Not Reported
	Salofalk	C	Unknown	1 Gram, Every Week	Not Reported
	Pentasa	C	Intracardiac	2 Gram, (0-0-2)	Not Reported
	Clobetasol Propionate	C	Unknown	Unk	Not Reported
	Clindamycin	C	Intravenous (not otherwise specified)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682209	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-019426		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
	Ceftriaxone			C	Unknown	Unk		Not Reported	
	Inipomp			C	Unknown	Unk		Not Reported	
	Rovamycine			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
	Xarelto			C	Oral	Unk		Not Reported	
	Diffu K			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682218	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019089		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain; Haematochezia	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Cyclical		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Apr-2020	17682574	EXPEDITED (15-DAY)		OT	NVSC2020HU102401		49 DAY	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection;	Tobramycin			S	Unknown			Novartis	
Conjunctivitis; Eye	Azithromycin			S	Unknown	High Dose		Not Reported	
Symptom; Eyelid Oedema;	Betadine			C	Ophthalmic	Drops		Not Reported	
Product Use In									
Unapproved Indication									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Apr-2020	17682792	EXPEDITED (15-DAY)		HO, LT, OT	FR-AUROBINDO-AUR- APL-2020-019423		67 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ventricular Extrasystoles;	Azithromycin			S	Oral	500 Mg D1 Then 250 Mg Per Day		Aurobindo	
Ventricular Tachycardia	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	14363441	EXPEDITED (15-DAY)		OT	ES- GLAXOSMITHKLINE- ES2018GSK001019			Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Apnoea; Deafness;	Flixotide			S		Unk		Glaxosmithkline	
Tonsillitis	Zitromax (Azithromycin)			S		1.5 MI, Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17237890	EXPEDITED (15-DAY)		OT	CA-ASTRAZENECA- 2020SE01450		69 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bacterial Disease	Benralizumab			S	Intravenous (not otherwise specified)	Unknown		Astrazeneca	
Carrier; Blood Count									
Abnormal; Bronchial									

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Secretion Retention; Bronchial Wall Thickening; Cough; Drug Ineffective;	Alvesco	S	Respiratory (inhalation)		Not Reported
Dyspnoea; Fall; Ill-Defined Disorder; Intervertebral Disc Protrusion; Malaise;	Alvesco	S	Respiratory (inhalation)		Not Reported
Obstructive Airways Disorder; Rales; Spinal Cord Compression;	Daxas	S	Oral		Not Reported
Sputum Discoloured; Therapeutic Product Effect Incomplete; Upper Limb Fracture; Wheezing; Wrist Fracture	Daxas	S	Oral		Not Reported
	Calcium	S	Unknown	Unknown	Not Reported
	Pantoprazole	S	Unknown		Not Reported
	Celebrex	S	Unknown	Unknown	Not Reported
	Pseudoephedrine- Chlorpheniramine	S	Unknown	Unknown	Not Reported
	Fluticasone Propionate W/Salmeterol Xinafoate	S	Respiratory (inhalation)	Unk,Two Times A Day	Not Reported
	Hydroxyzine	S	Unknown	Unknown	Not Reported
	Imodium	S	Unknown	Unknown	Not Reported
	Omalizumab	S	Unknown	Unknown	Not Reported
	Omalizumab	S	Unknown	225 Milligram, 2/Week	Not Reported
	Omalizumab	S	Unknown	225 Milligram	Not Reported
	Pms Azithromycin	S	Unknown		Not Reported
	Prednisone	S	Unknown	Unknown	Not Reported
	Singulair	S	Unknown		Not Reported
	Spiriva	S	Respiratory (inhalation)	2.5 Microgram, Qd	Not Reported
	Spiriva	S	Respiratory (inhalation)	Qd	Not Reported
	Ventolin	S	Unknown	Unknown	Not Reported
	Ventolin	S	Respiratory (inhalation)	Unknown	Not Reported
	Vitamin D Nos	S	Unknown	Unknown	Not Reported
	Zopiclone	S	Unknown		Not Reported
	Calcium Carbonate	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17667694	EXPEDITED (15-DAY)		DE	FR-JNJFOC-20200406743		84 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death	Daratumumab			S	Subcutaneous	Cycle 3: D1: 27-Feb-2020 And D15: 19-Mar-2020		Not Reported	
	Lenalidomide			S	Oral	Cycle 3: 27-Feb-2020 To 18-Mar-2020		Not Reported	
	Dexamethasone			S	Intravenous (not otherwise specified)	Cycle 3		Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Morphine			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683592	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2020-002338		74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Lacrimation Increased	Azithromycin 250 Mg Tablets Usp			S	Unknown	Unk		Aurobindo	
	Lisinopril			C	Unknown	Unk		Not Reported	
	Aspirin			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683593	NON-EXPEDITED			US-AUROBINDO-AUR- APL-2020-007051		14 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash Erythematous	Azithromycin 250 Mg Tablets Usp			S	Unknown	2 Tablets For First Day And 1 Tablet For Next Four Days		Aurobindo	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17683594	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-007417			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Feeling Abnormal; Malaise	Azithromycin 250 Mg Tablets Usp			S	Unknown	Unk		Aurobindo	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684775	EXPEDITED (15-DAY)		OT	IE-TEVA-2020-IE-1223586			Male	IRL
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Gastrointestinal Disorder; Gastrointestinal Pain; Irritable Bowel Syndrome	Azithromycin Teva			S	Unknown			Not Reported	
	Magnesium (G)			S	Unknown			Not Reported	
	Probiotics (Generic) Ireland			C				Not Reported	
	Turmeric			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17684975	EXPEDITED (15-DAY)		OT	NVSC2020AU104610			Female	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Pneumonia	Mekinist			S	Unknown	Unk		Novartis	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685893	NON-EXPEDITED			NVSC2017US006104			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Azithromycin 250 Mg			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17685959	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1039157		66 YR	Female	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyponatraemia	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Coaprovel			S	Oral	1 Dosage Form, Qd		Mylan	
	Nebivolol			C				Mylan	
	Amoxicilline /00249601/			C				Mylan	
	Xarelto			C				Mylan	
	Uvedose			C				Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686546	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3371605-00		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperbilirubinaemia	Kaletra			S	Oral			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17686584	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-018508		63 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo	
	Ceftriaxone			S	Intravenous (not otherwise specified)	2 Gram, Once A Day		Not Reported	
	Ceftriaxone			S				Not Reported	
	Dolquine			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17689305	DIRECT	Y	OT			80 YR	Male	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Therapy Cessation	Azithromycin	Y		S	Intravenous (not otherwise specified)			Not Reported	
	Hydroxychloroquine 400 Mg			C				Not Reported	
	Hydroxychloroquine 200 Mg			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Apr-2020	17690121	DIRECT		HO				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged	Hydroxychloroquine			S	Oral	400mg Bid For 1 Day Then 200bid For 1 Day Bid Po X 1 Day(S)		Not Reported	
	Azithromycin			S		500mg Qd X 1 250mg Daily For 3 Days Qd Po X 3 Day(S)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	12696295	EXPEDITED (15-DAY)		OT	CA-ROCHE-1821354		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Mycophenolate Mofetil			S	Oral			Not Reported	
	Sulfamethoxazole/Trimethoprim			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	
	Candidas			S	Intravenous (not otherwise specified)	Single-Dose Vial		Not Reported	
	Ciprofloxacin			S	Oral			Not Reported	
	Montelukast			S	Oral			Not Reported	
	Nifedipine			S	Oral			Not Reported	
	Pantoprazole Sodium			S	Oral			Not Reported	
	Pantoprazole Sodium			S	Intravenous (not otherwise specified)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Oral	Not Reported
Tacrolimus	S	Oral	Not Reported
Voriconazole	S	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	14366426	EXPEDITED (15-DAY)		HO, OT	PHHY2012CA109519		84 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Distension; Abdominal Pain; Amnesia; Asthenia; Blood Pressure Decreased; Blood Pressure Diastolic Decreased; Blood Pressure Systolic Increased; Body Temperature Decreased; Cellulitis; Cerebrovascular Accident; Cholelithiasis; Contusion; Decreased Appetite; Diarrhoea; Discomfort; Drug Hypersensitivity; Erythema; Fall; Furuncle; Heart Rate Decreased; Heart Rate Irregular; Hip Fracture; Hyperhidrosis; Injection Site Pain; Joint Injury; Malaise; Needle Issue; Pain In Extremity; Peripheral Swelling; Productive Cough; Pruritus; Pulmonary Congestion; Septic Rash; Skin Laceration; Skin Ulcer; Yellow Skin	Sandostatin Lar			S	Intramuscular	30 Mg, Qmo (Every 4 Weeks)		Novartis
	Sandostatin Lar			S	Intramuscular	30 Mg, Qmo (Every 4 Weeks)		Novartis
	Tamiflu			S	Oral	(To Take 1 Capsule Po Every 2nd Day For 14 Days)		Not Reported
	Codeine			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Zithromax			C	Unknown	(2 Pills First Day And 1 Pill Daily For 4 Days)		Not Reported
	Celexa			C	Unknown	10 Mg, Qd		Not Reported
	Risperdal			C	Oral	0.25 Mg		Not Reported
	Citalopram			C	Oral	0.5 Df, Qd		Not Reported
	Diltiazem			C	Oral	180 Mg, Qd		Not Reported
	Sennosides A&B			C	Oral	1 Df, Qd		Not Reported
	Haloperidol			C	Unknown			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	14712889	EXPEDITED (15-DAY)			US-ROCHE-2097796		65 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection	Ocrevus			S	Unknown	First And Second Dose ;Ongoing: No		Not Reported	
	Ocrevus			S	Unknown	Ongoing:Yes		Not Reported	
	Azithromycin			S	Unknown	Ongoing:No		Not Reported	
	Baclofen			C	Unknown	Yes		Not Reported	
	Gabapentin			C	Unknown	Yes		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	15884994	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2170769		42 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anxiety; Asthenia; Burning Sensation; Cognitive Disorder; Cystitis; Depression; Dizziness; Dizziness; Drug Intolerance; Emotional Disorder; Fatigue; Feeding Disorder; Feeling Abnormal; Feeling Abnormal; Feeling Hot; Impaired Gastric Emptying; Influenza; Insomnia; Intentional Overdose; Limb Discomfort; Malaise; Multiple Sclerosis Relapse; Musculoskeletal Stiffness; Night Sweats; Pain; Pain; Pain In Extremity; Suicide	Ocrevus			S	Intravenous (not otherwise specified)	300 Mg Day 0 And Day14, Then 600mg Every 6 Months		Not Reported	
	Azithromycin			S	Unknown	Tid For 10 Days But She Was Unable To Tolerate It And Has Been Taking One A Day.		Not Reported	
	Wellbutrin			S	Unknown			Not Reported	
	Lyrica			C				Not Reported	
	Cipralex [Escitalopram]			C				Not Reported	
	Oxycontin			C				Not Reported	
	Clonazepam			C	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Attempt; Weight
Decreased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	16631063	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-043438			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Pancreatitis Acute	Azithromycin			S	Unknown	Unk		Aurobindo
	Asacol			S	Unknown	Unk		Not Reported
	Azathioprine			S	Unknown	Unk		Not Reported
	5 Asa			S	Unknown	Unk		Not Reported
	Ethinylestradiol;Levonorgestrel			S	Unknown	Unk		Not Reported
	Infliximab			S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported
	Infliximab			S	Unknown	50 Milligram/Kilogram		Not Reported
	Levonorgestrel			S	Unknown	Unk		Not Reported
	Mercaptopurine			S	Unknown	Unk		Not Reported
	Mezavant			S	Unknown	Unk		Not Reported
	Para-Aminosalicylic Acid			S	Unknown	Unk		Not Reported
	Prednisone			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17518555	EXPEDITED (15-DAY)		HO, OT	US-AUROBINDO-AUR- APL-2020-010869			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Diarrhoea; Gastrointestinal Pain; Malaise; Product Physical Issue; Product Substitution Issue; Rectal Haemorrhage; Toxicity To Various Agents	Azithromycin 250 Mg Tablets Usp			S	Oral	2 Dosage Form, Daily, 1 In The Morning And 1 In The Evening		Aurobindo
	Azithromycin 250 Mg Tablets Usp			S				Aurobindo
	Cipro			S	Unknown	Unk		Not Reported
	Doxycycline			C	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Doxycycline			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17652487	EXPEDITED (15-DAY)		OT	US-TEVA-2020-US-1218194		50 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Granuloma; Histoplasmosis Disseminated; Mediastinal Mass	Methotrexate			S	Unknown			Barr	
	Methotrexate			S				Barr	
	Infliximab			S	Unknown			Not Reported	
	Infliximab			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17678973	EXPEDITED (15-DAY)		HO, OT	DE-MYLANLABS-2020M1038356		79 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Delirium	Azithromycin			S	Oral	500mg		Not Reported	
	Edoxaban			S	Oral	30mg		Mylan	
	Ampicillin And Sulbactam			C	Intravenous (not otherwise specified)	3 Gram, Q8h, 3x3g		Mylan	
	Bisoprolol			C	Oral	2.5 Milligram,2,5-0-2,5mg, 12 Hours		Mylan	
	Insuman Basal			C	Subcutaneous	4 International Unit, Qd (0-0-0-4ie)		Mylan	
	Sitagliptin			C	Oral	100 Milligram, Qd (100-0-0mg)		Mylan	
	Ceftriaxon			C	Oral	2 Gram, Qd, 1x2g		Mylan	
	Candesartan			C	Oral	32 Milligram, Qd, 32mg-0-0		Mylan	
	Amlodipin /00972401/			C	Oral	5 Milligram, 5-0-5mg, 12 Hours		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17686847	NON-EXPEDITED			US-PFIZER INC-2020157700		69 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17687219	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-244391			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Daily		Sun	
	Plaquenil 200 Mg, Comprime			S	Oral	600 Milligram, Daily		Not Reported	
	Enrobe								
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688786	EXPEDITED (15-DAY)		DE	FR-ADVANSZ PHARMA-202004003713			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown			Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17688902	EXPEDITED (15-DAY)		OT	IT-MYLANLABS-2020M1039492		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain; Haematochezia	Azithromycin			S	Oral	500 Milligram, Cycle		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689015	DIRECT	Y	DE			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Respiratory Failure; Sudden Death	Hydroxychloroquine			S	Oral			Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689685	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226003		66 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Amoxicilina / Clavulanico (Amoxicillin\Clavulanic Acid)			S	Oral	875 Mg,1 Df		Teva	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17689693	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016133US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Escitalopram Oxalate - Bp			S	Oral	10 Mg, Qd		Allergan	
	Plaquenil			S	Oral	600 Mg, Qd		Not Reported	
	Azithromycine Sandoz [Azithromycin Monohydrate]			S	Oral	250 Mg, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17690548	EXPEDITED (15-DAY)		OT	CN-BAXTER-2020BAX008147		86 YR	Female	CHN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Dry Mouth; Dysgeusia; Hypoaesthesia Oral; Nausea; Pallor	Metronidazole And Sodium Chloride Injection	S	Intravenous drip		Baxter
	Fuqixing	S	Intravenous drip		Not Reported
	Sodium Chloride	S	Intravenous drip	Sodium Chloride Injection + Fuqixing Injection	Not Reported
	Pantoprazole Sodium	S	Intravenous drip		Not Reported
	Pantoprazole Sodium	S			Not Reported
	Glucose	S	Intravenous drip		Not Reported
	Sodium Chloride	S	Intravenous drip	Sodium Chloride Injection + Pantoprazole Sodium Injection	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Apr-2020	17690600	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-019705		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Aurobindo
	Plaquenil			S	Oral	Unk		Not Reported
	Lovenox			C	Oral	Unk		Not Reported
	Paracetamol			C	Oral	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17662709	EXPEDITED (15-DAY)		OT	CN-PFIZER INC-2020152001		72 YR	Female	CHN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthenia; Chest Discomfort; Dysphagia; Dyspnoea; Muscular Weakness	Azithromycin			S	Intravenous drip	0.5 G, 1x/Day		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17664817	NON-EXPEDITED			US-PFIZER INC-2020152065		80 YR	Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Effective For Unapproved Indication; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, Daily (Scheduled For 5 Days)		Pfizer	
	Vitamin C [Ascorbic Acid]			S		1000 Mg, 3x/Day		Not Reported	
	Zinc			S		220 Mg, 3x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17682499	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA-1223412		50 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Alanine Aminotransferase Increased; Antisocial Behaviour; Arthralgia; Aspartate Aminotransferase Increased; Blood Albumin Increased; Blood Alkaline Phosphatase Increased; Chest Pain; Depression; Drug Dependence; Drug Withdrawal Syndrome; Hyperhidrosis; Insomnia; Nausea; Night Sweats; Rhinorrhoea; Substance Abuse; Vomiting	Morphine Sulfate			S	Oral	120 Milligram Daily;		Actavis	
	Acetaminophen/Oxycodone Hydrochloride			S	Oral			Actavis	
	Morphine Sulfate			S	Oral			Not Reported	
	Codeine			S	Unknown			Not Reported	
	Methadone			S	Oral			Not Reported	
	Oxycontin			S	Oral	80 Milligram Daily;		Not Reported	
	Zithromax			S	Unknown			Not Reported	
	Cocaine			S	Unknown			Not Reported	
	Cannabis Sativa			S	Respiratory (inhalation)			Not Reported	
	Alprazolam			C				Not Reported	
	Amitriptyline			C				Not Reported	
	Ativan			C				Not Reported	
	Cefalexin Monohydrate			C				Not Reported	
	Ciprofloxacin			C				Not Reported	
	Clonazepam			C				Not Reported	
	Demerol			C				Not Reported	
	Gravol			C				Not Reported	
	Imovane			C				Not Reported	
	Paroxetine Hydrochloride			C				Not Reported	
	Influenza Vaccine;Tetanus Vaccine			C				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17690794	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226002		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	200 Milligram Daily; 200 Mg/24h		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; 600mg/24h		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily; 2gr/24h		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17691425	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225669		33 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400mg		Teva	
	Hidroxiclороquina (2143a)			S	Oral	400 Mg / 12h The First Day, Then 400 Mg / 24h, Unit Dose 400 Mg		Teva	
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Does 500 Mg		Not Reported	
	Azitromicina (7019a)			S	Oral	500mg / 24h 1st Dose, Then 250mg / 24h, Unit Dose 250 Mg		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not	2gr/24h, Unit Dose 2 Gm		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxona (501a)			S				otherwise specified)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Apr-2020	17692356	NON-EXPEDITED		OT	US-PFIZER INC-2020158135			Unknown	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Pneumonia	Zithromax			S		Unk		Pfizer		
	Rocephin			S		Unk		Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Apr-2020	17692895	EXPEDITED (15-DAY)		HO	HU-TEVA-2020-HU-1226102		12 YR	Male	HUN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hypersensitivity; Mouth Swelling; Sensation Of Foreign Body; Swelling Of Eyelid	Azithromycin			S	Unknown			Not Reported		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
22-Apr-2020	17694029	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1225643		68 YR	Male	ESP	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400mg		Teva		
	Hidroxiclороquina (2143a)			S	Oral	1er Día 400 Mg/12 H, A Partir Del 2º Día 400mg/24 H		Teva		
	Azitromicina (7019a)			S	Oral	500 Mg 1st Dose, Later 250mg / 24h		Not Reported		
	Azitromicina (7019a)			S	Oral			Not Reported		
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Milligram Daily; Single Dose		Not Reported		
	Tocilizumab (8289a)			S				Not Reported		

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17694544	EXPEDITED (15-DAY)		HO	NVSC2020PT076890		78 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Infection; Vulvovaginal Candidiasis	Azithromycin			S	Unknown	Unk		Novartis	
	Ceftriaxone			S	Unknown	Unk		Not Reported	
	Econazole			C	Unknown	Unk		Not Reported	
	Fluconazole			C	Oral	2 Doses Of 150 Mg Every 72 Hours		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Apr-2020	17695215	EXPEDITED (15-DAY)		DE	IT-AUROBINDO-AUR-APL-2020-019985		70 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Transaminases Increased	Azithromycin Film-Coated Tablets			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	400 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	15084561	NON-EXPEDITED			US-PFIZER INC-2018256372		24 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Zithromax			S		Unk		Pfizer	
	Albuterol			C		2 Df, 4x/Day As Needed		Not Reported	
	Epipen			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	15988482	EXPEDITED (15-DAY)		OT	CA-009507513-1902CAN006490		10 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Actinic Keratosis; Drug Interaction; Dysplastic Naevus; Photodermatosis; Photosensitivity Reaction; Solar Lentigo; Squamous Cell Carcinoma Of Skin	Cancidas	S	Intravenous (not otherwise specified)	Unk	Merck
	Cancidas	S	Intravenous (not otherwise specified)	Unk	Merck
	Cancidas	S	Intravenous (not otherwise specified)	Unk	Merck
	Singulair	S	Oral	Unk	Merck
	Singulair	S	Oral	Unk	Merck
	Prednisone	S	Oral	Unk	Not Reported
	Tacrolimus	S	Oral	Unk	Not Reported
	Mycophenolate Mofetil	S	Oral	Unk	Not Reported
	Sulfadiazine (+) Trimethoprim	S	Oral	Unk	Not Reported
	Voriconazole	S	Oral	Unk	Not Reported
	Voriconazole	S			Not Reported
	Nifedipine	S	Oral	Unk	Not Reported
	Pantoprazole Sodium	S	Oral	Unk	Not Reported
	Pantoprazole Sodium	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Azithromycin	S	Oral	Unk	Not Reported
	Azithromycin	S	Oral	Dosage Form Not Specified	Not Reported
	Ciprofloxacin Hydrochloride	S	Oral	Unk	Not Reported
	Sulfamethoxazole (+) Trimethoprim	S	Oral	Unk	Not Reported
	Sulfamethoxazole (+) Trimethoprim	S	Oral	Unk	Not Reported
	Sulfatrim	S	Oral	Unk	Not Reported
	Voriconazole	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Pantoprazole	S	Oral	Dosage Form Not Specified	Not Reported
	Pantoprazole	S	Intravenous (not otherwise specified)	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ciprofloxacin S Oral Dosage Form Not Specified Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
23-Apr-2020	16975365	EXPEDITED (15-DAY)		HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR194666			Unknown	CAN

