



FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Disclaimers:

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Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The FOIA case report information may include both Electronic Submissions (Esubs) and Report Images (Non-Esubs). Case ID(s) will be displayed under separate cover pages for the different submission types.

Cover page Case ID(s) with an asterisk (***) indicate an invalid status and are not captured in the body of the report.

Esub Case ID(s) Submitted:

15899841	17265975	17394735	17412097	17416504	17425099	17425391
17433216	17439574	17498908	17507539	17519651	17548310	17560170
17563703	17579865	17581930	17581969	17583875	17601685	

Run by: STEPPERH

Date - Time: 11-MAY-2020 15:21 PM

Total number of cases (Esub): 20

Total number of inactive cases: 0



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15899841

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** **Outcomes:** OT, **Application Type:** NDA

FDA Rcvd Date: 27-Mar-2020 **Mfr Rcvd Date:** 24-Mar-2020 **Mfr Control #:** US-PFIZER INC-2019048311 **Application #:** 021234

Patient Information:

Age: 43 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Flector		1 DF/BID	Transdermal	1 patch to skin, twice a day	Pain		
2	CBD				UNK			
3	DICLOFENAC SODIUM			Oral	UNK			
4	Flector					Lumbo-sacral spondylosis		
5	HYDROCODONE				UNK			
6	OXYCODONE				UNK			
7	OXYMORPHONE				UNK			
8	PENNSAID				UNK			
9	PLAQUENIL [HYDROXYCHLOROQUIN E SULFATE]				UNK	Malaria		
10	VOLTAREN [DICLOFENAC SODIUM]				UNK			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Flector		Unk	NA	1706208			PFIZER	
2	CBD		Unk	NA					
3	DICLOFENAC SODIUM		Unk	NA					



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Case ID: 15899841

Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	
Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
4 Flector		Unk	NA				PFIZER	
5 HYDROCODONE		Unk	NA					
6 OXYCODONE		Unk	NA					
7 OXYMORPHONE		Unk	NA					
8 PENNSAID		Unk	NA					
9 PLAQUENIL [HYDROXYCHLOROQUIN E SULFATE]		Unk	NA					
10 VOLTAREN [DICLOFENAC SODIUM]		Unk	NA					

Event Information:

Preferred Term (MedDRA @ Version: 23.0)	ReC
Condition aggravated	NA
Coronavirus infection	NA
Drug ineffective	NA
Immunodeficiency	NA
Nasal congestion	NA
Pain	NA



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FOIA Case Report Information

Case ID: 15899841

Event/Problem Narrative:

This is a spontaneous report from a Pfizer-sponsored program, Pfizer RXPathways. A contactable consumer and physicians reported that a 43-year-old female patient started to receive diclofenac epolamine (FLECTOR 1.3%, transdermal patch; lot number: 1706208, expiry date: Jun2020), transdermal from an unspecified date to an unspecified date at 1 patch to skin, twice a day for pain and other spondylosis, lumbosacral region (M47.897); diclofenac sodium, oral from an unspecified date on an unspecified dose; oxymorphone, oxycodone, hydrocodone, diclofenac sodium (PENNSAID), diclofenac sodium (VOLTAREN) and cannabidiol (CBD), all for unspecified indication; and hydroxychloroquine sulfate (PLAQUENIL) as anti-malarial; all via an unspecified route of administration from an unspecified date at an unspecified dose for an unspecified indication. Medical history included auto degenerative disease of her spine (severe spinal degeneration for multiple reasons), auto immune inflammatory disease, mixed connective tissue disease with features of rheumatoid arthritis, a couple of surgeries 11 years before 29Jan2019, rheumatoid arthritis totally attacking her lumbar spine, a lot of pain and malaria. The patient's concomitant medications were not reported. The patient almost couldn't function without the patches (diclofenac epolamine patches). She had a lot of pain. She was applying for the PPAP for the diclofenac epolamine patches. So a pain doctor gave her diclofenac epolamine patches about 11 years before 29Jan2019. She had used them on and off like couple of years (unspecified dates) and then might take 6 months or a year and not use them and every time she put them back on, she was like why would ever had stop doing this. So in the meantime, she had been diagnosed with mixed connective tissue disease and rheumatoid arthritis and she just had another MRI (nuclear magnetic resonance imaging) on an unspecified date. Her problem had progressed in the past 5 years more than doubled and the spine doctor said that rheumatoid arthritis did not rarely affected the lumbar spine but her's was totally attacking her lumbar spine. The patient also took oxymorphone. She took oxycodone and switched to hydrocodone just because it was just not enough, it was not working on an unspecified date. She also took diclofenac sodium orally and she took hydroxychloroquine sulfate, an anti-malarial, and she used cannabidiol. She had tried putting diclofenac sodium (PENNSAID), diclofenac sodium (VOLTAREN) with the same intent with diclofenac epolamine patches on her spine and none of them came close even with all of that. If she didn't have diclofenac epolamine patches, she couldn't function. When asked permission to file a safety report, consumer stated, "It's probably not the best time, I supposed to be calling other patients. Is it something you can email to me? I want people to know, I want you guys to know, I have been marketing this product for you for 11 years and what I would say to you guys is you doing great with pain doctors but primary providers do not know about any topical thing and do not know about diclofenac epolamine patches". The patches that she had were little bit older. She could give the one that she used today (29Jan2019). She had noticed she would tell what because she was trying to collect these and when she wasn't using them years before and the ones that she could tell they got a little bit more yellow, they got a little older, they got a little dryer, they didn't work. They were still amazing compared to nothing but they didn't work as well and she could also feel them when they wear off. As of 24Mar2020, it was reported that the patient stated that she can't survive without these patches (FLECTOR). It was further reported that if she turn her head, pain goes down her legs, and so she really, really need these things. She was in a predicament. She can't live without them. It was reported that the patient was immune compromised. She was sparing and cutting and saving. It's really, really bad. She was flaring right now and also have congestion. The patient stated that she think she might have it (COVID19). The action taken in response to the events for diclofenac epolamine, oral diclofenac sodium, oxymorphone, oxycodone, hydrocodone, hydroxychloroquine sulfate, diclofenac sodium (PENNSAID), diclofenac sodium (VOLTAREN) and cannabidiol and the outcome of the events were unknown.

Follow-up (05Mar2019 and 06Mar2019): New information reported from product quality complaints includes suspect drug information, no safety relevant information reported. Acknowledged number received from Institut Biochimique (2019IBSA00101).



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15899841

Follow-up (16May 2019): Follow-up attempts are completed. No further information is expected.

Follow-up (11Mar2020): New information received from a contactable physician includes: new reporter, reporter details, suspect drug details (dosing regimen, route and indication).

Follow-up (24Mar2020): New information received from a contactable consumer via the Pfizer-sponsored program, Pfizer RXPathways includes: reaction data (additional events: "can't survive without these patches", if head was turned pain goes down to legs, immune compromised, flaring, congestion and "I think I might have it (COVID19)") and clinical course details.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Surgery	2008		UNKNOWN
Autoimmune disorder			
Connective tissue disorder			
Malaria			
Pain			
Rheumatoid arthritis			
Spinal osteoarthritis			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
MRI	RA totally attacking her lumbar spine				N



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 15899841

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: PFIZER

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17265975

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** 02-Jan-2020 **Outcomes:** OT, **Application Type:** NDA

FDA Rcvd Date: 21-Jan-2020 **Mfr Rcvd Date:** 14-Jan-2020 **Mfr Control #:** CA-ADVANZ PHARMA-202001000204 **Application #:** 009768

Patient Information:

Age: **Sex:** **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Hydroxychloroquine		200 MG/	Unknown	200 mg, qod	Product used for unknown indication	Jul-2014	
2	Hydroxychloroquine		400 MG/	Unknown	400 mg		Jul-2014	
3	leflunomide		20 MG/	Unknown	20 mg, qd	Product used for unknown indication	Jan-2016	
4	methotrexate			Unknown	UNK	Product used for unknown indication	Jul-2014	Feb-2018

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine		NA	NA	unknown			CONCORDIA	
2	Hydroxychloroquine		NA	NA	Unknown			CONCORDIA	
3	leflunomide		NA	NA	unknown				
4	methotrexate		Unk	NA	unknown				

Event Information:

Preferred Term (MedDRA @ Version: 23.0)	ReC
Drug ineffective	NA
Pulmonary fibrosis	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17265975

Event/Problem Narrative:

Case number 202001000204 is a business partner report (Reference ID:2020SA001532) send by physician on 02/jan/2020.

Case Description: Initial information regarding an unsolicited valid serious courtesy case of Canada received on 02-Jan-2020 from a physician via Pfizer Canada with reference number 2019560132.

This case involves an elderly male patient of unknown age who had pulmonary fibrosis and inefficacy, while he was treated with hydroxychloroquine sulfate [Hydroxychloroquine], leflunomide and methotrexate.

The patient's past medical history included hearing issues.

The patient's past medical treatment(s), vaccination(s) and family history were not provided.

Concomitant medications included pantoprazole, rosuvastatin, bisoprolol fumarate (Bisoprolol Sandoz); calcium carbonate (Jamp Calcium), risedronate sodium (Teva Risedronate), unspecified inhalers, Mint E drops and Nitro.

On an unknown date in Jul-2014, the patient started taking hydroxychloroquine sulfate (formulation and strength unknown) at dosage alternating between 200mg and 400mg daily (with an unknown batch number) for an unknown indication. On an unknown date in Jul-2014, the patient started taking methotrexate (formulation, route and strength unknown) at dosage unknown (with an unknown batch number) for an unknown indication. On an unknown date in Jan-2016, the patient started taking leflunomide (formulation and strength unknown) at dosage 20 mg QD (with an unknown batch number) for an unknown indication.

After an unknown duration, the patient developed inefficacy with hydroxychloroquine sulfate and leflunomide. Reportedly the patient presented inefficacy and contra-indication pulmonary fibrosis with methotrexate (exact onset date and latency unknown). Methotrexate was stopped in Feb-2018. Hydroxychloroquine sulfate and leflunomide were ongoing at time of report.