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Asthenia; Asthma;	Salbutamol Sulphate			S		Unk Unk, Prn		Glaxosmithkline
Bronchial Obstruction;	Singular			S		100 Mg, Unk		Glaxosmithkline
Chest Discomfort;	Reactine (Cetirizine			S		20 Mg, Bid		Glaxosmithkline
Conjunctivitis; Cough;	Hydrochloride\Pseudoephedrine							
Disease Recurrence;	Hydrochloride)							
Dizziness; Dyspnoea;	Breo Ellipta			S		Unk		Glaxosmithkline
Eosinophilia; Exposure	Advair			S		Unk		Glaxosmithkline
During Pregnancy; Feeling	Montelukast			S		10 Mg, Qd		Glaxosmithkline
Abnormal; Feeling Hot;	Vitamin D			S		Unk Unk, Z(10,000 U		Glaxosmithkline
Hypersensitivity;						Once A Week)		
Hyperventilation;	Azithromycin			S		250 Mg, Tid		Glaxosmithkline
Increased Bronchial	Nucala			S	Intravenous (not	100 Mg, Z (Monthly)		Glaxosmithkline
Secretion; Middle					otherwise specified)			
Insomnia; Nasal	Nucala			S	Intravenous (not	100 Mg, Z (Monthly)		Glaxosmithkline
Congestion; Nausea;					otherwise specified)			
Palpitations; Productive	Symbicort			S		2 Puff(S), Bid		Not Reported
Cough; Rhinitis;	Symbicort			S		4 Puff(S), Qod		Not Reported
Therapeutic Product Effect	Xolair			S		Unk		Not Reported
Incomplete; Urticaria;	Seebri			S		1 Df, Unk		Not Reported
Wheezing	Prednisone			S		15 Mg, Qd, 3 Or 4 Days		Not Reported
	Fasenra			S		Unk		Not Reported
	Zenhale			S		2 Puff(S), Bid		Not Reported
	Alvesco			S	Respiratory	2 Df, Qd (Tablets) (200)		Not Reported
					(inhalation)			

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Spiriva Respimat	S	2 Puff(S), Qd	Not Reported
Uniphyl	S	200 Mg, Unk	Not Reported
Uniphyl	S	600 Mg, Unk	Not Reported
Solumedrol	S	Unk	Not Reported
Medrol	S	Unk	Not Reported
Synthroid	S	0.1 Mg, Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17203217	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2019556535		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bacterial Disease Carrier; Blood Count Abnormal; Bronchial Secretion Retention; Bronchial Wall Thickening; Cough; Drug Ineffective; Dyspnoea; Fall; Ill-Defined Disorder; Intervertebral Disc Protrusion; Malaise; Obstructive Airways Disorder; Rales; Spinal Cord Compression; Sputum Discoloured; Therapeutic Product Effect Incomplete; Upper Limb Fracture; Wheezing; Wrist Fracture	Pantoprazole			S	Unknown	40 Mg, 1x/Day		Pfizer
	Calcium Carbonate			S	Unknown	Unk		Pfizer
	Celebrex			S		Unk		Pfizer
	Hydroxyzine Hcl			S	Unknown	Unk		Pfizer
	Azithromycin			S		250 Mg, 1x/Day		Pfizer
	Alvesco			S	Unknown	200 Ug, 2x/Day		Not Reported
	Alvesco			S	Unknown	300 Ug, 2x/Day		Not Reported
	Alvesco			S	Unknown	200 Milligram, Bid		Not Reported
	Alvesco			S	Unknown	300 Milligram, Bid		Not Reported
	Daxas			S	Respiratory (inhalation)	500 Ug, 1x/Day		Not Reported
	Daxas			S	Respiratory (inhalation)	100 Ug, 1x/Day		Not Reported
	Benralizumab			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Pseudoephedrine-Chlorpheniramine			S				Not Reported
	Fluticasone Propionate/Salmeterol Xinafoate			S	Respiratory (inhalation)	Unk, 2x/Day		Not Reported
	Imodium			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Omalizumab	S	Unknown	Unk	Not Reported
Omalizumab	S	Unknown	225 Mg, 2x/Week	Not Reported
Omalizumab	S	Unknown	225 Milligram	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Singulair	S	Unknown	10 Milligram, Qd	Not Reported
Spiriva	S	Respiratory (inhalation)	2.5 Ug, 1x/Day	Not Reported
Spiriva	S	Respiratory (inhalation)	Unk, Qd	Not Reported
Ventoline [Salbutamol]	S	Unknown	Unk	Not Reported
Ventoline [Salbutamol]	S	Respiratory (inhalation)	Unk	Not Reported
Vitamin D Nos	S	Unknown	Unk	Not Reported
Zopiclone	S		5 Mg, 1x/Day	Not Reported
Calcium	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17238264	EXPEDITED (15-DAY)	HO		NVSC2019HR085107		34 YR	Female	HRV

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Febrile Neutrophilic Dermatitis; Erythema Nodosum; Product Use In Unapproved Indication; Pyrexia; Rash	Azithromycin			S	Unknown	Unk		Novartis
	Acetaminophen (Paracetamol)			S	Unknown	Unk		Not Reported
	Ibuprofen			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17667413	EXPEDITED (15-DAY)		LT, OT	FR-VALIDUS PHARMACEUTICALS LLC-FR-2020VAL000290			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Ventricular Tachycardia	Furosemide			S	Intravenous (not	2 Df, Qd		Validus

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

			otherwise specified)		
Azithromycin	S	Oral	250 Mg, Qd		Not Reported
Plaquenil /00072603/	S	Oral	Unk		Not Reported
Sufentanil	C		Unk		Not Reported
Perfalgan	C		Unk		Not Reported
Noradrenalin /00127501/	C		Unk		Not Reported
Midazolam	C		Unk		Not Reported
Tazocilline	C		Unk		Not Reported
Transipeg /00754501/	C		Unk		Not Reported
Potassium Chloride	C		Unk		Not Reported
Nimbex /01302502/	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17678833	EXPEDITED (15-DAY)		HO, OT	PT-AUROBINDO-AUR- APL-2020-017603		64 YR	Male	PRT

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Off Label Use; Pathogen Resistance	Azithromycin			S	Unknown	Unk		Aurobindo
	Azithromycin			S				Aurobindo
	Amoxicillin+Clavulanic Acid			S	Unknown	Unk		Aurobindo
	Amoxicillin+Clavulanic Acid			S				Aurobindo
	Levofloxacin			S	Unknown	Unk		Aurobindo
	Piperacillin+Tazobactam Powder For Solution For Injection			S	Unknown	Unk		Aurobindo
	Vancomycin Powder For Solution For Infusion			S	Unknown	Unk		Aurobindo
	Gentamicin			S	Unknown	Unk		Not Reported
	Gentamicin			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Imipenem			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17695364	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR- APL-2020-020073		43 YR	Male	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697379	EXPEDITED (15-DAY)		OT	AU-ACCORD-179080			Male	AUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Graft Versus Host Disease; Scleroderma	Montelukast			S				Not Reported	
	Tacrolimus			S				Accord	
	Methotrexate			S				Accord	
	Mycophenolic Acid			S				Accord	
	Imatinib/Imatinib Mesilate			S				Not Reported	
	Ibrutinib			S				Not Reported	
	Rituximab			S				Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17697469	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226211		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Mg Daily		Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699017	NON-EXPEDITED			US-AKRON, INC.-2083071			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Vision Blurred;	Azasite 1% Opth Solution			S				Akorn	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Visual Acuity Reduced

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699215	EXPEDITED (15-DAY)		OT	HU-MYLANLABS-2020M1040458		49 DAY	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Conjunctivitis; Eye Symptom; Eyelid Oedema; Product Use In Unapproved Indication	Azithromycin			S	Unknown	High Dose		Not Reported	
	Tobramycin			S	Unknown	Unk		Mylan	
	Tobramycin			S				Mylan	
	Betadine /00080001/			C	Ophthalmic	Drops		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699405	EXPEDITED (15-DAY)		OT	FR-CADILA HEALTHCARE LIMITED-FR-ZYDUS-049151			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mechanical Urticaria; Pruritus	Venlafaxine			S	Oral	Unk		Cadila	
	Azithromycin			S	Oral	250 Milligram, Qd		Zydus Pharm	
	Rifadine [Rifampicin Sodium]			S	Oral	2 Dosage Form, Qd		Not Reported	
	Dexambutol			S	Oral	2 Dosage Form, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17699659	NON-EXPEDITED			NVSC2020US105890			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity; Rash	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700264	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016504US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Non-Infectious Endophthalmitis	Flurbiprofen Sodium Unk	S	Ophthalmic	1 Gtt, Tid	Allergan
	Aprokarm	S	Intraocular	Unk	Not Reported
	Azyter	S	Ophthalmic	1 Gtt, Bid	Not Reported
	Dexafree	S	Ophthalmic	1 Gtt, Qd	Not Reported
	Dexafree	S	Ophthalmic	1 Gtt, Bid	Not Reported
	Dexafree	S	Ophthalmic	1 Gtt, Tid	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700395	NON-EXPEDITED			PR-PFIZER INC- 2020159302		72 YR	Female	PRI
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Drug Ineffective; Mycoplasma Test Positive; Productive Cough	Zithromax			S		Unk		Pfizer	
	Avelox			S		Unk		Not Reported	
	Enbrel			C		50 Mg		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700421	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1040987			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700422	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1040990			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Every Other Day; For At Least 6 Months		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17700425	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040991			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17703460	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR-APL-2020-020222		43 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Nivaquine			S	Oral	200 Milligram, Once A Day (2-3 Cp Per Day)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Apr-2020	17703487	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-020274		46 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rectal Haemorrhage	Azithromycin Film-Coated Tablets			S	Oral	1 Dosage Form, Once A Day		Aurobindo	
	Tamiflu			S	Oral	2 Dosage Form, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17662214	EXPEDITED (15-DAY)		OT	CH-EMD SERONO-E2B_90076477		37 YR	Female	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Premenstrual Syndrome	Gonal-F			S	Subcutaneous	In Total		Not Reported	
	Gonal-F			S				Not Reported	
	Cetrotide			S		Therapy Start Date: Jan		Serono	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Puregon /01348901/	S		2019	
			Therapy Start Date: Jan 2019	Not Reported
Orgalutran	S	Subcutaneous	In Total	Not Reported
Decapeptyl /00975902/	S	Subcutaneous	In Total	Not Reported
Decapeptyl /00975902/	S	Subcutaneous	In Total	Not Reported
Azithromycine	S		In Total	Not Reported
Ethinylestradiol/Levonorgestrel	S		Therapy Start Date: Jan 2019 Ethinylestradiol: 0.02 Mg And Levonorgestrel: 0.1 Mg	Not Reported
Menopur	S		Therapy Start Date: Jan 2019	Not Reported
Merional	S		Therapy Start Date: Jan 2019	Not Reported
Trazodone	C			Not Reported
Trazodone	C			Not Reported
Zoloft	C			Not Reported
Dalmadorm	C			Not Reported
Imovane	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701011	EXPEDITED (15-DAY)		DE	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-244837		75 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Sudden Death	Levofloxacin			S	Unknown	Unk		Ranbaxy
	Azithromycin			S	Oral	500 Milligram, Daily		Sun
	Hidroxicloroquina Sulfato (2143su)			S	Oral	200 Milligram, Daily		Not Reported
	Lopinavir+Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported
	Enoxaparina Sodica (2482so)			C	Subcutaneous	40 Milligram, Daily		Not Reported
	Prednisona (886a)			C	Oral	20 Milligram, Daily		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxona (501a)			C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17701610	EXPEDITED (15-DAY)		HO, OT	CZ-AUROBINDO-AUR-APL-2020-020105		71 YR	Male	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bronchiectasis; Chronic Obstructive Pulmonary Disease; Condition Aggravated; Eosinophil Count Decreased; Sputum Increased; Treatment Noncompliance	Azithromycin			S	Unknown	Unk		Aurobindo	
	Roflumilast			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17702988	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226290		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Milligram Daily; Route Of Administration: Sng		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703265	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1226288		65 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiogenic Shock; Drug Interaction; Tachyarrhythmia	Hidroxiclороquina Sulfato (2143su)			S	Oral	200 Mg		Teva	
	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Tocilizumab (8289a)			C	Intravenous (not otherwise specified)			Not Reported	
	Ceftriaxona (501a)			C	Intravenous (not	1 Gram		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703409	EXPEDITED (15-DAY)		LT, OT	FR-AUROBINDO-AUR- APL-2020-020223		66 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Sinus Bradycardia	Levofloxacin			S	Intravenous (not otherwise specified)	1000 Milligram		Aurobindo	
	Plaquenil			S	Oral			Not Reported	
	Zithromac			S	Oral	500 Milligram, Once A Day		Not Reported	
	Zyvoxid			C	Intravenous (not otherwise specified)	1200 Milligram		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17703479	EXPEDITED (15-DAY)		HO	IT-ABBVIE-20K-083- 3376441-00		72 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Fibrillation; Hypertransaminasaemia; Off Label Use	Kaletra			S	Oral			Not Reported	
	Plaquenil			S	Oral			Not Reported	
	Zitromax Avium			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705186	NON-EXPEDITED			US-PFIZER INC- 2020162574		78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705685	EXPEDITED (15-DAY)		DE	FR-PFIZER INC- 2020162444		62 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Off Label Use; Product	Zithromax	S	Oral	500 Mg, 1x/Day	Pfizer
Use In Unapproved Indication; Sudden Death	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705686	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162461		71 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Drug Interaction; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Other	Unk		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported
	Primperan			S	Intravenous drip	30 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705929	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1226300		70 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycine Anhydre			S	Oral			Not Reported
	Plaquenil			S	Oral			Not Reported
	Lovenox			C	Oral			Not Reported
	Paracetamol			C	Oral			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705944	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226289		28 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxona (501a)	S	otherwise specified)		Not Reported
Paracetamol (12a)	S	Intravenous (not otherwise specified)	1 Gram Every 8 Hours	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705968	NON-EXPEDITED			US-PFIZER INC-2020163617		61 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Acetaminophen;Hydrocodone			S		Unk		Not Reported	
	Celexa [Celecoxib]			S		Unk		Not Reported	
	Biaxin			S		Unk		Not Reported	
	Seroquel			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17705972	NON-EXPEDITED		HO	US-PFIZER INC-2020163680			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective For Unapproved Indication; Off Label Use	Ampicillin			S		Unk		Pfizer	
	Azithromycin			S		Unk		Pfizer	
	Albuterol Sulfate			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17706318	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020162376			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Off Label Use; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706928	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040845			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706931	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040859			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706933	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040858			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod(For At Least 6 Months)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17706935	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040851			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod (For At Least 6 Months)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
24-Apr-2020	17707041	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040992			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707054	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040994			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707078	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040989			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707080	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040988			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Every Other Day; For At Least 6 Months			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707090	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1041157			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707164	EXPEDITED (15-DAY)		OT	CA-TARO-2020TAR00801			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Betaderm			S	Unknown	Unk		Taro
	Acetaminophene			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate			S	Unknown	Unk		Not Reported
	Apo Hydro			S	Unknown	Unk		Not Reported
	Atorvastatin			S	Unknown			Not Reported
	Avamys			S	Unknown	Unk		Not Reported
	Azithromycin Dihydrate			S	Unknown	Unk		Not Reported
	Bactroban			S	Unknown	Unk		Not Reported
	Betamethasone Dipropionate			S	Unknown	Unk		Not Reported
	Biaxin XI			S	Unknown	Unk		Not Reported
	Bisacodyl			S	Unknown	Unk		Not Reported
	Calcium Carbonate/ Magnesium Sulfate/Vitamin D3			S	Unknown	Unk		Not Reported
	Calcium Carbonate/Vitamin D3			S	Unknown	Unk		Not Reported
	Cetirizine			S	Unknown	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Clotrimazole			S	Unknown	Unk		Not Reported
	Cupric Oxide/ DL-Alpha Tocopheryl Acetate/ Vitamin C/ Xantofyl Palmita			S	Unknown	Unk		Not Reported
	Desonide			S	Unknown	Unk		Not Reported
	Dilaudid			S	Unknown	Unk		Not Reported
	Diphenhydramine			S	Unknown	Unk		Not Reported
	Entocort			S	Unknown	Unk		Not Reported
	Ertapenem Sodium			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Flovent	S	Unknown		Not Reported
Glycerine	S	Oral	Unk	Not Reported
Gramicidine/Neomycin Sulphate/Polymyxin B Sulphate	S	Unknown		Not Reported
Habitrol	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog	S	Intra-articular	Unk	Not Reported
Lomotil	S	Unknown	Unk Unk, Qid (4 Every 1 Day)	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/ Sodium Chloride/S	S	Unknown	Unk	Not Reported
Meteronidazole	S	Unknown	Unk	Not Reported
Mupirocin	S	Topical	Unk	Not Reported
Ms Ir	S	Unknown	Unk	Not Reported
Nadolol	S	Unknown	Unk	Not Reported
Nicoderm	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pantasa	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Pulmicort	S	Unknown		Not Reported
Refresh Tears	S	Unknown	Unk	Not Reported
Salinex [Benzalkonium Chloride]	S	Unknown	Unk	Not Reported
Sinus Rinse	S	Nasal	Unk	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Unk	Not Reported
Sulphamethoxazole /Trimethoprim	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	S	Unknown	Unk	Not Reported
Vitamin D3	S	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Calcium Carbonate/Vitamin D3			C			Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707174	EXPEDITED (15-DAY)		OT	CA-TARO-2020TAR00804			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Betaderm			S	Unknown			Taro	
	Betamethasone Dipropionate			S	Unknown			Not Reported	
	Clotrimazole			S	Unknown	Unk		Not Reported	
	Diphenhydramine			S	Unknown			Not Reported	
	Mupirocin			S	Unknown	Unk		Not Reported	
	Metronidazole			S	Unknown	Unk		Not Reported	
	Triamcinolone Acetonide			S	Unknown	Unk		Not Reported	
	Alprazolam			S	Unknown			Not Reported	
	Amoxicillin Trihydrate			S	Unknown			Not Reported	
	Apo Hydro			S	Unknown			Not Reported	
	Atorvastatin			S	Unknown			Not Reported	
	Atropine Sulphate+ Diphenoxylate Hydrochloride			S	Unknown			Not Reported	
	Avamys			S	Unknown	Unk		Not Reported	
	Azithromycin Dihydrate			S	Unknown			Not Reported	
	Bactrim			S	Unknown	Unk		Not Reported	
	Bactroban			S	Unknown			Not Reported	
	Biaxin XI			S	Unknown	Unk		Not Reported	
	Bisacodyl			S	Unknown	Unk		Not Reported	
	Calcium Carbonate And Vitamin D3			S	Unknown			Not Reported	
	Cetirizine Hydrochloride			S	Unknown	Unk		Not Reported	
	Clarithromycin			S	Unknown	Unk		Not Reported	
	Desonide			S	Unknown	Unk		Not Reported	
	Dilaudid			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Entocort	S	Unknown	Unk		Not Reported
	Ertapenem Sodium	S	Unknown			Not Reported
	Glycerine	S	Unknown			Not Reported
	Gramicidin + Gramicidin+ Polymyxin B Sulfate	S	Unknown			Not Reported
	Habitrol	S	Unknown			Not Reported
	Humira	S	Subcutaneous	Unk		Not Reported
	Kenalog	S	Intra-articular			Not Reported
	Ms Ir	S	Unknown	Unk		Not Reported
	Nadolol	S	Unknown	Unk		Not Reported
	Nicoderm	S	Unknown	Unk		Not Reported
	Nicotine	S	Unknown			Not Reported
	Pantoprazole	S	Unknown	Unk		Not Reported
	Paracetamol	S	Unknown	Unk		Not Reported
	Pentasa	S	Unknown	Unk		Not Reported
	Prednisone	S	Unknown			Not Reported
	Pregabalin	S	Unknown	Unk		Not Reported
	Pulmicort	S	Unknown	Unk		Not Reported
	Refresh Tears	S	Unknown	Unk		Not Reported
	Sinus Rinse	S	Nasal	Unk		Not Reported
	Statex (Morphine Sulfate)	S	Unknown	Unk		Not Reported
	Vitamin D3	S	Unknown	Unk		Not Reported
	Valsartan	C	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707179	EXPEDITED (15-DAY)		OT	CA-TARO- 2020TAR00806			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Betaderm			S	Unknown	Unk		Taro
	Betamethasone Dipropionate			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Clotrimazole	S	Unknown	Unk	Not Reported
Diphenhydramine	S	Unknown	Unk	Not Reported
Mupirocin	S	Topical	Unk	Not Reported
Mupirocin	S	Unknown	Unk	Not Reported
Acetaminophen	S	Unknown	Unk	Not Reported
Alprazolam	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	S	Unknown	Unk	Not Reported
Apo Hydro	S	Unknown	Unk	Not Reported
Ascorbic Acid;Copper; Tocopherol; Xantofyl; Zeaxanthin; Zinc	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	S	Unknown	Unk	Not Reported
Atropine Sulphate/Diphenoxylate Hydrochloride	S	Unknown	Unk	Not Reported
Avamys	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	S	Unknown	Unk	Not Reported
Biaxin XI	S	Unknown	Unk	Not Reported
Bisacodyl	S			Not Reported
Calcium Carbonate	S	Unknown	Unk	Not Reported
Calcium Carbonate\Calcium Citrate\Calcium Phosphate\Cholecalciferol\Vitam in D	S	Unknown		Not Reported
Calcium Carbonate\Calcium Citrate\Calcium Phosphate\Cholecalciferol\Vitam in D	S	Unknown	Unk	Not Reported
Calcium/Magnesium/ Vitamin D3	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Clarithromycin	S	Unknown	Unk	Not Reported
Desonide	S	Unknown	Unk	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Entocort	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk	Not Reported
Glycerin	S	Unknown	Unk	Not Reported
Gramicidin/ Neomycin Sulphate/Polymyxin Sulfate	S	Unknown	Unk	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog (Triamcinolone Acetonide)	S	Unknown	Unk	Not Reported
Lomotil	S	Oral	Unk Unk, Qid	Not Reported
Macrogol 3350;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	S	Unknown		Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Morphine Sulfate	S	Unknown	Unk	Not Reported
Mupirocin Calcium Dihydrate	S	Unknown	Unk	Not Reported
Nadolol	S	Unknown	Unk	Not Reported
Nicoderm	S	Unknown	Unk	Not Reported
Nicotine	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	S	Unknown	Unk	Not Reported
Pantoprazole	S	Unknown	Unk	Not Reported
Pentasa	S	Unknown	Unk	Not Reported
Prednisone	S	Unknown	Unk	Not Reported
Pregabalin	S	Unknown	Unk	Not Reported
Pulmicort	S	Unknown	Unk	Not Reported
Refresh Tears	S	Unknown	Unk	Not Reported
Salinex [Sodium Chloride]	S	Unknown	Unk	Not Reported
Sinus Rinse	S	Unknown	Unk	Not Reported
Sodium Chloride	S	Unknown	Unk	Not Reported
Statex [Morphine Sulfate]	S	Unknown	Unk	Not Reported
Supphamethoxazole; Trimethoprim	S	Unknown	Unk	Not Reported
Trimicinolone Acetonide	S	Intra-articular	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Vitamin D3	S	Unknown	Unk	Not Reported
Xanthofyl Palmitate	S	Unknown	Unk	Not Reported
Zeaxanthin	S	Unknown	Unk	Not Reported
Zinc Oxide	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	C	Unknown	Unk	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707255	NON-EXPEDITED			US-WOCKHARDT USA, LLC-2083116		83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Oral Discomfort	Azithromycin			S	Oral			Wockhardt	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707267	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016501US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Endophthalmitis	Flurbiprofen Sodium Unk			S	Ophthalmic	1 Gtt, Tid		Allergan	
	Azyter			S	Ophthalmic	1 Gtt, Bid		Not Reported	
	Dexafree			S	Ophthalmic	1 Gtt, Tid		Not Reported	
	Dexafree			S	Ophthalmic	1 Gtt, Bid		Not Reported	
	Dexafree			S	Ophthalmic	1 Gtt, Qd		Not Reported	
	Aprokam			S		Unk, Single		Not Reported	
	Lipanthyl			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707278	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016503US			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Non-Infectious	Flurbiprofen Sodium Unk			S	Ophthalmic	1 Drop, Tid, For One		Allergan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Endophthalmitis