Relevant laboratory test results included:

C-reactive protein - On 17-Dec-2019: 27 mg/L

Rheumatoid factor - On 17-Dec-2019: [positive]

X-ray - On 17-Dec-2019: [Visible Erosions on X-Rays]

On 17-Dec-2019: Health Assessment Questionnaire: 0.55

No action was taken with hydroxychloroquine sulfate and not applicable with leflunomide and unknown with methotrexate for the event pulmonary fibrosis. Not applicable for the event inefficacy for all suspect drugs.

It was not reported if the patient received a corrective treatment.



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17265975

The patient outcome is reported as unknown for pulmonary fibrosis and not applicable for inefficacy.
Seriousness criterion: medically significant for the event pulmonary fibrosis

A query mail was sent to the Business partner regarding the onset date of the event and the commencement of the suspect drug Plaquenil so that an estimated date for the event could be calculated.

Version (0.0) Comment: The case is assessed as serious and unlisted as per the company RSI. The company considered the events of pulmonary fibrosis and lack of drug effect to be possibly related to Hydroxychloroquine, as per WHO causality classification system. In presence of other suspect medications (Methotrexate, Leflunomide) contributory role of Hydroxychloroquine cannot be excluded in view of plausible latency as the event occurred while ongoing treatment with these medications. Additionally, limited information regarding medical history precludes further assessment of the case.

Query response was received on 14-Jan-2020 from business partner and version (1.0) was created.

Additional information: Action taken for methotrexate was updated to unknown as business partner confirmed that action taken with methotrexate was captured as unknown (although therapy stop date was provided for the drug). And for Leflunomide, the action taken updated to no action taken (since therapy was ongoing at time of report).

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Hypoacusis			UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
C-reactive protein	27	mg/L			N



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17265975

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	BISOPROLOL SANDOZ			UNK				
2	JAMP CALCIUM			UNK				
3	PANTOPRAZOLE			UNK				
4	ROSUVASTATIN			UNK				
5	TEVA RISEDRONATE			UNK				

Reporter Source:

Study Report?: No

Sender Organization: ADVANZ PHARMA

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17394735

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** RUS **Event Date:** Jan-2020 **Outcomes:** OT, **Application Type:** NDA

FDA Rcvd Date: 07-Apr-2020 **Mfr Rcvd Date:** 25-Mar-2020 **Mfr Control #:** RU-ADVANZ PHARMA-202002000642 **Application #:** 009768

Patient Information:

Age: **Sex:** **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		200 MG/	Oral	200 mg, qd (tablet)	Rheumatoid arthritis		
2	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		2 DF/	Oral	2 Dosage Form, qd (tablet) (increased the dose)		Jan-2020	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		NA	NA	unknown			CONCORDIA	
2	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		NA	NA	9R1XA			CONCORDIA	

Event Information:

Preferred Term (MedDRA @ Version: 23.0)	ReC
Drug ineffective	NA
Rheumatoid arthritis	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17394735

Event/Problem Narrative:

Case number 202002000642 is a business partner case (Reference ID: 2020SA028663) send by a consumer on 01/Feb/2020.

Case Description: Initial information received on 01-Feb-2020 from Russian Federation regarding an unsolicited valid serious case received from a patient.

This case involves a 70 years old female patient (156 cm and 60 kg) who developed an exacerbation, while she was treated with hydroxychloroquine sulfate (Plaquenil).

The patient's past medical history, medical treatment(s), and family history were not provided.

On an unknown date, the patient started taking hydroxychloroquine sulfate 200 mg tablet at a dose of 200mg every day (strength, route, batch number and expiry date: unknown) for rheumatoid arthritis.

On an unknown date in January 2020, the patient developed an exacerbation (rheumatoid arthritis aggravated) and increased the dose to 2 tablets daily because the drug did not help following intake of hydroxychloroquine sulfate.

This event was assessed as medically significant.

Upon follow-up it was clarified that patient continued to administer 2 tablets once per day. The patient visited the doctor, the doctor approved the therapy. According to the patient, improvement in health condition began.

No lab data reported.

Action taken: Dose increased.

It was not reported if the patient received a corrective treatment.

Event outcome: recovered on an unknown date.

Follow-up information was received on 26/Feb/2020 (reference ID: 2020SA028663) from consumer. Version (1.0) was created.

Additional information included: Event outcome updated from not recovered to recovering. Dose added for initial therapy. Text was amended accordingly.

Case comment v2: The case is assessed as serious and unlisted as per the company RSI. The company considered the events of rheumatoid arthritis aggravated and drug ineffective to be possibly related to Hydroxychloroquine, as per WHO causality classification system,



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17394735

as the event is reported with reasonable time relationship to drug intake. Drug ineffective could be due to progression of underlying rheumatoid arthritis.

Follow-up information was received on 25/Mar/2020 (reference ID: 2020SA028663) from consumer. Version (2.0) was created.

Additional information: Outcome of event Rheumatoid arthritis aggravated was updated from recovering to recovered. Narrative updated accordingly.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Rheumatoid arthritis			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17394735

Reporter Source:

Study Report?: No

Sender Organization: ADVANZ PHARMA

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17412097

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** USA **Event Date:** 03-Feb-2020 **Outcomes:** HO, **Application Type:** ANDA

FDA Rcvd Date: 13-Feb-2020 **Mfr Rcvd Date:** 10-Feb-2020 **Mfr Control #:** US-ZYDUS-047509 **Application #:** 040657

Patient Information:

Age: 94 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	
1	HYDROXYCHLOROQUIN E		200 MG/	Oral		Rheumatoid arthritis	02-Feb-2020	04-Feb-2020	
#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	HYDROXYCHLOROQUIN E		Yes	NA	Z903866			ZYDUS PHARM	

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
Acute cardiac event	NA
Acute cardiac event	Yes
Dizziness	NA
Dizziness	Yes



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17412097

Event/Problem Narrative:

On 10-Feb-2020, Zydus Pharmaceuticals was contacted via phone by a daughter on behalf of a currently 94-year-old female consumer (initials: (b) (6) DOB: (b) (6)) regarding adverse events she experienced while taking Zydus hydroxychloroquine sulfate 200 mg tablets. The reporter identified the following lot and expiry (lot: Z903866, exp: 08/31/2021). She agreed to submit a product sample for investigation, and sample retrieval was sent via FedEx on 10-Feb-2020. Her medical history is significant for rheumatoid arthritis, osteoporosis, atrial fibrillation, sinusitis, and pulmonary fibrosis. She has known drug allergies to Acyclovir, amlodipine, penicillin, allopurinol, amoxicillin, clindamycin, doxycycline, Levaquin, spironolactone, Fosamax, furosemide, lisinopril, sulfa, torsemide (reactions: UNK). She concomitantly takes the following medications (therapy dates: UNK - ongoing): albuterol twice daily, Eliquis, aspirin 81 mg once daily, calcium, vitamin D, carvedilol 12.5 mg twice daily, Claritin 10 mg once daily, erythromycin ointment, Evenity for osteoporosis, Flonase for sinusitis, folic acid 1 mg once daily, isosorbide 60 mg twice daily, levothyroxine 100 mcg once daily, warfarin, Plavix, and Lipitor. On 02-Feb-2020, she started therapy with Zydus hydroxychloroquine 200 mg sulfate tablets, one tablet by mouth twice daily for rheumatoid arthritis. On 03-Feb-2020, she began to experience dizziness (Dizziness). On (b) (6) she was hospitalized due to a cardiac event (Acute cardiac event). On (b) (6) she discontinued therapy with Zydus hydroxychloroquine 200 mg tablets. On an unknown date in (b) (6) while hospitalized, she was administered heparin. On an unknown date in (b) (6) while hospitalized, she underwent an echocardiogram (result: UNK). On (b) (6) (b) (6) she was discharged. Her daughter reports that the rheumatoid arthritis physician stated, 'it is not related to the medication.' On an unknown future date in (b) (6) her adverse events resolved. At the time of this report, she no longer takes the suspect medication and the outcomes of the adverse events remain resolved. No additional information was provided. External reference number: ZYD-20-AE-179.

Relevant Medical History:

Evenity (dose, frequency: UNK; therapy dates: UNK-Ongoing; indication: Osteoporosis)

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Atrial fibrillation			YES
Drug allergy			YES
Osteoporosis			YES
Pulmonary fibrosis			YES
Rheumatoid arthritis			YES
Sinusitis			YES

Medical History Product(s)	Start Date	End Date	Indications	Events



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17412097

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ALBUTEROL		Unknown		Drug use for unknown indication			
2	APIXABAN		Unknown		Drug use for unknown indication			
3	ASPIRIN	81 MG/	Unknown		Drug use for unknown indication			
4	ATORVASTATIN		Unknown		Drug use for unknown indication			
5	CALCIUM		Unknown		Drug use for unknown indication			
6	CARVEDILOL	12.5 MG/	Unknown		Drug use for unknown indication			
7	CLOPIDOGREL		Unknown		Drug use for unknown indication			
8	ERYTHROMYCIN		Unknown		Drug use for unknown indication			
9	FLUTICASONE		Unknown		Sinusitis			
10	FOLIC ACID	1 MG/	Unknown		Drug use for unknown indication			
11	ISOSORBIDE	60 MG/	Unknown		Drug use for unknown indication			
12	LEVOTHYROXINE	100 UG/	Unknown		Drug use for unknown indication			
13	LORATADINE	10 MG/	Unknown		Drug use for unknown indication			
14	VITAMIN D		Unknown		Drug use for unknown indication			
15	WARFARIN		Unknown		Drug use for unknown indication			



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17412097

Reporter Source:

Study Report?: No

Sender Organization: ZYDUS PHARM

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17416504

Case Information:

Case Type: NON-EXPEDITED **eSub:** Y **HP:** **Country:** USA **Event Date:** 29-Jan-2020 **Outcomes:** HO,