				Month	
Azyter	S	Ophthalmic	2 Drop, Qd		Not Reported
Dexafree /00016002/	S	Ophthalmic	1 Drop, Qd, During 7 Days		Not Reported
Dexafree /00016002/	S	Ophthalmic	1 Drop, Bid, During 7 Days		Not Reported
Dexafree /00016002/	S	Ophthalmic	1 Drop, Tid, During 15 Days		Not Reported
Aprokam	S		Unk		Not Reported
Silodyx	C	Unknown	Unk		Not Reported
Tadenan	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707293	EXPEDITED (15-DAY)		OT	FR-ALLERGAN-2016494US			Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Endophthalmitis; Product Preparation Error; Product Prescribing Issue; Product Use In Unapproved Indication	Flurbiprofen Sodium Unk			S	Ophthalmic	1 Drop, Tid For 1 Month On The Right Eye		Allergan
	Dexafree			S	Ophthalmic	1 Drop, Tid For 15 Days On The Right Eye		Not Reported
	Dexafree			S	Ophthalmic	1 Drop, Bid For 7days On The Right Eye		Not Reported
	Dexafree			S	Ophthalmic	1 Drop, Qd For 7 Days On The Right Eye		Not Reported
	Aprokam			S		Unk, Qd		Not Reported
	Azyter			S	Ophthalmic	1 Drop, Bid Morning And Evening For 3 Days On The Right Eye		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Apr-2020	17707828	EXPEDITED (15-DAY)		HO	ES-009507513-2004ESP006461		73 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia;	Ertapenem Sodium			S	Intravenous (not	1 G Day		Merck

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Haemorrhage; Hepatitis Acute				otherwise specified)		
	Piperacillin Sodium (+) Tazobactam Sodium	S	Intravenous (not otherwise specified)	C/24 H		Not Reported
	Azithromycin	S	Oral	500 Mg Per Day		Not Reported
	Dolquine	S	Oral	400 Mg Per Day		Not Reported
	Dolquine	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	15944356	EXPEDITED (15-DAY)		HO, OT	CA-ROCHE-2260729		65 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Abscess	Xolair			S	Subcutaneous			Not Reported
Oral; Acne; Anxiety;	Xolair			S	Subcutaneous			Not Reported
Asthenia; Asthma; Back	Xolair			S	Subcutaneous			Not Reported
Pain; Blood Cholesterol	Xolair			S	Subcutaneous			Not Reported
Increased; Blood Pressure	Xolair			S	Subcutaneous			Not Reported
Systolic Increased;	Xolair			S	Subcutaneous			Not Reported
Bronchitis; Burning	Xolair			S	Subcutaneous			Not Reported
Sensation; Cyst;	Xolair			S	Subcutaneous			Not Reported
Depression; Dermatitis	Xolair			S	Subcutaneous			Not Reported
Contact; Diarrhoea;	Xolair			S	Subcutaneous			Not Reported
Dizziness; Drug	Xolair			S	Subcutaneous			Not Reported
Ineffective; Dyspnoea;	Xolair			S	Subcutaneous			Not Reported
Fatigue; Fear; Headache;	Xolair			S	Subcutaneous			Not Reported
Heart Rate Increased;	Xolair			S	Subcutaneous			Not Reported
Injection Site Urticaria;	Xolair			S	Subcutaneous			Not Reported
Intervertebral Disc	Xolair			S	Subcutaneous			Not Reported
Protrusion; Lacrimation	Xolair			S	Subcutaneous			Not Reported
Increased; Laziness;	Xolair			S	Subcutaneous			Not Reported
Malaise; Mental Disorder;	Xolair			S	Subcutaneous			Not Reported
Muscle Spasms; Muscular	Xolair			S	Subcutaneous			Not Reported
Weakness; Myopia;	Xolair			S	Subcutaneous			Not Reported
Nasopharyngitis; Neck	Xolair			S	Subcutaneous			Not Reported
Pain; Nervousness;	Xolair			S	Subcutaneous			Not Reported
Osteoarthritis; Pain;	Xolair			S	Subcutaneous			Not Reported
Pruritus; Rhinorrhoea;	Xolair			S	Subcutaneous			Not Reported
Sleep Disorder; Sputum	Xolair			S	Subcutaneous			Not Reported
Retention; Suicidal	Xolair			S	Subcutaneous			Not Reported
Ideation; Tendonitis;	Xolair			S	Subcutaneous			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tinnitus; Tremor; Vision Blurred; Weight Decreased	Xolair	S	Subcutaneous		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Paxil [Paroxetine Hydrochloride]	S	Unknown		Not Reported
	Paxil [Paroxetine Hydrochloride]	S	Unknown		Not Reported
	Paxil [Paroxetine Hydrochloride]	S			Not Reported
	Atorvastatin	C	Oral	1 Df, Qd	Not Reported
	Prednisone	C	Oral	1 Df, Qd	Not Reported
	Singulair	C	Oral	1 Df, Qd	Not Reported
	Ventolin [Salbutamol]	C	Respiratory (inhalation)	2 Df, Qid	Not Reported
	Spiriva	C	Respiratory (inhalation)	2 Df, Qd	Not Reported
	Zenhale	C	Respiratory (inhalation)	2 Df(200 Ug, Formoterol Fumarate, 5 Ug, Mometasone Furoate), Qid	Not Reported
	Paroxetin [Paroxetine]	C	Oral	1 Df, Qd	Not Reported
	Trazodone	C	Oral	1 Df, Qd	Not Reported
	Lorazepam	C	Oral	1 Df, Qd	Not Reported
	Asa	C	Oral	1 Df, Qd	Not Reported
	Oxazepam	C	Oral	1 Df, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17692806	NON-EXPEDITED			US-UNITED THERAPEUTICS-UNT- 2020-006031			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pain; Pharyngitis Streptococcal; Pruritus	Tyvaso			S		Unk		Not Reported	
	Tyvaso			S		18-54 Mg, Qid		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Letairis			C	Unknown	Unk		Not Reported	
	Revatio			C	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17707942	EXPEDITED (15-DAY)		DE, OT	FR-ADVANSZ PHARMA-202004003750			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17707946	EXPEDITED (15-DAY)		HO	FR-ADVANSZ PHARMA-202004003809			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17707959	EXPEDITED (15-DAY)		HO, OT	FR-ADVANSZ PHARMA-202004004072			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Off Label Use	Hydroxychloroquine			S	Unknown	Unk		Concordia	
	Hydroxychloroquine			S				Concordia	
	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Apr-2020	17708172	EXPEDITED (15-DAY)		LT	IT-AXELLIA-003094		74 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Vancomycin			S	Unknown			Xellia Pharmaceuticals	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Unknown	Not Reported
Cefepime	S	Unknown	Not Reported
Fibrin	C	Other	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17708324	EXPEDITED (15-DAY)		HO, OT	NVSC2020BR110581		47 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Anosmia; Back Pain;	Cosentyx			S	Unknown	Unk		Novartis
Blood Pressure Abnormal;	Azithromycin			S	Unknown	Unk		Not Reported
Coronavirus Infection;								
Discomfort; Dyspnoea;								
Headache; Malaise; Pain;								
Palate Injury; Traumatic								
Lung Injury								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Apr-2020	17709300	EXPEDITED (15-DAY)		DE	FR-AUROBINDO-AUR-APL-2020-020616			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Disorder; Off	Azithromycin			S	Unknown	Unk		Aurobindo
Label Use	Azithromycin			S				Aurobindo
	Plaquenil			S	Unknown	Unk		Not Reported
	Plaquenil			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	14247102	NON-EXPEDITED			US-PFIZER INC-2017514619		73 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Malaise; Memory	Zithromax			S	Oral	250 Mg, Daily		Pfizer
Impairment; Poor Quality	Zithromax			S				Pfizer
Sleep								

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	15850484	NON-EXPEDITED			US-PFIZER INC-2019023770		45 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Drug Intolerance; Gastrointestinal Disorder	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17244156	EXPEDITED (15-DAY)		DE, LT	IT-MYLANLABS-2020M1001922		48 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Blister; Conjunctivitis; Epidermolysis; Mucosal Inflammation; Oropharyngeal Pain; Pyrexia; Toxic Epidermal Necrolysis	Azithromycin			S	Unknown	Unk		Not Reported	
	Allopurinol			S	Unknown	150 Milligram, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17306309	EXPEDITED (15-DAY)		HO	PT-MYLANLABS-2020M1006724		78 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Infection; Vulvovaginal Candidiasis	Azithromycin			S	Unknown	Unk		Not Reported	
	Azithromycin			S				Not Reported	
	Ceftriaxone			S	Unknown	2 Gram, Qd		Mylan	
	Ceftriaxone			S				Mylan	
	Econazole			C		Unk		Mylan	
	Fluconazole			C	Oral	2 Dosage Form, Q3d (Doses Of 150 Mg Every 72 Hours)		Mylan	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17566271	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1028736		23 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anuria; Decreased Appetite; General Physical Health Deterioration; Myalgia; Rhabdomyolysis; Transaminases Increased; Vomiting	Oxomemazine			S	Oral	Unk		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Seretide			C		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17598192	EXPEDITED (15-DAY)			RU-PFIZER INC-2020113776		48 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose	Azithromycin			S		1.0 G, 2x/Day (4.5 Days, Total Course Dose - 9.0 G)		Pfizer	
	Amoxicillin And Clavulanate Potassium			C		Unk, 2x/Day (875/125 Mg For 32 Days)		Not Reported	
	Ryzodeg			C		30 lu, 2x/Day		Not Reported	
	Novorapid			C		10 lu, 1x/Day, In The Afternoon		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17659064	EXPEDITED (15-DAY)		DE, OT	TH-ROCHE-2577353		44 YR	Male	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Creatinine Increased; Cerebral Haemorrhage; Injection Site Extravasation; Intentional Product Use	Actemra			S	Intravenous (not otherwise specified)	8 Mg/Kg/Day		Not Reported	
	Hydroxychloroquine			S	Unknown			Not Reported	
	Lopinavir			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Issue; Off Label Use; Proteinuria; Renal Failure	Ritonavir	S	Unknown	Not Reported
	Favipiravir	S	Unknown	Not Reported
	Darunavir	S	Unknown	Not Reported
	Azithromycin	S	Intravenous (not otherwise specified)	Not Reported
	Piperacillin	S	Unknown	Not Reported
	Tazobactam	S	Unknown	Not Reported
	Vancomycin	S	Unknown	Not Reported
	Enoxaparin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17702991	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226210		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Propofol Infusion Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Propofol 2% Injectable Baxter, 1			S	Intravenous (not otherwise specified)	Sedation		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
	Dexametasona (722a)			C	Intravenous (not otherwise specified)			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709465	EXPEDITED (15-DAY)		OT	IT-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245136		41 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Distension; Abdominal Pain; Haematochezia	Azithromycin			S	Oral	Cyclical, Tablet		Sun	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709467	EXPEDITED (15-DAY)		OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245124		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis	Azithromycin			S	Oral	500 Milligrams, Daily		Sun	
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported	
	Ceftriaxone Base			C	Unknown	Unk		Not Reported	
	Inipomp			C	Unknown	Unk		Not Reported	
	Rovamycine			C	Unknown	Unk		Not Reported	
	Paracetamol			C	Unknown	Unk		Not Reported	
	Xarelto 10 Mg, Comprime Pellicule			C	Oral	Unk		Not Reported	
	Diffu K			C	Oral	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709497	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES- 1226643		20 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17709947	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES- 1226986		63 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis; Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Milligram Daily;	Not Reported
Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec	S	Intravenous (not otherwise specified)	3 Dosage Forms Daily; Every 8 Hours	Not Reported
Amoxicilina / Acido Clavulanico 1 G / 200 Mg Polvo Para Solucion Inyec	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710025	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226989		52 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Cholestatic	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17710046	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226987		36 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	4 Dosage Forms Daily; 120 Tablets		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S				Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily; 30		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Tablets

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711000	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040853			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711003	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040849			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711005	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040850			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711024	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040852			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711026	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040860			Unknown	FRA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711028	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040855			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711414	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1041155			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711447	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040993			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	Every Other Day; For At Least 6 Months		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17711449	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040986			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod(For		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atleast 6 Months)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711452	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040995			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod (For At Least 6 Months)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17711810	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020167297		78 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrioventricular Block First Degree; Bundle Branch Block Left; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712080	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226652		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily; 500 Mg/24h		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily; 400 Mg/24h		Teva	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg Single Dose		Not Reported	
	Tocilizumab (8289a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not	2 Gram Daily; 2gr/24h		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Ceftriaxona (501a)			S			otherwise specified)			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712129	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226773		49 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Hepatitis	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
Ceftriaxona (501a)			S						Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712146	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040996			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod(For At Least 6 Months)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712168	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1040997			Unknown	FRA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Qod(For At Least 6 Months)		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
27-Apr-2020	17712393	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1226967		65 YR	Male	ESP
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatitis Acute; Hyperbilirubinaemia	Azitromicina (7019a)	S	Oral	500 Milligram Daily;	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Milligram Daily;	Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gram	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712394	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES- 1226772		30 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported
	Azitromicina (7019a)			S				Not Reported
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva
	Hidroxiclороquina (2143a)			S				Teva
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported
	Ceftriaxona (501a)			S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712430	EXPEDITED (15-DAY)		OT	FR-MYLANLABS- 2020M1041156			Unknown	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Treatment Failure	Azithromycin			S	Unknown	250 Milligram, Every Other Day; For At Least 6 Months		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712652	NON-EXPEDITED			US-AKRON, INC.- 2083165			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Burns; Eye Swelling; Sinus Disorder; Sinus Operation	Azasite 1%			S				Akorn