Application Type: NDA

FDA Rcvd Date: 24-Feb-2020 **Mfr Rcvd Date:** 10-Feb-2020 **Mfr Control #:** US-ACTELION-A-US2020-201797

Application #: 022260

Patient Information:

Age: 70 YR

Sex: Female

Weight: 63.49 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Veletri		/min	Intravenous (not otherwise specified)	28 ng/kg, per min	Pulmonary arterial hypertension		
2	Opsumit		10 MG/QD	Oral	10 mg, qd	Pulmonary arterial hypertension		
3	PLAQUENIL			Unknown		Product used for unknown indication		
4	PREDNISON			Unknown		Product used for unknown indication		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Veletri		Unk	Unk	MM210J0101			ACTELION	
2	Opsumit		Unk	Unk	ZM018B0101			ACTELION	
3	PLAQUENIL		Unk	Unk					
4	PREDNISON		Unk	Unk					

Event Information:

Preferred Term (MedDRA ® Version: 23.0)

ReC

Bacteraemia

NA

Blood culture positive

NA

Brevibacterium infection

NA

Catheter management

NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17416504

Catheter site infection	NA
Device related infection	NA
Ear infection	NA
Immunosuppression	NA
Sepsis	NA

Event/Problem Narrative:

Case initial reception date: 06FEB20: This spontaneous case was reported by a nurse and concerns a 70-year-old female patient with primary pulmonary hypertension who experienced line infection and bacteremia starting on an unspecified date during the use of Opsumit (Macitentan) and Veletri (Epoprostenol Sodium). No medical history information was provided. Concomitant medications included ambrisentan and rivaroxaban. The first shipment date of Opsumit was on 13Sep18 but an exact start date was not provided. Opsumit was started on an unspecified date at 10 mg qd and it was unknown whether it was ongoing at the time of the report. The first shipment date of Veletri was on 30Jul18 but an exact start date was not provided. Veletri was started on an unspecified date. The dose at the time of the event was 28 ng/kg per min and it was unknown whether it was ongoing at the time of the report.

On (b) (6) the patient was hospitalized due to line infection and bacteremia. The outcome of line infection and bacteremia was not reported. The reporter did not provide a causality assessment for bacteremia and line infection.

Follow-up reception date 10Feb20: The nurse for the prescribing physician confirmed that this patient with pulmonary arterial hypertension (PAH) related to connective tissue disorder / scleroderma was hospitalized from (b) (6) to (b) (6) due to a line infection, blood stream infection, local infection at the catheter insertion site and bacteremia starting on (b) (6). The patient also had severe bilateral ear infections starting on an unspecified date. It was noted that the patient did have a risk factor for infection which included immunosuppression and the primary cause of the infection was the immunosuppression. The patient did not develop septicemia. The patient had her central catheter Hickman SL placed back in Jul18.

The patient did not have any catheter problems or extension line problems prior to the infection. Per the nurse, the patient's in-line filter and drug storage, drug preparation and catheter maintenance (including extension tube replacement) were followed per labelling recommendations and instructions. The type of pump used to administer the diluted solution was a CADD legacy pump. The patient had no associated signs and symptoms suggestive of an infection and no tests performed (e.g white blood cell count) to provide evidence of an infection. Blood culture from peripheral vein and culture from the catheter tip were positive for Brevibacterium casei. Culture was not performed on the drainage at the catheter exit site. It was unknown if cultures were performed on the skin at the catheter exit site. As treatment, the Hickman line was discontinued and a new line was placed on (b) (6). The patient was also treated with vancomycin IV starting on (b) (6) and was discharged home on IV vancomycin for 2 weeks (expected stop date of (b) (6)).



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17416504

Relevant medical history included scleroderma. The patient was not on other parenteral prostacyclin prior to the start of Veletri. Co-suspect medications included immunosuppressants plaquenil and prednisone. It was unknown if Veletri 28ng/kg/min and Opsumit remained ongoing at the time of the report.

The outcome was resolved. The nurse assessed the events as not related to Veletri and Opsumit.

Company comment: "Although the reporter assessed the cases as "non-suspected", Actelion provided a causality of "suspected".

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Pulmonary arterial hypertension			
Scleroderma			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Blood culture	negative	N/A			Y
Blood culture	positive	N/A			Y

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	LETAIRIS							
2	XARELTO							



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17416504

Reporter Source:

Study Report?: No

Sender Organization: ACTELION

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425099

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Event Date: 05-Feb-2020 Outcomes: HO,OT, Application Type: BLA

FDA Rcvd Date: 24-Apr-2020 Mfr Rcvd Date: 20-Mar-2020 Mfr Control #:US-GLAXOSMITHKLINE-US2020023487 Application #: 125370

Patient Information:

Age: 68 YR Sex: Female Weight:

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Benlysta		/wk	Intravenous (not otherwise specified)	UNK UNK, WE	Product used for unknown indication	Jan-2020	
2	Cipro			Unknown	UNK	Urinary tract infection		
3	PLAQUENIL			Unknown	UNK	Urinary tract infection		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Benlysta		NA	NA				GLAXOSMITHKLINE	
2	Cipro		Unk	NA				GLAXOSMITHKLINE	
3	PLAQUENIL		Unk	NA					

Event Information:

Preferred Term (MedDRA Ⓜ Version: 23.0)	ReC
Adverse drug reaction	NA
Anaemia	NA
Dizziness	NA
Haemolytic uraemic syndrome	NA
Hypotension	NA
Nausea	NA
Product dose omission	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425099

Renal injury

NA

Urinary tract infection

NA

Event/Problem Narrative:

This case was reported by a consumer via call center representative and described the occurrence of nausea in a 68-year-old female patient who received belimumab (Benlysta) powder for infusion for product used for unknown indication.

On an unknown date, the patient started Benlysta (intravenous) at an unknown dose weekly. On 5th February 2020, an unknown time after starting Benlysta, the patient experienced hypotension. On an unknown date, the patient experienced nausea and dizziness. Benlysta was continued with no change. On an unknown date, the outcome of the nausea, dizziness and hypotension were unknown.

It was unknown if the reporter considered the nausea, dizziness and hypotension to be related to Benlysta.

Additional details:

This case received from GSK response center. Newly established consumer of Benlysta IV (intravenous) reported Nausea, Dizziness, and Hypotension post infusion. Her last infusion was 05 February 2020. She stated that she became Nauseated and Dizzy intermittently for several days after the infusion. At her latest infusion, she experienced hypotension. She stated her "diastolic dropped into the low forties". She planed to continue benlysta. Consented to follow up. All information was not available. No additional information was provided.

Follow up was reported on 20 March 2020 from Consumer (patient) via GSK Response Center. Newly established consumer of Benlysta IV (intravenous) reported urinary tract infection, hospitalization, hemolytic uremic syndrome, anemia, kidney damage, and missed Dose. The patient started Benlysta IV two months ago and received the three loading doses. She contracted a urinary tract infection (added new event urinary tract infection) and had a missed dose (added new event missed dose) to take antibiotics. She explained that while taking Cipro and Plaquenil (Co-suspect products added ciprofloxacin hydrochloride (Cipro) unknown for urinary tract infection and hydroxychloroquine (Plaquenil) for urinary tract infection), she had a drug reaction (added new event drug interaction) resulting in a one week hospitalization for hemolytic uremic syndrome (serious criteria hospitalization), anemia (serious criteria hospitalization) and kidney damage (serious criteria hospitalization). She stated that her kidney damage was improved, and she received two pints of blood for Anemia. She has been home from the Hospital for one week. She has not restarted Benlysta. The action taken with Cipro was unknown. The action taken with Plaquenil was unknown. On an unknown date, the outcome of the hemolytic uremic syndrome, anemia, urinary tract infection, drug interaction and missed dose were unknown and the outcome of the renal injury was recovering/resolving. It was unknown if the reporter considered the hemolytic uremic syndrome, anemia, renal injury, urinary tract infection and drug interaction to be related to Benlysta. It was unknown if the reporter considered the hemolytic uremic syndrome, anemia, renal injury and drug interaction to be related to Cipro. It was unknown if the reporter considered the hemolytic uremic syndrome, anemia, renal injury and drug interaction to be related to Plaquenil. Consented to follow up. All information was not available. Case US2020050276 was identified as follow-up to case US2020023487. Case US2020050276 was deleted



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425099

due to being created in error. All future correspondence will be submitted to case US2020023487.

This report is being resubmitted to capture corrections. The information was received on 20 March 2020 and is as follows: Event drug interaction. New event adverse drug reaction added for patient taking taking Cipro and Plaquenil, she had a drug reaction. On an unknown date outcome of adverse drug reaction was unknown. It was unknown if the reporter considered the adverse drug reaction to be related to Benlysta, Cipro and Plaquenil.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?		
Medical History Product(s)	Start Date	End Date	Indications	Events	

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Diastolic blood pressure	dropped, dropped into the low forties	unknown			N

Concomitant Products:

#	Product Name	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No Sender Organization: GLAXOSMITHKLINE 503B Compounding Outsourcing Facility?:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425099

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425391

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: DEU Event Date: 29-Jan-2020 Outcomes: OT, Application Type: NDA

FDA Rcvd Date: 18-Feb-2020 Mfr Rcvd Date: 05-Feb-2020 Mfr Control #: DE-ADVANSZ PHARMA-202002000759 Application #: 009768

Patient Information:

Age: Sex: Weight:

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	
1	Hydroxychloroquine		1 DF/	Unknown	1 Dosage Form, qd, film coated tablet	Product used for unknown indication	23-Jan-2020	30-Jan-2020	
#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine	7 Day	NA	NA	Unknown			CONCORDIA	

Event Information:

Preferred Term (MedDRA @ Version: 23.0) ReC

Haemorrhage NA

Event/Problem Narrative:

Case number 202002000759 is a business partner report (reference ID: 2020SA033307) sent by consumer on 05/Feb/2020.

Case Description: Initial information received on 05/Feb/2020 from Germany regarding an unsolicited valid serious case received from the patient.