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17712848	EXPEDITED (15-DAY)		HO	NVSC2020DE110271		43 YR	Female	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Pain; Cardiovascular Disorder; Chills; Dehydration; Diarrhoea; Nausea	Azithromycin			S	Oral	500 Mg		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17714865	EXPEDITED (15-DAY)		HO	US-GENERICUS, INC.- 2020GNR00013		10 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chapped Lips; Cheilitis; Lip Swelling; Off Label Use; Oral Pruritus; Pharyngeal Erythema; Rash	Tobramycin			S	Intravenous (not otherwise specified)	Unk, 2x/Day		Genericus	
	Tobramycin			S		300 Mg, 2x/Day		Genericus	
	Tobramycin (Iv)			S		Unk, 1x/Day		Not Reported	
	Smz/Tmp			S		Unk		Not Reported	
	Azithromycin			S		Unk		Not Reported	
	Ofloxacin			S		Unk		Not Reported	
	Sucralfate			C				Not Reported	
	Creon			C				Not Reported	
	Pulmozyme			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715061	EXPEDITED (15-DAY)		HO, OT	CA-SAKK- 2020SA095613AA		78 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Anaemia; Aspiration; Asthma; Blood	Lansoprazole			S	Unknown	Unk		Not Reported	
	Risedronate Sodium			S	Unknown	Unk		Not Reported	
Calcium Increased; Blood	Morphine Hydrochloride			S	Unknown	10 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Creatinine Increased;	Paracetamol	S	Unknown	1000 Mg	Not Reported
Blood Test Abnormal;	Atrovent	S	Unknown	Unk	Not Reported
Bronchiectasis;	Azithromycin	S	Unknown	Unk	Not Reported
Bronchopulmonary	Budesonide	S	Unknown	Unk	Not Reported
Aspergillosis Allergic;	Domperidone	S	Unknown	Unk	Not Reported
Constipation; Cough; Drug	Levothyroxine Sodium	S	Unknown	Unk	Not Reported
Hypersensitivity; Drug	Mometasone Furoate	S	Unknown	Unk	Not Reported
Ineffective; Dyspnoea;	Glyceryl Trinitrate	S	Unknown	Unk	Sanofi
Fatigue;	Candesartan Cilexetil	S	Oral	8 Mg, Qd	Not Reported
Gastrooesophageal Reflux	Pantoprazole	S	Unknown	Unk	Not Reported
Disease; Haemoptysis;	Pantoprazole	S	Unknown	Unk	Not Reported
Headache; Hypoxia; Liver	Quetiapine Fumarate	S	Unknown	Unk	Not Reported
Function Test Increased;	Senna Alexandrina	S	Unknown	Unk	Not Reported
Lower Respiratory Tract	Pramipexole Hydrochloride	S	Oral	0.25 Mg	Not Reported
Infection; Lung Opacity;	Pramipexole Hydrochloride	S	Oral	0.5 Mg	Not Reported
Musculoskeletal Stiffness;	Ranitidine	S		Unk	Sanofi
Obstructive Airways	Rosuvastatin Calcium	S	Unknown	Unk	Not Reported
Disorder; Oedema	Montelukast Sodium	S	Unknown	Unk	Not Reported
Peripheral; Pain; Pleural	Tiotropium Bromide	S	Unknown	1 Df, Qd	Not Reported
Effusion; Pneumonia;	Zopiclone	S	Unknown	Unk	Not Reported
Pulmonary Fibrosis;	Morphine Hydrochloride	S	Oral	10 Mg	Not Reported
Pyrexia; Rales; Sputum	Budesonide/Formoterol Fumarate	S	Unknown	2 Df, Bid	Not Reported
Discoloured; Total Lung	Levothyroxine Sodium	S	Unknown	Unk	Not Reported
Capacity Decreased;	Trazodone Hydrochloride	S	Unknown	10 Mg	Not Reported
Transaminases Increased;	Trazodone Hydrochloride	S	Unknown	10 Mg	Not Reported
Tremor; Upper Respiratory	Influenza Vaccine	S	Unknown		Unknown
Tract Infection; Wheezing	Pregabalin	S	Oral	75 Mg	Not Reported
	Montelukast	S	Oral	10 Mg, Qd	Not Reported
	Dexilant	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Efinaconazole	S	Unknown	Unk	Not Reported
	Mepolizumab	S	Unknown	100 Mg	Not Reported
	Mepolizumab	S	Unknown	100 Mg	Not Reported
	Prevnar	S	Unknown	Unk	Not Reported
	Sennoside A+B	S	Unknown	Unk	Not Reported
	Ventolin [Salbutamol]	S	Unknown	Unk	Not Reported
	Vitamin D Nos	S	Oral	Unk	Not Reported
	Xolair	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715434	NON-EXPEDITED			US-TEVA-2020-US-1226872		84 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azithromycin			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715715	EXPEDITED (15-DAY)		HO, OT	FR-AUROBINDO-AUR-APL-2020-020561		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycin			S	Oral	250 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	
	Rocephin			S	Oral	2 Gram, Once A Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715746	EXPEDITED (15-DAY)		DE, OT	FR-AUROBINDO-AUR-APL-2020-020590			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715753	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020591			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	
	Plaquenil			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715768	EXPEDITED (15-DAY)		DS	CA-AUROBINDO-AUR-APL-2020-020204			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use In Unapproved Indication; Therapy Non-Responder	Montelukast			S	Unknown	Unk		Aurobindo	
	Fluticasone			S	Unknown	Unk		Not Reported	
	Mycophenolate Mofetil			S	Oral	720 Milligram, Two Times A Day		Not Reported	
	Pms Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715790	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1226775		54 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Hidroxiclороquina (2143a)			S	Oral	400 Milligram Daily;		Teva	
	Hidroxiclороquina (2143a)			S				Teva	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715830	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245242		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400mg Dia		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Apr-2020	17715835	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245249		52 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Paracetamol			S	Oral	1gr Cada 8 Horas		Ohm Lab	
	Simvastatina Alter 10 Mg Comprimidos Recubiertos Con Película Efg ...			S	Oral	0-0-1 ()		Not Reported	
	Dolquine 200 Mg Comprimidos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17223407	EXPEDITED (15-DAY)		OT	CA-AUROBINDO-AUR- APL-2019-108398		69 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Bacterial Disease Carrier; Blood Count Abnormal; Bronchial	Pantoprazole			S	Unknown	40 Milligram, Once A Day		Aurobindo	
	Alvesco			S	Unknown	200 Milligram, Two Times		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Secretion Retention; Bronchial Wall Thickening; Cough; Drug Ineffective; Dyspnoea; Fall; Ill-Defined Disorder; Intervertebral Disc Protrusion; Malaise; Obstructive Airways Disorder; Rales; Spinal Cord Compression; Sputum Discoloured; Therapeutic Product Effect Incomplete; Upper Limb Fracture; Wheezing; Wrist Fracture	Alvesco	S	Unknown	A Day 300 Microgram, Two Times A Day	Not Reported
	Benralizumab	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Calcium	S	Unknown	Unk	Not Reported
	Celebrex	S	Unknown	Unk	Not Reported
	Chlorphenamine Maleate;Pseudoephedrine Hydrochloride	S	Unknown	Unk	Not Reported
	Daxas	S		500 Microgram, Once A Day	Not Reported
	Daxas	S		100 Microgram, Once A Day	Not Reported
	Fluticasone Propionate;Salmeterol	S		2 Dosage Form, Two Times A Day	Not Reported
	Hydroxyzine	S	Unknown	Unk	Not Reported
	Imodium	S	Unknown	Unk	Not Reported
	Omalizumab	S	Unknown	Unk	Not Reported
	Omalizumab	S	Unknown	225 Milligram	Not Reported
	Pms Azithromycin	S	Unknown	250 Milligram, Once A Day	Not Reported
	Prednisone	S	Unknown	Unk	Not Reported
	Singulair	S	Unknown	10 Milligram, Once A Day	Not Reported
	Spiriva	S	Unknown	2 Dosage Form, Once A Day	Not Reported
	Spiriva	S		Unk, Once A Day	Not Reported
	Ventolin	S		Unk	Not Reported
	Ventolin	S	Unknown	Unk	Not Reported
	Vitamin D	S	Unknown	Unk	Not Reported
	Zopiclone	S	Unknown	5 Milligram, Once A Day	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17555986	EXPEDITED (15-DAY)		OT	FR-SA-2020SA068404		75 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Eye Disorder; Eye Infection; Hypersensitivity; Visual Impairment	Xyzall			S	Unknown	Unk		Sanofi	
	Ketotifen Fumarate			S	Unknown	1 Drop, Bid (In Morning And Evening For 10 Days)		Not Reported	
	Ketotifen Fumarate			S	Unknown	Unk		Not Reported	
	Hexamidine Isetionate			S	Ophthalmic	1 Drop, Tid (Morning, Midday And Evening In Each Eye)		Not Reported	
	Hexamidine Isetionate			S	Ophthalmic	1 Drop, Qd (Midday In Each Eye)		Not Reported	
	Azyter			S	Unknown	Unk (In Both Eyes)		Not Reported	
	Levofree			S	Ophthalmic	1 Df (10 Days)		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17620078	EXPEDITED (15-DAY)		OT	ES-ABBVIE-20K-144-3348741-00			Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use	Kaletra			S	Oral			Not Reported	
	Kaletra			S				Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Chloroquine			S	Unknown			Not Reported	
	Ceftriaxone			C				Not Reported	
	Tocilizumab			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17678663	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1224966		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hepatitis Acute	Azitromicina (7019a)	S	Oral	500 Mg Day	Not Reported
	Azitromicina (7019a)	S			Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	Unit Dose : 200 Mg 400mg Day	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S			Not Reported
	Ceftriaxona (501a)	S	Intravenous (not otherwise specified)	2 Gr Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17687239	EXPEDITED (15-DAY)		LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-244297		80 YR	Female	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligrams, Daily		Sun
	Lasilix			S	Intravenous (not otherwise specified)	2 Dosage Form, Daily		Not Reported
	Plaquenil			S	Oral	()		Not Reported
	Sufentanil			C	Intravenous (not otherwise specified)	()		Not Reported
	Perfalgan 10 Mg/ML, Solution Pour Perfusion			C	Intravenous (not otherwise specified)	()		Not Reported
	Noradrenaline (Tartrate De)			C	Intravenous (not otherwise specified)	()		Not Reported
	Midazolam			C	Intravenous (not otherwise specified)	()		Not Reported
	Tazocilline			C	Intravenous (not otherwise specified)	4 Dosage Form, Daily		Not Reported
	Transipeg			C	Oral	()		Not Reported
	Potassium (Chlorure De)			C	Intravenous (not otherwise specified)	()		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17691116	EXPEDITED (15-DAY)		HO, LT	ES-TEVA-2020-ES-1225788		62 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Hepatitis; Long Qt Syndrome	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Azitromicina (7019a)			S				Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S S	Oral	400 Milligram Daily;		Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17706119	EXPEDITED (15-DAY)		HO, LT, OT	NVSC2020CZ107975		62 YR	Female	CZE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Kidney Injury; Anaemia; Diarrhoea; Haematuria; Oliguria; Proteinuria; Renal Impairment; Renal Tubular Necrosis; Vomiting	Azithromycin			S	Unknown	Unk		Novartis	
	Cefepime			S	Unknown	Unk		Not Reported	
	Heparin			C	Unknown	Unk		Not Reported	
	Imunoglobulin			C	Intravenous (not otherwise specified)	Unk		Not Reported	
	Prednisone			C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715901	EXPEDITED (15-DAY)		DE	ES-TEVA-2020-ES-1228878		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Sudden Death	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Salbutamol (2297a)			S	Respiratory (inhalation)	0.1 Mg		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Propofol (2373a)	S	Intravenous (not otherwise specified)		Not Reported
Metoclopramida (1958a)	S	Intravenous (not otherwise specified)	10 Mg	Not Reported
Ipratropio Bromuro (1067br)	C	Respiratory (inhalation)	20 Mcg	Not Reported
Enoxaparina Sodica (2482so)	C	Subcutaneous		Not Reported
Cefotaxima (3840a)	C	Intravenous drip	4gram	Not Reported
Midazolam (2256a)	C	Intravenous drip	100 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715963	EXPEDITED (15-DAY)		OT	FR-AUROBINDO-AUR-APL-2020-020588			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Discomfort; Loss Of Consciousness; Off Label Use; Ventricular Arrhythmia	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715975	EXPEDITED (15-DAY)		DE	PT-AUROBINDO-AUR-APL-2020-020594			Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Resistance	Sildenafil			S	Unknown	Unk		Aurobindo	
	Ampicillin			S	Unknown	Unk		Not Reported	
	Azitromicina			S	Unknown	Unk		Not Reported	
	Gentamicin			S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17715976	NON-EXPEDITED			US-AUROBINDO-AUR-APL-2020-017172		1 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Dispensing Error; Product Reconstitution Quality Issue	Azithromycin For Oral Suspension Usp 200 Mg/5ml	S	Unknown	Unk	Aurobindo

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716272	EXPEDITED (15-DAY)		HO, OT	CA-DRREDDYS- USA/CAN/20/0122344		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count	Atorvastatin			S	Oral			Not Reported
Abnormal; Bronchiectasis;	Amlodipine			S	Oral			Not Reported
Cardiac Failure	Azithromycin			S	Unknown			Not Reported
Congestive; Chronic	Bisoprolol			S	Unknown			Not Reported
Obstructive Pulmonary	Calcium Carbonate			S	Unknown			Not Reported
Disease; Constipation;	Citalopram			S	Unknown			Not Reported
Diastolic Dysfunction;	Docusate			S	Unknown			Not Reported
Dyspnoea; Ejection	Furosemide			S	Unknown			Not Reported
Fraction Abnormal;	Hydromorphone			S	Unknown			Not Reported
Emphysema; Lung	Risedronate			S	Oral			Not Reported
Hyperinflation; Obstructive	Salbutamol			S	Unknown			Not Reported
Airways Disorder;	Tiotropium			S	Unknown			Not Reported
Oedema Peripheral;	Xarelto			S	Oral	Coated Tablet		Not Reported
Oxygen Saturation	Salbutamol Sulfate			S				Not Reported
Abnormal; Productive	Lasix			C	Unknown			Not Reported
Cough; Pulmonary								
Embolism; Respiratory								
Failure; Sputum								
Discoloured; Therapeutic								
Product Effect Incomplete;								
Ventricular Dysfunction;								
Ventricular Hypokinesia;								
Wheezing								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17716778	EXPEDITED (15-DAY)		HO	US-TEVA-2020-US- 1225767		70 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardiac Arrest; Drug	Azithromycin			S	Oral	On Day 1		Not Reported
Interaction;	Azithromycin			S	Oral	250 Milligram Daily;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged; Unresponsive To Stimuli; Ventricular Fibrillation	Hydroxychloroquine	S	Oral	800 Milligram Daily; On Day 1	Teva
	Hydroxychloroquine	S	Oral	400 Milligram Daily;	Teva
	Ceftriaxone	C	Intravenous (not otherwise specified)	1 Gram Daily;	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717324	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020161803		59 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Breast Cancer	Novatrex			S	Oral	10 Mg, Weekly		Pfizer	
	Mabthera			S	Intravenous (not otherwise specified)	1000 Mg		Not Reported	
	Mabthera			S	Intravenous (not otherwise specified)	2000 Mg, Cyclic (1000 Mg On Day 1 And Day 15 Intercure 6 Months)		Not Reported	
	Remicade			S	Intravenous (not otherwise specified)	100 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717726	EXPEDITED (15-DAY)		HO	FR-MYLANLABS-2020M1041559		69 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Generalised Oedema; Weight Increased	Esomeprazole			S	Oral	Unk		Not Reported	
	Amlodipine			S	Oral	5 Milligram, Qd		Not Reported	
	Zithromax			S	Oral	Unk		Mylan	
	Aerius /01398501/			S	Oral	5 Milligram, Qd		Mylan	
	Novopulmon			S	Respiratory (inhalation)	Unk		Mylan	
	Rhinomaxil			S	Nasal	Unk		Mylan	
	Lantus			C		Unk		Mylan	
	Eucreas			C				Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Novatrex /00113801/	C		Mylan
Transipeg /00754501/	C		Mylan
Gliclazide	C		Mylan
Speciafoldine	C		Mylan
Kardegic	C		Mylan
Inegy	C	Unk	Mylan
Isoptine	C	Unk	Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17717816	NON-EXPEDITED			US-AKRON, INC.- 2083274			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus; Ocular Hyperaemia; Vision Blurred	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718047	NON-EXPEDITED			US-AKRON, INC.- 2083277			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Burns; Eye Irritation; Ocular Hyperaemia	Azasite			S				Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718287	NON-EXPEDITED			US-PFIZER INC- 2020164864			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718323	NON-EXPEDITED			US-AKRON, INC.- 2083271			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eye Pain; Eye Pruritus; Eye Swelling; Ocular Hyperaemia		Azasite		S		Akorn			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718649	EXPEDITED (15-DAY)		HO, LT	ES-ABBVIE-20K-144- 3380621-00		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Pancreatitis Acute	Kaletra 200/50			S	Oral			Not Reported	
	Metilprednisolona			S	Intravenous (not otherwise specified)			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Ceftriaxona			S	Intravenous (not otherwise specified)			Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Dolquine			S	Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17718686	NON-EXPEDITED			US-AKRON, INC.- 2083275			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Eye Pruritus; Heart Rate Irregular; Malaise	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17719064	EXPEDITED (15-DAY)		OT	US-PFIZER INC- 2020168386		59 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Drug Ineffective For Unapproved Indication; Off Label Use	Azithromycin			S		Unk		Pfizer	
	Cefepime Hcl			S		Unk		Pfizer	
	Vancomycin Hcl			S		Unk		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Meropenem	S	Unk	Pfizer
Isavuconazole	S	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Intravenous (not otherwise specified)	Not Reported
Sirolimus	C		Not Reported
Mycophenolate Mofetil	C	Unk	Not Reported
Prednisone	C	Unk	Not Reported
Oxygen	C	Respiratory (inhalation)	40 L (Via Heated High Flow Nasal Cannula)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17719107	NON-EXPEDITED			US-PFIZER INC-2020164664			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Doxycycline Hyclate			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17719611	EXPEDITED (15-DAY)		OT	NVSC2020CA111078			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angina Pectoris; Appetite Disorder; Asthma; Chest Discomfort; Chest Pain; Cough; Depressed Mood; Depressive Symptom; Dyspnoea; Dyspnoea Exertional; Fall; Flank Pain; Heart Sounds; Influenza; Injury; Insomnia; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Malaise; Nasal	Seebri Breezhaler			S	Unknown	1 Df, Qd		Novartis	
	Accupril			S	Unknown	1 Df, Qd		Not Reported	
	Advair			S	Respiratory (inhalation)	2.0 Df, Bid		Not Reported	
	Apo-Acetaminophen			S	Unknown	2.0 Df, Qid		Not Reported	
	Apo-Amitriptyline			S	Unknown	4.0 Df, Qd		Not Reported	
	Apo-Atorvastatin			S	Unknown	1.0 Df, Qd		Not Reported	
	Apo-Dimenhydrinate			S	Unknown	Unk		Not Reported	
	Apo-Prednisone			S	Unknown	3 Df, Qd		Not Reported	
	Apo-Prednisone			S	Unknown	4 Unk		Not Reported	



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Congestion; Nasopharyngitis; Productive Cough; Prolonged Expiration; Pyrexia; Rales; Respiration Abnormal; Rhinorrhoea; Sleep Disorder Due To A General Medical Condition; Stress; Upper Respiratory Tract Infection; Weight Decreased; Wheezing	Apo-Prednisone	S	Unknown	1 Unk	Not Reported
	Apo-Prednisone	S	Unknown	2 Unk	Not Reported
	Azithromycin	S	Unknown	3 Df	Not Reported
	Betamethasone Valerate	S	Unknown	Unk	Not Reported
	Combivent	S	Unknown	Unk	Not Reported
	Dicetel	S	Unknown	Unk	Not Reported
	Flovent	S	Unknown	Unk	Not Reported
	Fluoxetine	S	Unknown	2 Df, Bid	Not Reported
	Furosemide	S	Unknown		Not Reported
	Lactaid	S	Unknown	1 Df, Tid	Not Reported
	Loperamide	S	Subcutaneous	100 Mg	Not Reported
	Metformin Hydrochloride	S	Unknown	1 Df, Bid	Not Reported
	Mometasone	S	Unknown	2.0 Df, Bid	Not Reported
	Novorapid	S	Intravenous (not otherwise specified)	3 Df, Qd	Not Reported
	Prednisone	S	Unknown		Not Reported
	Ratio-Lactulose	S	Unknown	1.5 MI, Bid	Not Reported
	Rho-Nitro Pumpspray	S	Unknown	1 Df	Not Reported
	Singulair	S	Unknown	Unk	Not Reported
	Spiriva	S	Unknown	Unk	Not Reported
	Teva Montelukast	S	Unknown	1 Df, Qd	Not Reported
	Theophylline	S	Unknown	Unk	Not Reported
	Uniphyl	S	Unknown		Not Reported
	Ventolin	S	Unknown	Unk	Not Reported
	Vitamin B 12	S	Intravenous (not otherwise specified)	1.0 MI	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720141	EXPEDITED (15-DAY)		DE, OT	ES-PFIZER INC- 2020167361		75 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Off Label Use; Product Use In Unapproved Indication; Product Use Issue; Sudden Death	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer	
	Hydroxychloroquine Sulfate			S	Oral	200 Mg, 1x/Day		Not Reported	
	Levofloxacin			S		Unk		Not Reported	
	Lopinavir + Ritonavir			S	Oral	2 Df, 2x/Day		Not Reported	
	Ceftriaxone			C		Unk		Not Reported	
	Enoxaparin Sodium			C	Subcutaneous	40 Mg, 1x/Day		Not Reported	
	Prednisone			C	Oral	20 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720146	EXPEDITED (15-DAY)		DE, OT	MY-PFIZER INC-2019019877		334 DAY	Male	MYS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Crying; Hepatomegaly; Off Label Use; Periorbital Oedema; Prescribed Overdose; Product Use Issue; Seizure; Sudden Death	Zithromax			S	Intravenous (not otherwise specified)	130 Mg, Single (Bolus Dose)		Pfizer	
	Zithromax			S	Intravenous (not otherwise specified)	45 Mg, Daily		Pfizer	
	Hydrocortisone			C	Intravenous (not otherwise specified)	35 Mg, 4x/Day (Every 6 Hours)		Not Reported	
	Rocephine			C	Intravenous (not otherwise specified)	250 Mg, Daily		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720916	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020972		55 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram (1 Total)		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720923	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-020973		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Metamizol			S	Intravenous (not otherwise specified)	2 Gram, Four Times/Day		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Paracetamol			S	Intravenous (not otherwise specified)	1 Gram, 3 Times A Day		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram 1 Total		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17720925	EXPEDITED (15-DAY)		OT	ES-AUROBINDO-AUR-APL-2020-020974		47 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Azithromycin			S				Aurobindo	
	Paracetamol			S	Oral	1 Gram, 3 Times A Day		Aurobindo	
	Dexketoprofen			S	Intravenous (not otherwise specified)	25 Milligram, 3 Times A Day		Not Reported	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	600 Milligram, 1 Total		Not Reported	
	Tocilizumab			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Apr-2020	17721027	EXPEDITED (15-DAY)		OT	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-		73 YR	Male	ESP

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

2020RR-245414

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Hepatitis	Azithromycin			S	Oral	500 Mg/24h		Sun
	Hidroxiclороquina (2143a)			S	Oral	200 Mg/24h		Not Reported
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600mg/24h		Not Reported
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2gr/24h		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	14936706	EXPEDITED (15-DAY)		DE, DS, HO	CA-ROCHE-2128776		61 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alveolitis; Atrial Fibrillation; Hypoxia	Trastuzumab			S	Unknown			Not Reported
	Amiodarone			S	Unknown			Not Reported
	Ceftriaxone			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported
	Diltiazem Cd			S	Oral			Not Reported
	Dimenhydrinate			S	Intravenous (not otherwise specified)			Not Reported
	Doxorubicin			S	Intravenous (not otherwise specified)			Not Reported
	Enoxaparin			S	Subcutaneous			Not Reported
	Furosemide			S	Oral			Not Reported
	Hydralazine			S	Intravenous (not			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydromorphone	S	otherwise specified)	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	Not Reported
Morphine	S	Intravenous (not otherwise specified)	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	Not Reported
Pantoprazole	S	Intravenous (not otherwise specified)	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	Not Reported
Procytox	S	Intravenous (not otherwise specified) 2000mg/Vial	Not Reported
Adriamycin [Doxorubicin Hydrochloride]	S	Intravenous (not otherwise specified)	Not Reported
Aprepitant	C	Oral	Not Reported
Dexamethasone	C	Oral	Not Reported
Filgrastim	C	Subcutaneous	Not Reported
Gabapentin	C	Oral	Not Reported
Metoclopramide	C	Oral	Not Reported
Ondansetron	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17013661	EXPEDITED (15-DAY)		HO, OT	CA-JNJFOC-20191112235		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthenia; Asthma; Bronchial Obstruction; Chest Discomfort; Conjunctivitis; Cough; Disease Recurrence; Dizziness; Eosinophilia; Feeling Abnormal; Feeling Hot; Hypersensitivity; Hyperventilation; Increased Bronchial Secretion; Maternal Exposure During Pregnancy; Middle Insomnia; Nasal Congestion; Nausea; Palpitations; Productive Cough; Rhinitis; Therapeutic Product Effect Incomplete; Urticaria; Wheezing	Cetirizine Hydrochloride/Pseudoephedrine Hydrochloride	S	Unknown		Johnson And Johnson
	Benadryl	S	Unknown	As Needed	Not Reported
	Salbutamol Sulfate	S	Unknown	Unk, As Needed (Prn)	Not Reported
	Singular	S	Unknown	100mg	Not Reported
	Breo Ellipta	S	Unknown		Not Reported
	Advair	S	Unknown		Not Reported
	Xolair	S	Unknown		Not Reported
	Alvesco	S	Unknown		Not Reported
	Synthroid	S	Unknown	0.1 Milligram	Not Reported
	Montelukast	S	Unknown	10 Milligram, Once Daily (Qd)	Not Reported
	Vitamin D /00107901/	S	Unknown	1000 International Unit, Weekly (Qw)	Not Reported
	Symbicort	S	Unknown	2 Puffs, 2x/Day (Bid)	Not Reported
	Symbicort	S	Unknown	4 Puffs, Ev 2 Weeks(Qow)	Not Reported
	Seebri	S	Unknown		Not Reported
	Prednisone	S	Unknown	15 Milligram, Once Daily (Qd), 3 Or 4 Days	Not Reported
	Benralizumab	S	Unknown		Not Reported
	Zenhale	S	Unknown	2 Puff	Not Reported
	Spiriva	S	Unknown	2 Puff	Not Reported
	Uniphyl	S	Unknown		Not Reported
	Uniphyl	S	Unknown		Not Reported
	Medrol /00049601/	S	Unknown		Not Reported
	Solumedrol	S	Unknown		Not Reported
	Azithromycin	S	Unknown		Not Reported
	Nucala	S	Unknown	100 Mg, Monthly	Not Reported
	Nucala	S	Unknown		Not Reported
	Nucala	S	Unknown		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Nucala		S	Unknown					Not Reported
	Nucala		S	Unknown					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17252200	EXPEDITED (15-DAY)		HO	US-PFIZER INC-2020001990		9 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Angioedema; Mucosal Ulceration; Obliterative Bronchiolitis; Skin Ulcer; Stevens-Johnson Syndrome	Zithromax			S	Oral	Unk		Pfizer	
	Zithromax			S				Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17289551	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS-2020M1004408		77 YR	Female	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Bullous; Drug Ineffective; Erythema; Genital Ulceration; Pemphigoid; Pharyngeal Ulceration	Azithromycin			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17337208	EXPEDITED (15-DAY)		LT, OT	NVSC2020IT020106		74 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Empyema; Pleural Fistula; Pneumonia Necrotising; Pneumothorax; Subcutaneous Emphysema; Treatment Failure	Azithromycin			S	Unknown	Unk		Novartis	
	Vancomycin			S	Unknown	Unk		Not Reported	
	Cefepime			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17606947	NON-EXPEDITED			US-PFIZER INC-2020132759			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysphagia; Lip Swelling; Oropharyngeal Pain; Swollen Tongue	Azithromycin			S		Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17652827	EXPEDITED (15-DAY)		HO, OT	JP-DSJP-DSJ-2020-111238			Unknown	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Stevens-Johnson Syndrome	Olmesartan Od Tablets "Dsep"			S	Oral	20 Mg, Qd		Daiichi	
	Amlodipine /00972402/			C	Oral	5 Mg, Qd		Not Reported	
	Amlodipine /00972402/			C	Oral	2.5 Mg, Qd		Not Reported	
	Zithromac			S	Oral	500 Mg, Qd		Not Reported	
	Carbocisteine			C	Oral	500 Mg, Tid		Not Reported	
	Astomin /00426502/			C	Oral	20 Mg, Tid		Not Reported	
	Ambroxol Hydrochloride			C	Oral	15 Mg, Tid		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17674513	EXPEDITED (15-DAY)		HO	RU-TEVA-2020-RU-1224841		48 YR	Female	RUS
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Overdose; Hepatotoxicity; Medication Error	Azithromycin			S	Unknown	She Took At A Dose Of 1g, 2 Times A Day For 4.5 Days. The Total Course Dose Of Azithromycin Was 9g		Not Reported	
	Amoxicillin/Clavulanate			S	Oral	Amoxicillin/Clavulanate Orally 875/125 Mg 2 Times A Day For 32 Days		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Raizodeg	C	Insulin Degludec/Insulin Aspart (Raizodeg) 30 Units Twice A Day	Not Reported
Novorapid	C	Insulin Aspart (Novorapid) 10 Units In The Afternoon.	Not Reported
Cefazolin	C	Intravenous (not otherwise specified) Cefazolin 2g, 3 Times A Day Iv For 4 Days.	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17681153	EXPEDITED (15-DAY)		OT	GB-MYLANLABS-2020M1038255			Male	GBR
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Treatment Failure	Ceftriaxone			S	Intramuscular	500 Mg, Single		Not Reported	
	Ceftriaxone			S	Intramuscular	1 G, Single		Not Reported	
	Azithromycin			S	Oral	1 G, Single		Not Reported	
	Azithromycin			S	Oral	2 G, Single		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17687195	EXPEDITED (15-DAY)		OT	TH-ROCHE-2581494		38 YR	Male	THA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Pneumonitis; Product Use In Unapproved Indication	Actemra			S	Intravenous (not otherwise specified)			Not Reported	
	Tamiflu			S	Oral			Not Reported	
	Chloroquine			S	Oral			Not Reported	
	Azithromycin			S	Oral			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17710430	EXPEDITED (15-DAY)		DE	IT-TEVA-2020-IT-1226892		70 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transaminases Increased	Azithromycin	S	Oral	500 Mg	Not Reported
	Plaquenil	S	Oral	400 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721160	EXPEDITED (15-DAY)		HO, LT	FR-PFIZER INC-2020166841		58 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Coronavirus Infection; Infection	Novatrex			S	Oral	Unk		Pfizer	
	Cartrex			S	Oral	Unk		Not Reported	
	Metformin			C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721454	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245365		63 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Paracetamol			S	Oral	1 Gr Cada 8 Horas		Ohm Lab	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gr Dia		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721456	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD-2020RR-245370		47 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Mg Dia		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ceftriaxona (501a)

S

Intravenous (not
otherwise specified)

2 Gr Dia

Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721471	EXPEDITED (15-DAY)		LT	FR-TEVA-2020-FR-1227414		43 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cardio-Respiratory Arrest	Azithromycine Anhydre			S	Oral	250 Milligram		Not Reported
	Nivaquine [Chloroquine Sulfate]			S	Oral	2-3 Cp Per Day:200 Milligram		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721485	EXPEDITED (15-DAY)		OT	CA-ROCHE-2587485			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Depression; Dizziness; Drug Intolerance; Fatigue; Feeling Hot; Impaired Gastric Emptying; Pain In Extremity	Ocrevus			S	Intravenous (not otherwise specified)			Not Reported
	Azithromycin			S	Unknown			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721557	EXPEDITED (15-DAY)		HO	CA-ROCHE-2589690		33 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Condition Aggravated; Cystic Fibrosis; Drug Ineffective; Dyspnoea; Eosinophil Count Abnormal; Loss Of Personal Independence In Daily Activities; Lung Disorder; Sleep Disorder Due To A General Medical	Pulmozyme			S	Unknown	1 Mg/MI		Not Reported
	Hypersal			S	Unknown	7%		Not Reported
	Macrogol 3350			S	Unknown			Not Reported
	Azithromycin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition; Wheezing	Pulmicort	S	Unknown	Not Reported
	Salbutamol Sulfate	S	Unknown	Not Reported
	Symbicort	S	Unknown	Not Reported
	Tobramycin	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17721734	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227334		73 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Haemorrhage; Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Piperacilina Tazobactam 4/0.5 G Polvo Para Solucion Inyectable Efg, 1			S	Intravenous (not otherwise specified)	C/24 H		Not Reported	
	Ertapenem (2881a)			S	Intravenous (not otherwise specified)	1 Gram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722293	EXPEDITED (15-DAY)		HO	IT-TEVA-2020-IT-1227376		74 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coronavirus Infection; Sinus Bradycardia	Azitromicina Teva 500 Mg			S	Oral	500 Mg		Not Reported	
	Comprese Rivestite Con Film			S	Oral	400 Mg		Not Reported	
	Plaquenil			C	Oral	10 Mg		Not Reported	
	Stilnox 10 Mg Comprese Rivestite Con Film			C	Subcutaneous	8000 Ku		Not Reported	
	Clexane T			C	Oral	30 Mg		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722331	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1227029		46 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Rectal Haemorrhage	Azithromycin			S	Oral	1 Dosage Forms		Not Reported	
	Tamiflu 75 Mg Hard Capsules			S	Oral	2 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722337	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227335		50 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis Acute	Azitromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Oral	400 Milligram Daily;		Not Reported	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S				Not Reported	
	Tocilizumab (8289a)			S	Intravenous (not otherwise specified)	600 Mg		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17722605	EXPEDITED (15-DAY)		OT	DE-PFIZER INC-2020167390			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection	Azithromycin			S	Unknown	500 Mg, Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723098	NON-EXPEDITED			US-AKRON, INC.-2083301			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Eye Irritation; Eyelid Oedema; Infusion Site Vesicles; Ocular Hyperaemia		Azasite	S		Akorn				
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723263	NON-EXPEDITED			US-AKRON, INC.-2083302			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723347	EXPEDITED (15-DAY)		OT	NVSC2020ES114617		4 YR	Female	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asphyxia; Hypersensitivity; Pruritus; Rash	Azithromycin			S	Unknown	Unk		Novartis	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723415	NON-EXPEDITED			US-PFIZER INC-2020169880			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer	
	Hydrocodone Bitartrate And Acetaminophen			S		Unk		Not Reported	
	Levaquin			S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723630	NON-EXPEDITED			US-AKRON, INC.-2083304			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Skin Exfoliation	Azasite			S				Akorn	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723713	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020165921		48 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil Sulfate			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723860	NON-EXPEDITED			US-AKRON, INC.-2083305			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S					Akorn
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723878	NON-EXPEDITED			US-TAKEDA-2020TJP008628			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity	Lansoprazole			S	Unknown	Unk		Takeda	
	Codeine			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Unknown	Unk		Not Reported	
	Clindamycin			S	Oral	Unk		Not Reported	
	Doxycycline Hyclate			S	Unknown	Unk		Not Reported	
	Lanolin			S	Unknown	Unk		Not Reported	
	Lisinopril			S	Unknown	Unk		Not Reported	
	Spiriva			S	Unknown	Unk		Not Reported	
	Myrbetriq			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17723898	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020169257		51 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724051	NON-EXPEDITED			US-AKRON, INC.-2083306			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724074	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166830		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Phosphate]			S	Oral	Unk		Not Reported	
	Cefotaxime Mylan			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724096	NON-EXPEDITED			US-AKRON, INC.-2083313			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Hypersensitivity	Asazite			S				Akorn	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724544	EXPEDITED (15-DAY)		DE, OT	CA-PFIZER INC-2020172823		69 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blood Pressure Decreased; Cardiac Failure; Cardio-Respiratory Arrest	Azithromycin			S	Intravenous drip	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17724908	NON-EXPEDITED			US-PFIZER INC-2020169469		52 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pruritus	Azithromycin			S		Unk		Pfizer	
	Tyvaso			S	Respiratory (inhalation)	4x/Day (18-54 Mg (3-9 Breaths) Four Times A Day (Qid) Via Inhalation (Ih) Route)		Not Reported	
	Letairis			C		Unk		Not Reported	
	Revatio			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725059	NON-EXPEDITED			US-AKRON, INC.-2083326			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725450	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166847		45 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Agranulocytosis; Off Label	Azithromycin			S	Oral	500 Mg, Daily		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Use; Product Use In Unapproved Indication	Plaquenil [Hydroxychloroquine Sulfate]	S	Oral	600 Mg, Daily	Not Reported
	Ceftriaxone	C	Unknown	Unk	Not Reported
	Inipomp	C	Unknown	Unk	Not Reported
	Rovamycine [Spiramycin]	C	Unknown	Unk	Not Reported
	Paracetamol	C	Unknown	Unk	Not Reported
	Xarelto	C	Oral	Unk	Not Reported
	Diffu K	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725452	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC- 2020169681		57 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Opportunistic Infection; Product Use In Unapproved Indication	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	800 Mg, Single		Not Reported
	Tavanic			S	Oral	500 Mg, 1x/Day		Not Reported
	Advagraf			C	Oral	4 Mg, 1x/Day		Not Reported
	Calcimagon D3			C		Unk		Not Reported
	Cefuroxime			C	Intravenous (not otherwise specified)	1.5 G, 3x/Day		Not Reported
	Co-Amoxicillin			C	Intravenous (not otherwise specified)	1.2 G, 3x/Day		Not Reported
	Flagyl [Metronidazole]			C	Oral	500 Mg, 3x/Day		Not Reported
	Folic Acid			C		Unk		Not Reported
	Lasix [Furosemide]			C	Intravenous (not otherwise specified)	40 Mg, 1x/Day		Not Reported
	Myfortic			C	Oral	720 Mg, 2x/Day		Not Reported
	Tazobac			C	Intravenous (not otherwise specified)	2.25 G, 3x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725546	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172573			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cognitive Disorder; Depression; Dizziness; Drug Intolerance; Fatigue; Feeling Hot; Impaired Gastric Emptying; Pain In Extremity	Azithromycin			S		Unk		Pfizer	
	Ocrelizumab			S	Intravenous (not otherwise specified)	300 Mg Every 2 Weeks		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725765	EXPEDITED (15-DAY)		DE, OT	CH-JNJFOC-20200432974		72 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Death; Haemolytic Anaemia; Thrombocytopenia; Thrombotic Microangiopathy	Durogesic Matrix			S	Transdermal	Patch 25 Mcg/H : 1 Tous Les 3 Jours		Janssen	
	Plaquenil /00072602/			S	Oral	800 Mg/Jour Du 22 Au 23.03.2020, 400 Mg/Jour Du 24 Au 26.03.2020, 600 Mg/Jour Du 26 Au 30.03.2020		Not Reported	
	Doxycycline			S	Oral			Not Reported	
	Azithromycine			S	Oral			Not Reported	
	Amoxicillin And Clavulanate			S	Intravenous drip			Not Reported	
	Potassium Enoxaparin			S	Subcutaneous			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725780	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2020172591		80 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acid Fast Bacilli Infection; Respiratory Failure	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tobramycin	S	Respiratory (inhalation)	250 Mg	Not Reported
Adalat XL	C		Unk	Not Reported
Primidone	C		Unk	Not Reported
Synthroid	C		Unk	Not Reported
Ventolin [Salbutamol]	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725781	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166844		56 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bradycardia; Incorrect Product Administration Duration; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported
	Cefotaxime Mylan			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725786	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172536		11 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Alopecia; Madarosis	Azithromycin			S	Oral	400 Mg, 1x/Day		Pfizer
	Azithromycin			S	Oral	200 Mg, 1x/Day		Pfizer
	Fluoxetine			C	Unknown	Unk		Not Reported
	Gabapentin			C	Unknown	Unk		Not Reported
	Guanfacine Hydrochloride			C	Unknown	Unk		Not Reported
	Montelukast			C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725811	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172435		22 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Feeling Of Body Temperature Change; Nausea; Vertigo	Azithromycin	S	Oral	2 G, Single	Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17725849	EXPEDITED (15-DAY)		OT	CA-BAUSCH-BL-2020-012763			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Metronidazole			S	Unknown			Not Reported
	Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate			S	Unknown			Bausch And Lomb
	Triamcinolone Acetonide			S	Unknown			Not Reported
	Glycerine			S	Unknown			Not Reported
	Humira			S	Subcutaneous	Subcutaneous Solution		Not Reported
	Kenalog			S	Intra-articular	Suspension Intra-Articular		Not Reported
	Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride			S	Unknown			Not Reported
	Ms Ir			S	Unknown			Not Reported
	Mupirocin			S	Topical			Not Reported
	Mupirocin			S	Unknown			Not Reported
	Nadolol			S	Unknown			Not Reported
	Nicoderm			S	Unknown			Not Reported
	Nicotine Polacrilex			S	Unknown			Not Reported
	Pentasa			S	Unknown			Not Reported
	Pms-Azithromycin			S	Unknown			Not Reported
	Prednisone			S	Unknown			Not Reported
	Pregabalin			S	Unknown			Not Reported
	Pulmicort			S	Unknown			Not Reported
	Refresh Tears			S	Ophthalmic			Not Reported
	Sinus Rinse			S	Unknown			Not Reported
Sulfamethoxazole And			S	Unknown			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Trimethoprim	S	Unknown	Not Reported
Vitamin D3	S	Unknown	Not Reported
Acetoaminophen	S	Unknown	Not Reported
Alprazolam	S	Unknown	Not Reported
Amoxicillin Trihydrate	S	Unknown	Not Reported
Apo-Hydro	S	Unknown	Not Reported
Atorvastatin Calcium	S	Unknown	Not Reported
Avamys	S	Unknown	Spray Metered Dose
Betamethasone Dipropionate	S	Unknown	Not Reported
Betamethasone Valerate	S	Unknown	Not Reported
Biaxin XL	S	Unknown	Extended Release
Bisacodyl	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Clarithromycin	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Diphenhydramine	S	Unknown	Not Reported
Entocort	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Apr-2020	17727439	DIRECT	Y	DE			68 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Acute Myocardial Infarction; Cardiac Arrest; Cardiogenic Shock; Renal Failure	Hydroxychloroquine (Hydroxychloroquine So4 200mg Tab)			S	Oral			Not Reported
	Azithromycin (Azithromycin)			S	Intravenous (not	Other Strength:500 Mg/Vil;		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

500mg/Vil Inj)

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	16967544	EXPEDITED (15-DAY)		OT	NVSC2019NL016762		7 YR	Male	NLD

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Decreased Appetite; Feeding Disorder; Nausea; Product Administered To Patient Of Inappropriate Age; Product Use In Unapproved Indication; Vomiting	Azithromycin			S	Oral	10 Mg/Kg, Qd		Novartis
	Azithromycin			S				Novartis
	Clofazimine			S	Oral	50 Mg Once Daily, If Weight Is Above 40 Kg Then 100 Mg		Not Reported
	Clofazimine			S				Not Reported
	Granisetron			S	Unknown	Unk		Not Reported
	Minocycline			S	Unknown	Unk		Not Reported
	Imipenem/Cilastatin			S	Intravenous (not otherwise specified)	60/60 Mg/Kg/Day In 2 To 4 Doses		Not Reported
	Imipenem/Cilastatin			S	Topical	5 Mg/ML, Tid (Three Drops)		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	2.4 Mg/Kg, Qd (In 2 Doses)		Not Reported
	Tigecycline			S	Topical	5 Mg/ML, Tid (Three Drops)		Not Reported
	Tigecycline			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Sodium Chloride Solution			C	Intravenous (not otherwise specified)	Unk		Not Reported
	Dexamethasone			C	Unknown	Unk		Not Reported
	Dexamethasone			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17721873	EXPEDITED (15-DAY)		HO, OT	RU-TEVA-2020-RU- 1216092		6 YR	Unknown	RUS

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Body Temperature Abnormal; Drug Ineffective; Pneumonia; Suspected Counterfeit Product; Suspected Product Quality Issue	Sumamed	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17726434	EXPEDITED (15-DAY)		HO, LT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245618		67 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ventricular Extrasystoles; Ventricular Tachycardia	Azithromycin			S	Oral	500 Mg J1 Puis 250 Mg Par Jour ()		Sun
	Plaquenil			S	Oral	600 Milligrams, Daily		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727035	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020168024		63 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727036	EXPEDITED (15-DAY)		OT	FR-PFIZER INC- 2020167372		65 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Electrocardiogram Pr Prolongation; Electrocardiogram T Wave Inversion; Off Label Use;	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Product Use In
Unapproved Indication

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727217	EXPEDITED (15-DAY)		DE	ES-ABBVIE-20K-144-3384129-00		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Cardio-Respiratory Arrest	Kaletra 200/50			S	Oral			Not Reported	
	Kaletra 200/50			S				Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)			Not Reported	
	Azitromicina			S	Oral			Not Reported	
	Dolquine			S	Oral			Not Reported	
	Dolquine			S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727372	EXPEDITED (15-DAY)		HO	FR-SA-2020SA111792		67 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anaemia; Off Label Use	Plaquenil			S	Oral	600 Mg, Qd		Sanofi	
	Plaquenil			S				Sanofi	
	Doliprane			S	Oral	4000 Mg, Qd		Not Reported	
	Lovenox			S	Subcutaneous	1 Df, Qd		Sanofi	
	Azithromycin			S	Oral	1 Df, Qd		Not Reported	
	Kaleorid Lp			C	Oral	3 Df, Qd		Not Reported	
	Metformin Almus			C	Oral	Unk		Not Reported	
	Gliclazide Arrow			C	Oral			Not Reported	
	Atorvastatin Arrow			C	Oral	1 Df, Qd		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727903	NON-EXPEDITED			US-PFIZER INC-2020174244			Unknown	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727971	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020173514		43 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma-Chronic	Azithromycin			S	Unknown	Unk		Pfizer
Obstructive Pulmonary Disease Overlap	Ciprofloxacin Hcl			S	Unknown	Unk		Pfizer
Syndrome; Bronchiectasis;	Advair			S	Unknown	Unk		Not Reported
Cardiac Murmur; Chronic Obstructive Pulmonary Disease;	Atrovent			S	Unknown	Unk		Not Reported
Gastrooesophageal Reflux Disease; Lung Neoplasm	Avamys			S	Unknown	Unk		Not Reported
Malignant; Nasal Polyps;	Breo Ellipta			S	Unknown	Unk		Not Reported
Oedema Peripheral;	Combivent			S	Unknown	Unk		Not Reported
Rhinitis Allergic;	Duaklir Genuair			S	Unknown	Unk		Not Reported
Sarcoidosis; Total Lung Capacity Increased;	Inspiolto Respimat			S	Unknown	Unk		Not Reported
Wheezing	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Moxifloxacin Hydrochloride			S	Unknown	Unk		Not Reported
	Nasonex			S	Unknown	Unk		Not Reported
	Omnaris			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Seebri			S	Unknown	Unk		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Spiriva Respimat			S	Unknown	18 Ug		Not Reported
	Symbicort			S	Unknown	Unk		Not Reported
	Tudorza Genuair			S	Unknown	Unk		Not Reported
	Ultibro Breezhaler			S	Unknown	Unk		Not Reported
	Umeclidinium Bromide			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Umeclidinium Bromide/Vilanterol Trifenatate	S	Unknown	Unk	Not Reported
Ventolin [Salbutamol]	S	Unknown	400 Ug	Not Reported
Xolair	S	Unknown	Unk	Not Reported
Zenhale	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727975	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020172560		60 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bronchiectasis	Azithromycin			S	Unknown	Unk		Pfizer
	Breo Ellipta			S	Unknown	Unk, 1x/Day		Not Reported
	Prednisone			S	Unknown	Unk		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	Unk, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17727996	EXPEDITED (15-DAY)		OT	US-SLATE RUN PHARMACEUTICALS- 20US000002			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Maternal Exposure During Pregnancy	Azithromycin Usp			S	Unknown			Hainan Poly Pharmaceutical