This case involves a 65 years old female patient who reported heavy bleeding in the lower leg, while she was treated with hydroxychloroquine sulfate (Quensyl).

The patient's underlying condition included high blood pressure.
The patient's past medical treatment(s), vaccination(s) and family history were not provided.

Concomitant medications included apixaban (Eliquis); and amlodipine.



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425391

On 23/Jan/2020, the patient started taking hydroxychloroquine sulfate film coated tablets 1 DF daily (strength: 200mg, route, lot/batch number: unknown) for an unknown indication.

On 29/Jan/2020, patient had heavy bleeding in the lower leg (latency: 6 days).

Lab data: no lab data
Action taken: drug withdrawn on 30/Jan/2020
Corrective treatment: not reported
Event outcome: unknown

Seriousness criteria: medically significant (heavy bleeding in the lower leg).

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Hypertension			YES	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	AMLODIPINE			UNK		02-Feb-2016		1458 DAY
2	ELIQUIS			UNK		01-Mar-2017		1065 DAY



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17425391

Reporter Source:

Study Report?: No

Sender Organization: ADVANZ PHARMA

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17433216

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: CHE Event Date: 22-Jan-2020 Outcomes: HO, Application Type: BLA

FDA Rcvd Date: 19-Feb-2020 Mfr Rcvd Date: 13-Feb-2020 Mfr Control #: CH-ROCHE-2551375 Application #: 103705

Patient Information:

Age: 49 YR Sex: Female Weight:

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	MABTHERA			Intravenous drip	2x 500 mg	Polyarthritis	Mar-2018	
2	ARAVA		10 MG/QD	Oral		Polyarthritis	Feb-2018	20-Jan-2020
3	CIMIFEMIN		13 MG/QD	Oral		Menopausal symptoms		
4	PANTOZOL [PANTOPRAZOLE SODIUM SESQUIHYDRATE]		40 MG/	Oral		Product used for unknown indication		
5	PLAQUENIL [HYDROXYCHLOROQUIN E SULFATE]		200 MG/QD	Oral		Polyarthritis	Feb-2018	
6	ZALDIAR			Oral		Pain		22-Jan-2020

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	MABTHERA	1 Year	Unk	NA	UNKNOWN				
2	ARAVA	1 Year	No	NA	UNKNOWN				
3	CIMIFEMIN		Unk	NA	UNKNOWN				
4	PANTOZOL [PANTOPRAZOLE SODIUM SESQUIHYDRATE]		Unk	NA	UNKNOWN				
5	PLAQUENIL [HYDROXYCHLOROQUIN	1 Year	Unk	NA	UNKNOWN				



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17433216

Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)		Start Date	End Date
Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC	
E SULFATE]									
6 ZALDIAR		Unk	NA	UNKNOWN					

Event Information:

Preferred Term (MedDRA Ⓜ Version: 23.0)

ReC

Hepatic enzyme increased

NA

Event/Problem Narrative:

AER 2551375 is a spontaneous case, received on 13/Feb/2020 from a physician in Switzerland via health authority Swissmedic (reference number: CH-SM-2020-10758) and the European Medicine Agency (EMA). It concerns a 49 year old female patient who developed elevated liver enzymes while being treated with leflunomide (Arava), hydroxychloroquine sulfate (Plaquenil), rituximab (Mabthera), paracetamol;tramadol hydrochloride (Zaldiar), cimicifuga racemosa rhizome (Cimifemin) and pantoprazole sodium sesquihydrate (Pantozol).

The patient's concomitant medication included prednisolone (Prednisolon). No medical history, past drugs and concurrent conditions were reported.

On an unknown date in /Feb/2018, the patient started therapy with oral leflunomide (lot number: unknown), 10 mg, once a day and oral hydroxychloroquine sulfate (lot number: unknown) 200 mg once a day for polyarthritis. On an unknown date in /Mar/2018, she received ntravenous drip rituximab (lot number: unknown), 2x 500 mg, every 5 months for polyarthritis. On an unknown date, she received oral paracetamol;tramadol hydrochloride (lot number: unknown) once a day (dose not reported) for pain, oral cimicifuga racemosa rhizome (lot number: unknown), 13 mg, once a day for menopausal symptoms, oral pantoprazole sodium sesquihydrate (lot number: unknown), 40 mg, as required for an unknown indication. On 20/Jan/2020, leflunomide was stopped. On ^{(b) (6)} a liver enzyme increase was detected (AST (aspartate aminotransferase): 92 U/l (<35 U/l); ALT (alanine aminotransaminase): 126 U/l (<35 U/l); GGT (Gamma-glutamyltransferase): 57 U/l (< 40U/l); ALP (Alkaline phosphatase): 36 U/l (35-105 U/l)) and was hospitalised. On same day, therapy with paracetamol;tramadol hydrochloride was switched to tramadol. The transaminases remained stable. Her hospitalisation was prolonged due to the increased transaminases.

At the time of the report, event elevated liver enzymes was persisting. Therapy status of hydroxychloroquine sulfate, rituximab, cimicifuga racemosa rhizome and pantoprazole sodium sesquihydrate was not reported.