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728298	EXPEDITED (15-DAY)		DE	BR-BAYER-2020- 072489		53 YR	Female	BRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Death	Chloroquine			S				Bayer
	Azitromicina			S				Not Reported
	Tamiflu			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728446	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020172451		60 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Parainfluenzae Virus Infection; Pneumonia	Azithromycin			S	Unknown	Unk		Pfizer	
	Asa			S	Unknown	Unk		Not Reported	
	Daxas			S	Unknown	Unk		Not Reported	
	Ipratropium Bromide/Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Mepolizumab			S	Subcutaneous	100 Mg		Not Reported	
	Mepolizumab			S	Subcutaneous	100 Mg		Not Reported	
	Spiriva			S	Unknown	Unk		Not Reported	
	Symbicort Turbohaler			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728448	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020172400		62 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Drug Hypersensitivity; Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	Unk		Pfizer	
	Advair			S	Unknown	Unk		Not Reported	
	Atrovent			S	Unknown	Unk		Not Reported	
	Nucala			S	Intravenous (not otherwise specified)	100 Mg		Not Reported	
	Prednisone			S	Unknown	10 Mg		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728449	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020173813		66 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Accident; Animal Bite;	Azithromycin	S	Oral	250 Mg, Every 3 Weeks	Pfizer
Blood Pressure Systolic	Omalizumab	S	Subcutaneous	Unk	Not Reported
Increased; Dyspnoea; Gait	Omalizumab	S	Subcutaneous	Unk	Not Reported
Inability; Ligament	Omalizumab	S	Subcutaneous	Unk	Not Reported
Rupture; Mobility	Omalizumab	S	Subcutaneous	Unk	Not Reported
Decreased; Off Label Use;	Omalizumab	S	Subcutaneous	300 Mg (1 Every 2 Weeks)	Not Reported
Patella Fracture; Stress;	Omalizumab	S	Subcutaneous	Unk	Not Reported
Tibia Fracture	Omalizumab	S	Subcutaneous	Unk	Not Reported
	Prednisone	C	Unknown	Unk	Not Reported
	Prednisone	C	Unknown	1 Df	Not Reported
	Spiriva	C	Respiratory (inhalation)	1 Df, 1x/Day	Not Reported
	Symbicort Turbuhaler	C	Respiratory (inhalation)	3 Df, 2x/Day	Not Reported
	Ventolin [Salbutamol]	C	Respiratory (inhalation)	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728479	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172388		52 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count	Azithromycin			S	Unknown	1 Df, 1x/Day		Pfizer	
Abnormal; Chest	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
Discomfort; Cough;	Spiriva			S	Respiratory (inhalation)	2 Df, 1x/Day		Not Reported	
Dyspnoea; Malaise;	Symbicort Turbuhaler			S	Respiratory (inhalation)	2 Df, 3x/Day		Not Reported	
Oropharyngeal Pain;	Zenhale			S	Unknown	Unk		Not Reported	
Therapeutic Product Effect Incomplete									

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728480	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172540		75 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Blood Count Abnormal; Cough; Lung Hyperinflation; Lung Neoplasm Malignant; Middle Insomnia; Obstructive Airways Disorder; Productive Cough; Wheezing	Azithromycin	S	Unknown	500 Mg, 3x/Day	Pfizer
	Clavulin [Amoxicillin Sodium;Clavulanate Potassium]	S	Unknown	Unk	Not Reported
	Levaquin	S	Unknown	Unk	Not Reported
	Moxifloxacin Hydrochloride	S	Unknown	Unk	Not Reported
	Prednisone	S	Unknown	50 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	40 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	20 Mg, 1x/Day	Not Reported
	Prednisone	S	Unknown	30 Mg, 1x/Day	Not Reported
	Salbutamol Sulfate	S	Unknown	Unk	Not Reported
	Symbicort Turbohaler	S	Unknown	3 Df, 3x/Day	Not Reported
	Symbicort Turbohaler	S	Unknown	2 Df, 2x/Day	Not Reported
	Tiotropium	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728486	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172565		62 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Infection; Malaise; Pneumonia; Product Dose Omission	Azithromycin			S	Unknown	Unk		Pfizer
	Advair			S	Unknown	Unk		Not Reported
	Nucala			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Prednisone			S	Unknown	10 Mg		Not Reported
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728487	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020172556		48 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Asthma; Back Pain; Chest Discomfort; Dyspnoea	Zithromax	S	Unknown	Unk	Pfizer
Exertional; Palpitations; Productive Cough; Sputum Discoloured	Mepolizumab	S	Unknown	100 Mg	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported
	Mepolizumab	S	Intravenous (not otherwise specified)	100 Mg	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728528	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020172476		54 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Blood Count Abnormal; Cough; Dyspnoea;	Azithromycin			S	Unknown	250 Mg, 1x/Day		Pfizer
Gastrooesophageal Reflux Disease; Therapeutic Product Effect Incomplete	Montelukast			S	Unknown	10 Mg, 1x/Day		Not Reported
	Pulmicort			S	Unknown	Unk		Not Reported
	Salbutamol Sulfate			S	Unknown	2 Df		Not Reported
	Singulair			S	Unknown	Unk		Not Reported
	Spiriva			S	Unknown	2 Df, 1x/Day		Not Reported
	Symbicort Turbohaler			S	Unknown	2 Df, 2x/Day		Not Reported
	Erythromycin			C	Unknown	250 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728536	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020172860		25 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Osteonecrosis; Therapeutic Product Effect Incomplete	Azithromycin			S	Unknown	Unk, 1x/Day		Pfizer
	Advair			S	Unknown	Unk, 2x/Day		Not Reported
	Nucala			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Nucala			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Prednisone			S	Unknown	10 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Salbutamol Sulfate	S	Unknown	Unk	Not Reported
Salbutamol Sulfate	S	Respiratory (inhalation)	2.5 Mg, 2x/Day	Not Reported
Singular	S	Unknown	10 Mg, 1x/Day	Not Reported
Tiotropium	S	Unknown	2.5 Ug, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728568	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020173508		73 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain;	Azithromycin			S	Unknown	Unk		Pfizer
Arthralgia; Blood Pressure Diastolic Abnormal; Blood Pressure Diastolic Decreased; Blood Pressure Fluctuation; Blood Pressure Increased; Blood Pressure Systolic Abnormal; Bone Contusion; Bone Disorder; Bronchitis; Bursitis; Chapped Lips; Contusion; Cough; Diarrhoea; Drug Ineffective; Erythema; Eye Contusion; Fall; Fatigue; Gastroenteritis; Haemorrhoids; Heart Rate Decreased; Hyperkeratosis; Ingrowing Nail; Injury; Intentional Product Use Issue; Joint Swelling; Ligament Injury; Ligament Sprain; Lip Dry; Lower Respiratory Tract Infection; Musculoskeletal Pain; Musculoskeletal Stiffness; Nail Infection; Nasopharyngitis; Neck Injury; Off Label Use; Oral	Actemra			S	Intravenous (not otherwise specified)	300 Mg (1 Every 4 Weeks)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	300 Mg (1 Every 4 Weeks)		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	600 Mg		Not Reported
	Actemra			S	Intravenous (not otherwise specified)	300 Mg (1 Every 4 Weeks)		Not Reported
	Arthrotec			C		Unk		Not Reported
	Atenolol			C		Unk		Not Reported
	Folic Acid			C		Unk		Not Reported
	Hydroxychloroquine Sulfate			C		Unk		Not Reported
	Lectopam			C		Unk		Not Reported
	Methotrexate			C		Unk		Not Reported
	Synthroid			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Herpes; Oxygen
Saturation Decreased;
Pain; Pain In Extremity;
Peripheral Swelling;
Polyarthritis; Procedural
Pain; Psoriasis; Rash;
Rhinitis; Sinus
Congestion; Skin
Laceration; Vaginal
Haemorrhage; Weight
Decreased; Weight
Increased

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728573	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2020172528		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Dyspnoea; Loss Of Personal Independence In Daily Activities; Lower Respiratory Tract Infection; Malaise; Sleep Disorder Due To A General Medical Condition; Wheezing	Azithromycin			S	Unknown	250 Mg, 1x/Day		Pfizer
	Breo Ellipta			S	Unknown	25 Ug, 1x/Day		Not Reported
	Nucala			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Salbutamol Sulfate			S	Unknown	100 Ug		Not Reported
	Umeclidinium Bromide			S	Unknown	62.5 Ug, 1x/Day		Not Reported
	Ventolin Nebules			S	Unknown	2.5 MI		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728600	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2020173564		75 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthralgia; Asthenia; Cough; Decreased Appetite; Diarrhoea; Drug Interaction; Dry Mouth; Dyspnoea; Eye Colour Change; Feeling Abnormal; Intercepted	Azithromycin			S	Unknown	250 Mg [3 Every 1 Weeks]		Pfizer
	Ofev			S	Oral	100 Mg, 2x/Day		Not Reported
	Ofev			S	Oral	150 Mg		Not Reported
	Loperamide			C		Unk		Not Reported
	Ultram [Tramadol Hydrochloride]			C		Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Product Prescribing Error;
Labelled Drug-Drug
Interaction Medication
Error; Myocardial
Infarction;
Nasopharyngitis; Oral
Fungal Infection;
Pneumonia; Productive
Cough; Tremor

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17728787	NON-EXPEDITED			US-ABBVIE-19S-163-2796763-00			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Chest Discomfort; Dyspnoea	Creon			S	Oral	5 Caps With Meals And 2 Caps With Snacks		Not Reported	
	Creon			S	Oral			Not Reported	
	Aztreonam Lysine			S	Respiratory (inhalation)	28 Days On And 28 Days Off		Not Reported	
	Pulmozyme			S	Respiratory (inhalation)			Not Reported	
	Ventolin			S	Respiratory (inhalation)			Not Reported	
	Ventolin			S				Not Reported	
	Omeprazole			S	Oral			Not Reported	
	Mvw Complete Formulation D3000			S	Oral			Not Reported	
	Loratadine			S	Oral			Not Reported	
	Symdeko			S	Oral	1 Yellow Tab Am And 1 Blue Tab Pm		Not Reported	
	Tobramycin			S	Respiratory (inhalation)	5 MI Every 12 Hours For 28 Days On And 28 Days Off		Not Reported	
	Azithromycin			S	Oral	1 Tab Every Monday, Wednesday, Friday		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Orkambi			S		Oral			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729057	NON-EXPEDITED			US-AKRON, INC.- 2083362			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eye Pain; Eye Swelling	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729099	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020172624		58 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Candida Infection; Off Label Use; Pneumonia	Azithromycin			S	Unknown	250 Mg [1 Every 3 Days]		Pfizer	
	Amoxicillin			S	Unknown	500 Mg [1 Every 5 Days]		Pfizer	
	Stelara			S	Subcutaneous	45 Mg [1 Every 8 Weeks]		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729140	NON-EXPEDITED			US-AKRON, INC.- 2083349			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blepharitis; Erythema Of Eyelid	Azasite			S	Ophthalmic			Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729197	EXPEDITED (15-DAY)		DE	ES-FRESENIUS KABI- FK202004240		39 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Sudden Death	Propofol (Manufacturer Unknown)			S	Intravenous (not otherwise specified)			Not Reported	
	Salbutamol			S	Respiratory (inhalation)			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Azithromycin	S	Oral	Not Reported
Hydroxychloroquine Sulfate	S	Oral	Not Reported
Metoclopramide Hydrochloride	S	Intravenous (not otherwise specified)	Not Reported
Ipratropium Bromide	C	Respiratory (inhalation)	Not Reported
Enoxaparin Sodium	C	Subcutaneous	Not Reported
Cefotaxime	C	Intravenous drip	Not Reported
Midazolam	C	Intravenous drip	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729206	EXPEDITED (15-DAY)		HO, OT	CZ-MYLANLABS-2020M1042219			Female	CZE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Hyperkeratosis; Hyperplasia; Limb Discomfort; Mass; Product Use In Unapproved Indication; Pyoderma Gangrenosum; Vasculitis	Azithromycin			S	Oral	Unk		Not Reported
	Doxyhexal /00055701/			S	Oral	100 Mg, Bid		Mylan
	Doxyhexal /00055701/			S	Oral	Unk		Mylan
	Pentasa			C	Unknown	2 G (0-0-2)		Mylan
	Clobetasol Propionate			C	Unknown	Unk		Mylan
	Clindamycin			C	Intravenous (not otherwise specified)	Unk		Mylan
	Salofalk /00747601/			C	Unknown	1 G, Qw		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729278	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172706			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cognitive Disorder; Depression; Dizziness; Drug Intolerance; Fatigue; Feeling Hot; Ill-Defined Disorder; Impaired Gastric	Azithromycin			S	Unknown	Unk		Pfizer
	Ocrevus			S	Intravenous (not otherwise specified)	300 Mg [1 Every 2 Weeks]		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

Emptying; Pain In
Extremity

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729281	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC- 2020172582		35 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenia; Asthma; Bronchial Obstruction; Chest Discomfort; Conjunctivitis; Cough; Disease Recurrence; Dizziness; Dyspnoea; Eosinophilia; Feeling Abnormal; Feeling Hot; Hypersensitivity; Hyperventilation; Increased Bronchial Secretion; Maternal Exposure During Pregnancy; Middle Insomnia; Nasal Congestion; Nausea; Palpitations; Productive Cough; Rhinitis; Therapeutic Product Effect Incomplete; Urticaria; Wheezing	Azithromycin			S	Unknown	250 Mg, Three Times A Day		Pfizer	
	Methylprednisolone			S	Unknown	Unk		Pfizer	
	Solu-Medrol			S	Unknown	Unk		Pfizer	
	Advair			S	Unknown	Unk		Not Reported	
	Alvesco			S	Unknown	Unk		Not Reported	
	Benadryl			S	Unknown	Unk, As Needed		Not Reported	
	Benralizumab			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	Unk		Not Reported	
	Cetirizine			S	Unknown	20 Mg, Twice A Day		Not Reported	
	Hydrochloride/Pseudoephedrine Hydrochloride								
	Ergocalciferol			S	Unknown	1000 Iu, Weekly		Not Reported	
	Glycopyrronium Bromide			S	Unknown	1 Df		Not Reported	
	Montelukast			S	Unknown	10 Mg, Once A Day		Not Reported	
	Nucala			S	Unknown	100 Mg		Not Reported	
	Omalizumab			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	15 Mg, Once A Day		Not Reported	
	Salbutamol			S	Unknown	Unk, As Needed		Not Reported	
	Singulair			S	Unknown	100 Mg		Not Reported	
	Spiriva			S	Unknown	2 Df		Not Reported	
	Symbicort Turbohaler			S	Unknown	2 Df, Twice A Day		Not Reported	
	Symbicort Turbohaler			S	Unknown	4 Df (1 Every 2 Weeks)		Not Reported	
	Synthroid			S	Unknown	0.1 Mg		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Uniphyl	S	Unknown	200 Mg		Not Reported
	Uniphyl	S	Unknown	600 Mg		Not Reported
	Zenhale	S	Unknown	2 Df		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729286	EXPEDITED (15-DAY)		DS	CA-PFIZER INC-2020172941		4 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Deafness; Paraesthesia; Stress; Tinnitus	Azithromycin			S		200 Mg, 1x/Day		Pfizer	
	Azithromycin			S		180 Mg, 1x/Day		Pfizer	
	Azithromycin			S		90 Mg, 1x/Day		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729287	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172513			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Diarrhoea; Dyspnoea; Nausea; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S		Unk		Pfizer	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729292	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172518		76 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mental Status Changes	Azithromycin			S	Unknown	Unk		Pfizer	
	Tigecycline			S	Unknown	Unk		Pfizer	
	Cilastatin Sodium/Imipenem			S	Unknown	Unk		Not Reported	
	Minocycline			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729294	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172788		63 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blister; Choking Sensation; Cough; Drug Hypersensitivity; Dyspnoea; Hot Flush; Mouth Swelling; Pharyngeal Oedema; Rash; Swelling; Swelling Face; Throat Tightness	Azithromycin			S	Oral	2 Df, 1x/Day		Pfizer	
	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729536	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020173379		72 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthma; Blood Count Abnormal; Chest Discomfort; Condition Aggravated; Cough; Drug Ineffective; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Gastroesophageal Reflux Disease; Lung Disorder; Lung Hyperinflation; Lung Opacity; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pain In Extremity; Rhinorrhoea; Sputum Discoloured; Therapeutic Product Effect Incomplete; Total Lung Capacity Abnormal; Weight Increased;	Amlodipine Besilate			S	Unknown	Unk		Pfizer	
	Solu-Medrol			S	Unknown	Unk		Pfizer	
	Zithromax			S	Unknown	Unk		Pfizer	
	Atrovent			S	Unknown	Unk		Not Reported	
	Breo Ellipta			S	Unknown	Unk		Not Reported	
	Cipralext [Escitalopram]			S	Unknown	Unk		Not Reported	
	Escitalopram Oxalate			S	Unknown	Unk		Not Reported	
	Levothyroxine			S	Unknown	Unk		Not Reported	
	Olodaterol			S	Unknown	Unk		Not Reported	
	Hydrochloride/Tiotropium Bromide								
	Piperacillin Sodium/Tazobactam Sodium			S	Unknown	Unk		Not Reported	
	Prednisone			S	Unknown	Unk		Not Reported	
	Salbutamol Sulfate			S	Unknown	Unk		Not Reported	
	Singulair			S	Unknown	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Wheezing	Spiriva	S	Unknown	Unk	Not Reported
	Synthroid	S	Unknown	Unk	Not Reported
	Theophylline	S	Unknown	Unk	Not Reported
	Uniphyl	S	Unknown	Unk	Not Reported
	Zantac	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729546	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020173720		69 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Asthma; Chest Discomfort; Cough; Depressed Mood; Dyspnoea; Insomnia; Intentional Dose Omission; Laboratory Test Abnormal; Lower Respiratory Tract Infection; Productive Cough; Respiratory Tract Congestion; Sputum Discoloured; Wheezing	Azithromycin			S	Unknown	Unk		Pfizer
	Atrovent			S	Unknown	Unk		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Mepolizumab			S	Intravenous (not otherwise specified)	100 Mg		Not Reported
	Montelukast			S	Unknown	Unk		Not Reported
	Prednisone			S	Unknown	10 Mg, 1x/Day		Not Reported
	Prednisone			S	Unknown	50 Mg		Not Reported
	Pulmicort			S	Unknown	2 Df, 2x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Theophylline	S	Unknown	600 Mg	Not Reported
Ventolin [Salbutamol]	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729563	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020173601		34 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chapped Lips; Cough; Dry Mouth; Dysphagia;	Azithromycin			S	Unknown	250 Mg		Pfizer
Eczema; Eye Pruritus; Eye Swelling; Fatigue;	Omalizumab			S	Subcutaneous	300 Mg		Not Reported
Formication;	Omalizumab			S	Subcutaneous	Unk		Not Reported
Hypoaesthesia Oral; Lip Dry; Lip Swelling; Mouth Swelling; Oral Pruritus;	Benadryl			C	Oral	1 Df		Not Reported
Peripheral Swelling; Pruritus; Psoriasis; Respiratory Tract Infection; Skin Exfoliation; Speech Disorder;	Cetirizine Hydrochloride			C	Oral	1 Df, 1x/Day		Not Reported
Stomatitis; Stress; Swelling; Therapeutic Response Shortened; Urticaria	Prednisone			C	Oral	1 Df		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729601	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172356			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haematemesis	Azithromycin			S		Unk		Pfizer

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729669	EXPEDITED (15-DAY)		DE	ES-PFIZER INC-2020171686		65 YR	Female	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Cardiogenic Shock; Off Label Use; Product Use In Unapproved Indication; Tachyarrhythmia	Azithromycin	S	Oral	500 Mg, 1x/Day	Pfizer
	Hydroxychloroquine Sulfate	S	Oral	200 Mg, 1x/Day	Not Reported
	Tocilizumab	C	Intravenous (not otherwise specified)	Unk	Not Reported
	Ceftriaxon	C	Intravenous (not otherwise specified)	1 G, 1x/Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729715	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020172729		68 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Cardiac Failure; Emphysema	Azithromycin			S	Unknown	Unk		Pfizer
	Fluticasone			S	Unknown	2 Df, 2x/Day		Not Reported
	Rabeprazole			S	Unknown	Unk		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Tiotropium Bromide			C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729787	EXPEDITED (15-DAY)		HO	ES-PFIZER INC-2020171239		53 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Off Label Use; Product Use Issue; Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Azithromycin			S				Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported
	Dolquine			S				Not Reported
	Propofol			S	Intravenous (not otherwise specified)	6.6 Mg/Kg Every Hour		Not Reported
	Dexamethasone			C	Intravenous (not otherwise specified)	4 Mg, 1x/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729803	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

2020173000

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abortion Spontaneous	Azithromycin			S	Unknown	Unk		Pfizer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729805	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC-2020171215		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis Acute; Off Label Use; Product Use In Unapproved Indication	Azithromycin			S	Oral	500 Mg, 1x/Day (500 Mg Day)		Pfizer	
	Azithromycin			S	Other	400 Mg, Daily (Via Nasogastric Tube)		Pfizer	
	Dolquine		S	Not Reported					
	Dolquine		S	Not Reported					
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729870	NON-EXPEDITED			US-AKRON, INC.-2083363			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Vision Blurred	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729928	NON-EXPEDITED			US-AKRON, INC.-2083364			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17729966	NON-EXPEDITED			US-AKRON, INC.-2083366			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Burns	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730013	NON-EXPEDITED			US-AKRON, INC.- 2083368			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730018	EXPEDITED (15-DAY)		OT	CA-TEVA-2020-CA- 1229514			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Atorvastatin Calcium			S	Unknown			Teva	
	Acetaminophene			S	Unknown			Not Reported	
	Alprazolam			S	Unknown			Actavis	
	Amoxicillin Trihydrate			S	Unknown			Teva	
	Betamethasone Dipropionate			S	Unknown			Actavis	
	Betamethasone Dipropionate			S	Unknown			Actavis	
	Clarithromycin			S	Unknown			Actavis	
	Diphenhydramine			S	Unknown			Not Reported	
	Nicotine Polacrilex			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Actavis	
	Pregabalin			S	Unknown			Teva	
	Sulfamethoxazole And Trimethoprim			S	Unknown			Teva	
	Apo Hydro			S	Unknown			Not Reported	
	Avamys			S	Unknown			Not Reported	
	Biaxin XI			S	Unknown			Not Reported	
	Bisacodyl			S	Unknown			Not Reported	

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Calcium Carbonate/Vitamin D3	S	Unknown	Not Reported
Cetirizine	S	Unknown	Not Reported
Clotrimazole	S	Unknown	Not Reported
Desonide	S	Unknown	Not Reported
Entocort	S	Unknown	Not Reported
Ertapenem Sodium	S	Unknown	Not Reported
Flovent	S	Unknown	Not Reported
Glycerine	S	Unknown	Not Reported
Gramicidin /Neomycin Sulfate/Polymyxin B Sulfate	S	Unknown	Not Reported
Humira	S	Subcutaneous	Not Reported
Kenalog	S	Unknown	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride	S	Unknown	Not Reported
Metronidazole	S	Unknown	Not Reported
Ms Ir	S	Unknown	Not Reported
Mupirocin	S	Topical	Not Reported
Mupirocin	S	Unknown	Not Reported
Nadolol	S	Unknown	Not Reported
Nicoderm	S	Unknown	Not Reported
Pentasa	S	Unknown	Not Reported
Pms-Azithromycin	S	Unknown	Not Reported
Pulmicort	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sinus Rinse	S	Unknown	Not Reported
Triamcinolone Acetonide	S	Unknown	Not Reported
Vitamin D3	S	Unknown	Not Reported
Valsartan	C	Unknown	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730062	NON-EXPEDITED			US-AKRON, INC.- 2083369			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Skin Burning Sensation	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730118	NON-EXPEDITED			US-AKRON, INC.- 2083370			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain	Azasite			S				Akorn	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730145	EXPEDITED (15-DAY)		OT	HU-BAUSCH-BL-2020- 012195		49 DAY	Female	HUN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection; Conjunctivitis; Eye Symptom; Eyelid Oedema; Product Use In Unapproved Indication	Tobramycin Tobramycin Azithromycin Betadine			S S S C	Unknown Unknown Ophthalmic	High Dose		Bausch And Lomb Bausch And Lomb Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730304	EXPEDITED (15-DAY)		HO, OT	PT-MYLANLABS- 2020M1042335		64 YR	Male	PRT
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pathogen Resistance	Azithromycin Vancomycin Piperacillin/Tazobactam Amoxicillin/Clavulanic Acid Levofloxacin			S S S S S	Unknown Unknown Unknown Unknown Unknown	Unk Unk Unk Unk Unk		Not Reported Not Reported Not Reported Not Reported Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Imipenem			S		Unknown		Unk		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Apr-2020	17730346	NON-EXPEDITED			US-PFIZER INC-2020174951			Female	USA	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Hypersensitivity; Rash	Azithromycin			S		Unk		Pfizer		
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Apr-2020	17730374	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020172567		76 YR	Male	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Abdominal Pain Upper;	Azithromycin			S	Unknown	Unk (3 Every 1 Weeks)		Pfizer		
Asthenia; Cough;	Ofev			S	Oral	150 Mg, 2x/Day		Not Reported		
Decreased Appetite;	Ofev			S	Oral	150 Mg, 2x/Day		Not Reported		
Diarrhoea; Dyspnoea;	Ofev			S	Oral	100 Mg, 2x/Day		Not Reported		
Large Intestine Infection;										
Muscular Weakness;										
Nausea; Off Label Use;										
Product Use In										
Unapproved Indication;										
Viral Infection; Vomiting;										
Weight Decreased										
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
30-Apr-2020	17730477	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172824		40 YR	Male	CAN	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>		
Drug Ineffective;	Azithromycin			S	Unknown	625 Mg, 1x/Day		Pfizer		
Mycobacterium Avium	Ciclosporin			S	Unknown	Unk		Not Reported		
Complex Infection	Ethambutol			S	Unknown	800 Mg, 1x/Day		Not Reported		
	Mycophenolate Mofetil			S	Unknown	Unk		Not Reported		
	Prednisone			S	Unknown	Unk		Not Reported		

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rifampin	S	Unknown	300 Mg, 1x/Day	Not Reported
Insulin	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730751	EXPEDITED (15-DAY)	OT		NVSC2020CA113431			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Amoxicillin Trihydrate			S	Unknown	Unk		Novartis
	Atorvastatin Calcium			S	Unknown	Unk		Not Reported
	Atropine Sulfate,Diphenoxylate Hydrochloride			S	Oral	Unk		Not Reported
	Clarithromycin			S	Unknown	Unk		Not Reported
	Pantoprazole			S	Unknown	Unk		Not Reported
	Pregabalin			S	Unknown	Unk		Not Reported
	Salinex [Sodium Chloride]			S		Unk		Not Reported
	Sodium Chloride			S		Unk		Not Reported
	Triamcinolone Acetonide			S	Intra-articular	Unk		Not Reported
	Morphine Sulfate			S	Unknown	Unk		Not Reported
	Zinc Oxide		Y	S	Unknown	Unk		Not Reported
	Acetaminophene			S	Unknown	Unk		Not Reported
	Alprazolam			S	Unknown	Unk		Not Reported
	Apo Hydro			S	Unknown	Unk		Not Reported
	Ascorbic Acid			S	Unknown	Unk (Copper, Xantofyl, Zeaxanthin, Zinc)		Not Reported
	Avamys			S	Unknown	Unk (Spray, Metered Dose)		Not Reported
	Azithromycin Dihydrate			S	Unknown	Unk		Not Reported
	Betaderm			S	Unknown	Unk		Not Reported
	Betamethasone Dipropionate			S	Unknown	Unk		Not Reported
	Biaxin XL			S	Unknown	Unk (Extended Release)		Not Reported
	Bisacodyl			S	Unknown	Unk		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Calcium Carbonate	S	Unknown	Unk	Not Reported
Cetirizine	S	Unknown	Unk	Not Reported
Clotrimazole	S	Unknown	Unk	Not Reported
Desonide	S	Unknown	Unk	Not Reported
Dilaudid	S	Unknown	Unk	Not Reported
Diphenhydramine Hcl	S	Unknown	Unk	Not Reported
Entocort	S	Unknown	Unk (Sustained Release)	Not Reported
Ertapenem Sodium	S	Unknown	Unk	Not Reported
Flovent	S	Unknown	Unk	Not Reported
Glycerine	S	Oral	Unk (Liquid)	Not Reported
Gramicidin	S	Unknown	Unk (Gramcidine, Neomycin Sulfate, Polymixin B Sulfate)	Not Reported
Humira	S	Subcutaneous	Unk	Not Reported
Kenalog	S	Unknown	Unk	Not Reported
Lomotil	S	Oral	Unk Unk, Q6h (4 Every 1 Days)	Not Reported
Macrogol	S	Unknown	Unk (Macrogol 3350, Potassium Chloride, Sodium Bicarbonate, Sodium Chloride, So)	Not Reported
Metronidazole	S	Unknown	Unk	Not Reported
Mupirocin	S	Topical	Unk	Not Reported
Mupirocin	S	Unknown	Unk	Not Reported
Mupirocin Calcium	S	Unknown	Unk (Mupirocin Calcium Dihydrate)	Not Reported
Nadolol	S	Unknown	Unk	Not Reported
Nicoderm	S	Unknown	Unk	Not Reported
Nicotine	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	S	Unknown	Unk	Not Reported
Pentasa	S	Unknown	Unk	Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Prednisone	S	Unknown	Unk	Not Reported
Pulmicort	S	Unknown	Unk	Not Reported
Refresh Tears	S	Ophthalmic	Unk	Not Reported
Sinus Rinse	S		Unk	Not Reported
Statex (Morphine Sulfate)	S	Unknown	Unk	Not Reported
Vitamin D3	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	S	Unknown	Unk	Not Reported
Zeaxanthin	S	Unknown	Unk	Not Reported
Calcium	C	Unknown	Unk (Calcium Carbonate, Vitamin D3)	Not Reported
Valsartan	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730790	EXPEDITED (15-DAY)		OT	NVSC2020BE116145		35 YR	Female	BEL

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dyspnoea; Pharyngeal Swelling	Azithromycin			S	Oral			Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17730900	EXPEDITED (15-DAY)		OT	US-BAYER-2020-070314		46 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cough; Haemoptysis; Influenza Like Illness; Labelled Drug-Drug Interaction Medication Error; Pulmonary Alveolar Haemorrhage	Acetylsalicylic Acid		Y	S				Bayer
	Ustekinumab			S				Not Reported
	Azithromycin			S				Not Reported
	Fluticasone + Salmeterol			S				Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17731367	NON-EXPEDITED			US-CSPC OUYI PHARMACEUTICAL CO., LTD.-2083375			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Rash	Azithromycin			S				Cspc Ouyi Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Apr-2020	17731373	NON-EXPEDITED			US-CSPC OUYI PHARMACEUTICAL CO., LTD.-2083376			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dysgeusia; Parosmia	Azithromycin			S				Cspc Ouyi Pharmaceutical	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17653955	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR- APL-2020-017958		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Levofloxacin			S	Unknown	Unk		Aurobindo	
	Lopinavir;Ritonavir			S	Oral	2 Dosage Form, Two Times A Day		Not Reported	
	Hydroxychloroquine Sulfate			S	Oral	200 Milligram, Once A Day		Not Reported	
	Tacrolimus			S	Oral	Unk		Not Reported	
	Enoxaparin Sodium			C	Subcutaneous	40 Milligram, Once A Day		Not Reported	
	Ceftriaxone			C	Unknown	Unk		Not Reported	
	Prednisone			C	Oral	20 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17711229	NON-EXPEDITED			US-PFIZER INC- 2020165712			Female	USA

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Hypersensitivity	Azithromycin			S		Unk		Pfizer
	Clindamycin			S		Unk		Unknown
	Doxycycline Hyclate			S		Unk		Pfizer
	Lansoprazole			S		Unk		Pfizer
	Codeine			S		Unk		Not Reported
	Lanolin			S		Unk		Not Reported
	Lisinopril			S		Unk		Not Reported
	Spiriva			S		Unk		Not Reported
	Myrbetriq			S		Unk		Not Reported
	Pcm			S		Unk		Not Reported
	Advair			S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17716072	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-020311		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Electrocardiogram Qt Prolonged; Long Qt Syndrome; Sudden Death	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo
	Salbutamol			S	Respiratory (inhalation)	0.1 Milligram, Four Times/Day		Not Reported
	Dolquine			S	Oral	400 Milligram, Two Times A Day		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Metoclopramide			S	Intravenous (not otherwise specified)	10 Milligram, 3 Times A Day		Not Reported
	Ipratropium Bromide			C	Respiratory (inhalation)	20 Microgram, Four Times/Day		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Cefotaxime			C	Intravenous drip	4 Gram, Two Times A Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Midazolam	C	Intravenous drip	100 Milligram, Once A Day	Not Reported
Tocilizumab	C	Intravenous (not otherwise specified)	600 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17721946	EXPEDITED (15-DAY)		HO	ES-TEVA-2020-ES-1227338		66 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatitis	Aziticromicina (7019a)			S	Oral	500 Milligram Daily;		Not Reported	
	Aziticromicina (7019a)			S				Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	2 Gram Daily;		Not Reported	
	Ceftriaxona (501a)			S				Not Reported	
	Dolquine			S	Oral	400 Milligram Daily; Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos		Not Reported	
	Dolquine			S				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17724166	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020166893		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17727561	EXPEDITED (15-DAY)		LT	FR-MYLANLABS-2020M1042619		80 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypokalaemia; Ventricular Tachycardia	Azithromycin			S	Oral	250 Milligram, Qd		Not Reported	
	Lasilix /00032601/			S	Intravenous (not	2 Dosage Form, Qd		Mylan	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Plaquenil /00072603/	S	otherwise specified)			
Sufentanil	C	Oral	Unk		Mylan
Perfalgan	C	Intravenous (not otherwise specified)	Unk		Mylan
Noradrenaline /00127501/	C	Intravenous (not otherwise specified)	Unk		Mylan
Midazolam	C	Intravenous (not otherwise specified)	Unk		Mylan
Tazocilline	C	Intravenous (not otherwise specified)	4 Dosage Form, Qd		Mylan
Transipeglib	C	Oral	Unk		Mylan
Potassium Chloride	C	Intravenous (not otherwise specified)	Unk		Mylan
Nimbex /01302502/	C	Intravenous (not otherwise specified)	Unk		Mylan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17731626	EXPEDITED (15-DAY)		OT	CA-SA-2020SA112456			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Metronidazole			S	Unknown			Sanofi
	Triamcinolone Acetonide			S	Unknown			Sanofi
	Glycerine			S	Unknown			Not Reported
	Morphine Sulfate			S				Not Reported
	Nadolol			S				Not Reported
	Nicoderm			S				Sanofi
	Nicotine Polacrilex			S				Not Reported
	Mesalazine			S				Sanofi
	Azithromycin			S				Not Reported
	Prednisone			S				Not Reported
	Pregabalin			S				Not Reported
	Budesonide			S				Not Reported
	Sulfamethoxazole/Trimethoprim			S				Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Ergocalciferol	S		Sanofi
Paracetamol	S		Not Reported
Alprazolam	S	Unknown	Not Reported
Amoxicillin Trihydrate	S		Not Reported
Hydrochlorothiazide	S		Not Reported
Desonide	S		Not Reported
Atorvastatin	S		Not Reported
Betamethasone Dipropionate	S		Not Reported
Betamethasone Valerate	S		Not Reported
Clarithromycin	S		Not Reported
Bisacodyl	S		Sanofi
Clotrimazole	S		Not Reported
Diphenhydramine	S		Sanofi
Budesonide	S		Not Reported
Triamcinolone Acetonide	S	Intra-articular	Sanofi
Mupirocin	S	Topical	Not Reported
Flovent	S		Not Reported
Ertapenem Sodium	S		Not Reported
Cetirizine	S		Not Reported
Humira	S	Subcutaneous	Not Reported
Calcium Carbonate/Vitamin D3	S		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Chloride	S		Not Reported
Neomycin And Polymyxin B Sulfates And Gramicidin	S	Unknown	Not Reported
Refresh Tears	S	Ophthalmic	Not Reported
Sinus Rinse	S		Not Reported
Avamys	S		Not Reported
Valsartan	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732418	EXPEDITED (15-DAY)	HO		ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245759		53 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Propofol Infusion Syndrome	Azithromycin			S	Oral	500 Mg Dia		Sun	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Propofol 2% Injectable Baxter, 1	S	Intravenous (not otherwise specified)	Sedacion ()	Not Reported
Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Mg Dia	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732521	EXPEDITED (15-DAY)			US-ADVANZ PHARMA-202004002893			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Effective For Unapproved Indication; Off Label Use	Hydroxychloroquine			S		Unk		Concordia	
	Azithromycin			S		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732522	EXPEDITED (15-DAY)		HO	CA-ROCHE-2590508		48 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterovirus Infection; Transplant Rejection	Valganciclovir			S	Unknown			Not Reported	
	Abacavir			S	Unknown			Not Reported	
	Mycophenolic Acid			S	Unknown			Not Reported	
	Azithromycin			S	Unknown			Not Reported	
	Sulfamethoxazole			S	Unknown			Not Reported	
	Tacrolimus			S	Unknown			Not Reported	
	Tivicay			S	Unknown			Not Reported	
	Trimethoprim			S	Unknown			Not Reported	
	Prednisone			S	Unknown			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732523	EXPEDITED (15-DAY)		HO	CA-ROCHE-2590487		48 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Enterovirus Infection;	Valganciclovir			S	Oral			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Transplant Rejection	Abacavir	S	Unknown	Not Reported
	Azithromycin	S	Unknown	Not Reported
	Mycophenolic Acid	S	Unknown	Not Reported
	Prednisone	S	Unknown	Not Reported
	Sulfamethoxazole	S	Unknown	Not Reported
	Tacrolimus	S	Unknown	Not Reported
	Tivicay	S	Unknown	Not Reported
	Trimethoprim	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17732668	EXPEDITED (15-DAY)		LT, OT	JP-PFIZER INC-2020168162		38 YR	Male	JPN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Ventricular Fibrillation	Azithromycin			S		500 Mg, Daily		Pfizer	
	Azithromycin			S				Pfizer	
	Dexmedetomidine Hydrochloride			S		Unk		Pfizer	
	Dexmedetomidine Hydrochloride			S				Pfizer	
	Hydroxychloroquine			S		400 Mg, Daily		Not Reported	
	Hydroxychloroquine			S				Not Reported	
	Favipiravir			C				Not Reported	
	Methylprednisolone			C		1 Mg/Kg		Not Reported	
	Ceftriaxone			C		2 G		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733747	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172544		59 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Cough; Dyspnoea; Hypotension; Pneumonia; Rheumatoid Arthritis; Sinusitis; Tooth Fracture	Zithromax			S		Unk		Pfizer	
	Orencia			S	Subcutaneous	125 Mg, Weekly		Not Reported	
	Prednisone			S		Unk		Not Reported	
	Cardizem [Diltiazem			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hydrochloride]			
Celebrex	C	Unk	Not Reported
Esomeprazole [Esomeprazole Sodium]	C	Unk	Not Reported
Gabapentin	C	Unk	Not Reported
Hydroxychloroquine Sulfate	C	Unk	Not Reported
Polysaccharide-Iron Complex	C	Unk	Not Reported
Rosuvastatin Calcium	C	Unk	Not Reported
Synthroid	C	Unk	Not Reported
Trazodone	C	Unk	Not Reported
Zolpidem Tartrate	C	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733748	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020173531		53 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dermatitis Contact; Diabetes Mellitus; Hypertension; Staphylococcus Test Positive	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer
	Atrovent			S	Unknown	Unk		Not Reported
	Breo Ellipta			S	Unknown	1 Df		Not Reported
	Ipratropium/Salbutamol			S	Unknown	Unk		Not Reported
	Prednisone			S	Oral	45 Mg		Not Reported
	Salbutamol			S	Unknown	Unk		Not Reported
	Seebri Breezhaler			S	Unknown	1 Df, 1x/Day		Not Reported
	Singulair			S	Oral	1 Df, 1x/Day		Not Reported
	Theophylline			S	Oral	450 Mg, 1x/Day		Not Reported
	Xolair			S	Intravenous (not otherwise specified)	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733796	EXPEDITED (15-DAY)		OT	CA-PFIZER INC-2020172965		33 YR	Female	CAN

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Discomfort; Abdominal Rigidity; Nausea; Syncope; Urticaria; Vomiting	Azithromycin			S	Oral	250 Mg, 1x/Day		Pfizer	
	Ciprodex [Ciprofloxacin Hydrochloride]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733797	EXPEDITED (15-DAY)		DE, HO, OT	CA-PFIZER INC- 2020173460		74 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Asthma; Blood Pressure Increased; Decreased Appetite; Dyspnoea; Forced Expiratory Volume Decreased; Forced Vital Capacity Decreased; Heart Rate Increased; Inappropriate Schedule Of Product Administration; Influenza; Malaise; Obstructive Airways Disorder; Off Label Use; Oxygen Saturation Decreased; Product Use In Unapproved Indication	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Xolair			S	Subcutaneous	Unk		Not Reported	
	Xolair			S	Subcutaneous	150 Mg		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733798	EXPEDITED (15-DAY)		OT	CA-PFIZER INC- 2020173013		12 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acne; Autism Spectrum Disorder; Blood Pressure Decreased; Cough; Dermatitis; Eczema; Forced Expiratory Volume Decreased; Heart Rate	Azithromycin			S	Oral	1 Df, 1x/Day		Pfizer	
	Fluoxetine			S		Unk		Not Reported	
	Xolair			S		300 Mg		Not Reported	
	Avamys			C		Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Abnormal; Lower Respiratory Tract Infection; Malaise; Nasal Congestion; Obstructive Airways Disorder; Oropharyngeal Pain; Pharyngeal Paraesthesia; Rash Pustular; Staphylococcal Infection; Syncope	Intuniv Prozac Quetiapine	C C C	Unk Unk Unk	Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733799	EXPEDITED (15-DAY)		HO, OT	CA-PFIZER INC-2020173305		39 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Asthma; Bronchospasm; Candida Infection; Cerebrovascular Accident; Dyspnoea; Heart Rate Increased; Hemiplegia; Inappropriate Schedule Of Product Administration; Oxygen Saturation Decreased; Peritonsillar Abscess; Pharyngeal Inflammation; Pilonidal Cyst; Postoperative Wound Complication; Productive Cough; Pulmonary Pain; Respiratory Rate Increased; Rhonchi; Therapy Partial Responder; Wheezing	Azithromycin Potassium Acetate Xolair Xolair Levaquin Prednisone Singulair Spiriva Ventolin [Salbutamol] Zenhale			S S S S C C C C C C	Unknown Unknown Subcutaneous Subcutaneous	Unk Unk 375 Mg 1 Every 2 Weeks Unk Unk Unk Unk Unk Unk		Pfizer Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17733800	EXPEDITED (15-DAY)		HO, LT, OT	CA-PFIZER INC-2020173076		62 YR	Male	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Atrial Fibrillation; Atrial Flutter; Cardiac Arrest; Torsade De Pointes	Azithromycin	S	Oral	500 Mg, 1x/Day	Pfizer
	Azithromycin	S	Intravenous (not otherwise specified)	500 Mg, 1x/Day	Pfizer
	Atorvastatin Calcium	C		Unk	Not Reported
	Bisoprolol	C		Unk	Not Reported
	Enoxaparin	C		Unk	Not Reported
	Ferrous Gluconate	C		Unk	Not Reported
	Ipratropium/Salbutamol	C		Unk	Not Reported
	Prednisone	C		Unk	Not Reported
	Thyroxine	C		Unk	Not Reported
	Zopiclone	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734176	EXPEDITED (15-DAY)		DE, OT	CH-SA-2020SA109443		72 YR	Male	CHE

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Haemolytic Anaemia; Off Label Use; Thrombocytopenia; Thrombotic Microangiopathy	Plaquenil			S	Oral	800 Mg/Day From 22 To 23 Mar 2020, 400 Mg/Day From 24 To 26 Mar 2020, 600 Mg/Day From 26 To 30 Mar 2		Sanofi
	Plaquenil			S				Sanofi
	Doxycycline			S	Oral	200 Mg		Not Reported
	Azithromycin			S	Oral	250 Mg		Not Reported
	Amoxicillin Trihydrate/Potassium Clavulanate			S	Intravenous drip	3.6 G, Qd		Not Reported
	Enoxaparin Sodium			S	Subcutaneous	40 Mg		Sanofi
	Fentanyl			S	Transdermal	25 Ug/H		Not Reported
	Piperacillin + Tazobactam			C	Intravenous (not otherwise specified)	13.5 G		Not Reported
	Paracetamol			C		500 Mg, Qid		Not Reported
	Paracetamol			C		500 Mg		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Humulus Lupulus Extract;Valeriana Officinalis Extract	C			Not Reported
Macrogol	C	Unk Unk, Qd		Not Reported
Metoclopramide	C	10 Mg, Tid		Not Reported
Relaxane	C	Unk Unk, Tid		Not Reported
Supradyn [Minerals Nos;Vitamins Nos]	C	Unk Unk, Qd		Not Reported
Redormin [Remifentanil Hydrochloride]	C	500 Mg, Qd		Not Reported
Dexamethasone	C	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734523	EXPEDITED (15-DAY)		LT, OT	FR-PFIZER INC-2020171826		79 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardio-Respiratory Arrest; Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication; Torsade De Pointes; Ventricular Arrhythmia	Zithromax			S	Other	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734550	EXPEDITED (15-DAY)		HO	FR-PFIZER INC-2020171235		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Loss Of Consciousness; Malaise; Off Label Use; Product Use In Unapproved Indication; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	Unk		Not Reported	
	Lovenox [Enoxaparin Sodium]			C		Unk		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17734929	EXPEDITED (15-DAY)		OT	FR-MYLANLABS-2020M1042716			Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Nightmare; Product Use In Unapproved Indication; Psychomotor Hyperactivity	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Plaquenil /00072602/			S	Oral	600 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736227	EXPEDITED (15-DAY)		DE	ES-MYLANLABS-2020M1043094		75 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Sudden Death	Levofloxacin			S	Unknown	Unk		Not Reported	
	Azithromycin			S	Oral	500 Milligram, Qd		Not Reported	
	Lopinavir/Ritonavir			S	Oral	2 Dosage Form, Bid		Not Reported	
	Hidroxiclороquina Sulfato			S	Oral	200 Milligram, Qd		Mylan	
	Ceftriaxona /00672201/			C	Unknown	Unk		Mylan	
	Enoxaparina Sodica			C	Subcutaneous	40 Milligram, Qd		Mylan	
	Prednisona			C	Oral	20 Milligram, Qd		Mylan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736716	EXPEDITED (15-DAY)		HO, OT	ES-AUROBINDO-AUR-APL-2020-021403		60 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Milligram, Once A Day(Dia)		Aurobindo	
	Azithromycin			S				Aurobindo	
	Hydroxychloroquine			S	Oral	400 Milligram, Once A Day(Dia)		Not Reported	
	Hydroxychloroquine			S				Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Tocilizumab		S	Intravenous (not otherwise specified)	600 Milligram			Not Reported
		Tocilizumab		S					Not Reported
		Ceftriaxone		S	Intravenous (not otherwise specified)	2 Gram, Once A Day(Dia)			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-May-2020	17736746	EXPEDITED (15-DAY)		HO, LT, OT	ES-AUROBINDO-AUR-APL-2020-021570		58 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypertriglyceridaemia; Pancreatitis Acute	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Ceftriaxona			S	Intravenous (not otherwise specified)	1 Gram, Once A Day		Not Reported	
	Dolquine			S	Oral	200 Milligram, Two Times A Day		Not Reported	
	Kaletra			S	Oral	2 Dosage Form, Two Times A Day		Not Reported	
	Metilprednisolona			S	Intravenous (not otherwise specified)	250 Milligram, Once A Day		Not Reported	
	Tocilizumab			S	Intravenous (not otherwise specified)	560 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736776	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-019740		77 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Off Label Use; Thrombocytopenia	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	
	Clexane			S	Subcutaneous	4 Kilo-International Unit, Once A Day		Not Reported	
	Plaquenil			S	Oral	600 Milligram, Once A Day		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736808	EXPEDITED (15-DAY)		HO	FR-AUROBINDO-AUR-APL-2020-020857			Unknown	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hospitalisation; Off Label Use	Azithromycin			S	Unknown	Unk		Aurobindo	
	Plaquenil			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736811	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-017600			Unknown	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Use Issue; Scar; Stevens-Johnson Syndrome	Azithromycin			S	Unknown	Unk		Aurobindo	
	Azithromycin			S				Aurobindo	
	Ibuprofen			S	Unknown	Unk		Not Reported	
	Paracetamol			S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736837	EXPEDITED (15-DAY)		OT	ES-TEVA-2020-ES-1228515		67 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hyperbilirubinaemia	Azitromicina (7019a)			S	Oral	500 Mg		Not Reported	
	Ceftriaxona (501a)			S	Intravenous (not otherwise specified)	1 Gram		Not Reported	
	Kaletra 200/50 Mg Comprimidos Recubiertos Con Pelicula , 120 Comprimid			S	Oral	2 Dosage Forms		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736873	EXPEDITED (15-DAY)		OT	IT-AUROBINDO-AUR-APL-2020-020465		82 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Electrocardiogram Qt Prolonged; Off Label Use	Azithromycin	S	Oral	500 Milligram, Once A Day	Aurobindo
	Haloperidol	S	Oral	5 Gtt Drops, Once A Day	Not Reported
	Plaquenil	S	Oral	600 Milligram, Once A Day	Not Reported
	Teicoplanin	S	Intravenous (not otherwise specified)	400 Milligram, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736886	EXPEDITED (15-DAY)		HO	FR-TEVA-2020-FR-1228537		55 YR	Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cholestasis; Condition Aggravated; Hepatocellular Injury	Azithromycine Anhydre			S	Oral	250 Mg		Not Reported	
	Plaquenil			S	Oral	600 Mg		Not Reported	
	Rocephin			S	Oral	2 G		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-May-2020	17736912	EXPEDITED (15-DAY)		DE	CA-ROCHE-2587799		61 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alveolitis; Atrial Fibrillation; Hypoxia	Trastuzumab			S	Unknown			Not Reported	
	Amiodarone			S	Unknown			Not Reported	
	Diltiazem			S	Unknown			Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported	
	Digoxin			S	Intravenous (not otherwise specified)			Not Reported	
	Dimenhydrinate			S	Intravenous (not otherwise specified)			Not Reported	
	Doxorubicin			S	Intravenous (not otherwise specified)			Not Reported	
	Doxorubicin Hydrochloride			S	Unknown			Not Reported	
	Enoxaparin			S	Subcutaneous			Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Furosemide	S	Oral	Not Reported
Hydralazine	S	Intravenous (not otherwise specified)	Not Reported
Hydromorphone	S	Unknown	Not Reported
Hydromorphone Hydrochloride	S	Intravenous (not otherwise specified)	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
Methylprednisolone	S	Intravenous (not otherwise specified)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	Not Reported
Metoprolol	S	Intravenous (not otherwise specified)	Not Reported
Morphine	S	Unknown	Not Reported
Morphine Sulphate	S	Unknown	Not Reported
Paclitaxel	S	Intravenous (not otherwise specified)	Not Reported
Pantoprazole Sodium Anhydrous	S	Intravenous (not otherwise specified)	Not Reported
Azithromycin	S	Intravenous (not otherwise specified)	Not Reported
Procytos	S	Intravenous (not otherwise specified)	Not Reported
Ceftriaxone	C	Intravenous (not otherwise specified)	Not Reported
Aprepitant	C	Oral	Not Reported
Dexamethasone	C	Oral	Not Reported
Filgrastim	C		Not Reported
Gabapentin	C		Not Reported
Metoclopramide	C		Not Reported
Ondansetron	C		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737313	EXPEDITED (15-DAY)		HO	CA-PFIZER INC-2020173222		79 YR	Male	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Blister; Laryngeal Discomfort; Lip Swelling; Oral Disorder; Product Dose Omission; Senile Pruritus	Azithromycin			S	Oral	500 Mg, Single		Pfizer	
	Cefazolin			S	Intraperitoneal	1500 Mg, 1x/Day		Pfizer	
	Amlodipine			C		Unk		Not Reported	
	Asa			C		Unk		Not Reported	
	Bisoprolol			C		Unk		Not Reported	
	Docusate Sodium			C		Unk		Not Reported	
	Eprex			C		Unk		Not Reported	
	Fluticasone			C		Unk		Not Reported	
	Kayexalate			C		Unk		Not Reported	
	Megestrol			C		Unk		Not Reported	
	Nepafenac			C		Unk		Not Reported	
	One Alpha			C		Unk		Not Reported	
	Pantoprazole			C		Unk		Not Reported	
	Salbutamol			C		Unk		Not Reported	
	Sevelamer			C		Unk		Not Reported	
	Vitamin D [Ergocalciferol]			C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-May-2020	17737316	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020161825		40 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged; Off Label Use; Product Use In Unapproved Indication	Zithromax			S	Oral	250 Mg, 1x/Day		Pfizer	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Oral	600 Mg, 1x/Day		Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17675113	EXPEDITED (15-DAY)		OT	IT-TEVA-2020-IT-1223643		61 YR	Female	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain Upper; Drug-Induced Liver Injury	Azithromycin Augmentin			S S				Not Reported Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17737424	EXPEDITED (15-DAY)		HO, OT	IT-AUROBINDO-AUR-APL-2020-021232		96 YR	Male	ITA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arrhythmia; Extrasystoles	Azithromycin Film-Coated Tablets			S	Unknown	500 Milligram, Once A Day		Aurobindo	
	Plaquenil			S	Unknown	400 Milligram, Once A Day		Not Reported	
	Lasix			C	Unknown	25 Milligram, Once A Day		Not Reported	
	Novorapid			C	Unknown	Unk		Not Reported	
	Normix			C	Unknown	Unk		Not Reported	
	Dobetin			C	Unknown	Unk		Not Reported	
	Lantus			C	Unknown	Unk		Not Reported	
	Movicol			C	Unknown	Unk		Not Reported	
	Deltacortene			C	Unknown	Unk		Not Reported	
	Pantorc			C	Unknown	20 Milligram, Once A Day		Not Reported	
	Cardirene			C	Unknown	75 Milligram, Once A Day		Not Reported	
	Metoprololo			C	Unknown	50 Milligram, Once A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739591	EXPEDITED (15-DAY)		DE, OT	ES-AUROBINDO-AUR-APL-2020-021847		74 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Atrial Flutter; Cardio-Respiratory Arrest	Azithromycin			S	Oral	500 Milligram, Once A Day		Aurobindo	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Tocilizumab	S	Intravenous (not otherwise specified)	600 Milligram,1 Total	Not Reported
Kaletra	S	Oral	2 Dosage Form, Two Times A Day	Not Reported
Kaletra	S			Not Reported
Dolquine	S	Oral	400 Milligram, Once A Day	Not Reported
Dolquine	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739747	EXPEDITED (15-DAY)		HO	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245893		70 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bradycardia; Loss Of Consciousness; Malaise; Ventricular Extrasystoles	Azithromycin			S	Oral	Unk		Sun	
	Plaquenil			S	Oral	Unk		Not Reported	
	Lovenox			C	Oral	Unk		Not Reported	
	Paracetamol			C	Oral	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17739900	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245906		64 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Hepatitis	Azithromycin			S	Oral	500 Mg Dia		Sun	
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos			S	Other	400 Mg Dia ()		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740669	EXPEDITED (15-DAY)		HO	ES-SUN PHARMACEUTICAL INDUSTRIES LTD- 2020RR-245901		63 YR	Male	ESP
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Condition Aggravated; Hepatitis	Azithromycin	S	Oral	500 Mg Dia	Sun
	Tocilizumab (8289a)	S	Intravenous (not otherwise specified)	600 Mg ; In Total	Not Reported
	Dolquine 200 Mg Comprimidos Recubiertos, 30 Comprimidos	S	Oral	400 Mg Dia	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17740724	EXPEDITED (15-DAY)		DE, OT	ES- GLAXOSMITHKLINE- ES2020073213		39 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Interaction; Long Qt Syndrome; Sudden Death	Metoclopramide			S	Intravenous (not otherwise specified)	10 Mg, Tid		Glaxosmithkline
	Salbutamol			S	Respiratory (inhalation)	0.1 Mg, Qid		Glaxosmithkline
	Azithromycin			S	Oral	500 Mg, Qd		Glaxosmithkline
	Dolquine			S	Oral	400 Mg		Not Reported
	Propofol			S	Intravenous (not otherwise specified)	Unk		Not Reported
	Enoxaparin Sodium			C	Subcutaneous	Unk		Not Reported
	Cefotaxim			C	Intravenous drip	4 G, Bid		Not Reported
	Tocilizumab			C	Intravenous (not otherwise specified)	600 Mg, Qd		Not Reported
	Midazolam			C	Intravenous drip	100 Mg, Qd		Not Reported
	Ipratropii Bromidum			C	Respiratory (inhalation)	20 ?G		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741494	EXPEDITED (15-DAY)		HO, OT	ES-PFIZER INC- 2020171727		28 YR	Male	ESP

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Condition Aggravated; Hepatitis; Off Label Use; Product Use In	Azithromycin			S	Oral	500 Mg, 1x/Day		Pfizer
	Dolquine			S	Oral	400 Mg, 1x/Day		Not Reported

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unapproved Indication	Ceftriaxone	S	Intravenous (not otherwise specified)	2 G, 1x/Day	Not Reported
	Ceftriaxone	S			Not Reported
	Paracetamol	S	Intravenous (not otherwise specified)	1 G, 3x/Day (Every 8 Hours)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741499	EXPEDITED (15-DAY)		OT	NL-PFIZER INC-2020171580			Male	NLD
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Diarrhoea; Diarrhoea	Azithromycin			S	Oral	1 Df, 1x/Day, 1 Bottle		Pfizer	
Haemorrhagic; Gastric	Azithromycin/Teva			C	Oral	1 Df, 1x/Day, 1 Bottle		Not Reported	
Hypermotility; Off Label Use; Poor Quality Product Administered; Product Taste Abnormal; Product Use In Unapproved Indication; Vomiting									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741579	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171234		63 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Interaction; Electrocardiogram Qt Prolonged	Zithromax			S	Oral	Unk		Pfizer	
	Hydroxyzine Arrow			S	Oral	25 Mg, Single		Not Reported	
	Plaquenil [Hydroxychloroquine Sulfate]			S	Other	600 Mg, 1x/Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741587	EXPEDITED (15-DAY)		OT	FR-PFIZER INC-2020171158		41 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Chest Discomfort; Off Label Use; Product Use In	Zithromax			S	Oral	Unk		Pfizer	
	Plaquenil [Hydroxychloroquine			S	Oral	Unk		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unapproved Indication		Phosphate]							
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741631	EXPEDITED (15-DAY)		HO, LT, OT	CH-PFIZER INC-2020169696		83 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Acute Coronary Syndrome; Acute Myocardial Infarction; Electrocardiogram Qt Prolonged; Hypernatraemia; Hypocalcaemia; Pyrexia	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Zithromax			S	Oral	500 Mg, 1x/Day		Pfizer	
	Cordarone			S	Oral	200 Mg		Pfizer	
	Cordarone			S	Oral	200 Mg, 3x/Day		Pfizer	
	Cordarone			S	Oral	200 Mg, 3x/Day		Pfizer	
	Cordarone			S	Intravenous (not otherwise specified)	300 Mg (In Total)		Not Reported	
	Cordarone			S	Intravenous (not otherwise specified)	900 Mg		Not Reported	
	Cordarone			S	Intravenous (not otherwise specified)	150 Mg (In Total)		Not Reported	
	Cordarone			S	Intravenous (not otherwise specified)	300 Mg, 3x/Day ((In Total))		Not Reported	
	Cordarone			S	Intravenous (not otherwise specified)	100 Mg (In Total)		Not Reported	
	Pradif			C	Oral	400 Ug, 1x/Day		Not Reported	
	Amlodipine			C	Oral	10 Mg, 1x/Day		Not Reported	
	Aspirin Cardio			C	Oral	100 Mg, 1x/Day		Not Reported	
	Atorvastatin			C	Oral	40 Mg, 1x/Day		Not Reported	
	Metoprolol			C	Oral	12.5 Mg, 2x/Day		Not Reported	
	Esidrex			C	Oral	25 Mg, 1x/Day		Not Reported	
	Nexium Mups [Esomeprazole Magnesium]			C	Oral	40 Mg, 1x/Day		Not Reported	
	Tazobac			C	Intravenous (not otherwise specified)	4.5 Mg, 3x/Day		Not Reported	
	Co-Amoxicillin			C	Intravenous (not	1.2 G, Cyclic (Every 8h)		Not Reported	

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

otherwise specified)

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741680	EXPEDITED (15-DAY)		OT	DE-MYLANLABS-2020M1042774			Male	DEU
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chlamydial Infection	Azithromycin			S	Unknown	500 Mg			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-May-2020	17741749	EXPEDITED (15-DAY)		OT	CH-SA-2020SA114056		51 YR	Male	CHE
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hepatocellular Injury	Plaquenil			S	Oral	In Total			Sanofi
	Amoxicillin Sodium/Potassium Clavulanate			S	Intravenous drip	1.2 G, Qid			Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid			Not Reported
	Lopinavir/Ritonavir			S	Oral	400 Mg, Bid			Not Reported
	Clexane			S	Subcutaneous	40 Mg, Qd			Sanofi
	Clexane			S	Subcutaneous	40 Mg, Bid			Sanofi
	Clexane			S	Subcutaneous	Unk			Sanofi
	Clexane			S	Subcutaneous	40 Mg, Bid			Sanofi
	Paracetamol			S	Intravenous (not otherwise specified)	Max 3x/D ; As Necessary			Not Reported
	Piperacillin/Tazobactam			S	Intravenous drip	4.5 G, Tid			Not Reported
	Azithromycin			S	Oral	500 Mg, Qd			Not Reported
	Ipramol			C		Unk			Not Reported
	Temesta [Lorazepam]			C					Not Reported
	Tavanic			C					Not Reported
	Atracurium			C		Unk			Not Reported
	Fentanyl			C		Unk			Not Reported
	Dormicum [Midazolam Hydrochloride]			C		Unk			Not Reported

**FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report**

Phosphate [Potassium Bicarbonate;Sodium Phosphate Monobasic]	C	Unk	Not Reported
Antibiotics For Otic And Nasal Use	C	Unk	Not Reported
Torsemide	C		Not Reported
Potassium Benerva	C		Not Reported
Heparin	C	Unk	Not Reported
Solu-Medrol	C	Unk	Not Reported
Novorapid	C	Unk	Not Reported
Relistor	C	Unk	Not Reported
Novasource Gi Control	C	Unk	Not Reported
Ventolin [Salbutamol]	C	Unk, Prn	Not Reported
Movicol [Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;Sodium Ch	C	Unk, Prn	Not Reported