The health authority assessed the elevated liver enzymes as related to leflunomide, hydroxychloroquine sulfate, rituximab,



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17433216

paracetamol;tramadol hydrochloride, cimicifuga racemosa rhizome and pantoprazole sodium sesquihydrate. The reporter did not provide causality of event elevated liver enzymes with leflunomide, hydroxychloroquine sulfate, rituximab, paracetamol;tramadol hydrochloride, cimicifuga racemosa rhizome and pantoprazole sodium sesquihydrate.

No further information was provided.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Aspartate aminotransferase increased	92	U/L			N
Gamma-glutamyltransferase increased	57	U/L			N
Alanine aminotransferase increased	126	U/L			N
Blood alkaline phosphatase increased	36	U/L	35	105	N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	PREDNISOLON [PREDNISOLONE]		Oral		Polyarthritis	Feb-2018		1 YR



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17433216

Reporter Source:

Study Report?: No

Sender Organization: ROCHE

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17439574

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CHE **Event Date:** 22-Jan-2020 **Outcomes:** HO, **Application Type:** NDA

FDA Rcvd Date: 20-Feb-2020 **Mfr Rcvd Date:** 13-Feb-2020 **Mfr Control #:** CH-SA-2020SA038476 **Application #:** 020905

Patient Information:

Age: 49 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	ARAVA		10 MG/QD	Oral	10 mg, QD	Polyarthrititis	Feb-2018	20-Jan-2020
2	CIMIFEMIN		13 MG/QD	Oral	13 mg, QD	Menopausal symptoms		
3	MABTHERA			Intravenous (not otherwise specified)	2x 500 mg every 5 month	Polyarthrititis	Mar-2018	
4	PANTOZOL [PANTOPRAZOLE SODIUM SESQUIHYDRATE]		40 MG/	Oral	AS NECESSARY			
5	PARACETAMOL/TRAMAD OL HYDROCHLORIDE			Oral	UNK	Pain		
6	PLAQUENIL		200 MG/QD	Oral	200 mg, QD	Polyarthrititis	Feb-2018	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	ARAVA	23 Month	NA	NA				SANOFI	
2	CIMIFEMIN		Unk	NA					
3	MABTHERA		Unk	NA					
4	PANTOZOL [PANTOPRAZOLE SODIUM SESQUIHYDRATE]		Unk	NA					
5	PARACETAMOL/TRAMAD OL HYDROCHLORIDE		Unk	NA					



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17439574

Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	
Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
6 PLAQUENIL	23 Month	Unk	NA				SANOFI	

Event Information:

Preferred Term (MedDRA Ⓜ Version: 23.0)

ReC

Hepatic enzyme increased

NA

Event/Problem Narrative:

Initial information regarding this unsolicited valid serious case downloaded from Eudravigilance database without narrative (level 2A), was received on 13-Feb-2020 from a physician via Health Authority of Switzerland (Worldwide Unique Case Identification Number: CH-SM-2020-10758). The following narrative is based on the information retrieved from all other accessible data.

This case involves a 49 years old female patient who experienced elevated liver enzymes (Hepatic enzyme increased), while she was treated with leflunomide (Arava), hydroxychloroquine sulfate [Plaquenil], paracetamol/ tramadol hydrochloride, rituximab (Mabthera), cimicifuga racemosa rhizome (Cimifemin) and pantoprazole sodium sesquihydrate (Pantozol).

The patient's past medical history, medical treatment, vaccination and family history were not provided.

Concomitant medications included prednisolon for polyarthritis.

From an unknown date in February 2018 to 20-Jan-2020, the patient started leflunomide at a dose of 10 mg daily orally and hydroxychloroquine sulfate at a dose of 10 mg daily orally, both for Polyarthritis.

From an unknown date in March 2018, the patient started rituximab via intravenous not otherwise specified route for Polyarthritis.

On an unknown date, the patient started paracetamol/tramadol hydrochloride orally for Pain, cimicifuga racemosa rhizome at a dose of 13 mg daily orally for Menopausal symptoms and pantoprazole sodium sesquihydrate at a dose of 40 mg a necessary orally for unknown indication.

On (b) (6) approximately (b) (6) ear (b) (6) month after first and (b) (6) days after last dose of leflunamide; (b) (6) year (b) (6) month after starting hydroxychloroquine sulfate; (b) (6) ye r (b) (6) m nths after starting ritu m ab; (unknown latency) after initiati n of other suspect drugs, the patient experienced elevated liver enzymes (Hepatic enzyme increased).



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17439574

On (b) (6) Alanine aminotransferase was 126 U/L; Aspartate aminotransferase was 92 U/L; Blood alkaline phosphatase - was 36 U/L and Gamma-glutamyltransferase was 57 U/L.

Seriousness criteria was hospitalization for this event.

Action taken was not applicable for leflunamide and unknown for other suspect drugs.

It was not reported if the patient received a corrective treatment.

The event outcome was reported as not resolved.

No further relevant information was provided.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Gamma-glutamyltransferase	57	U/L			N
Blood alkaline phosphatase	36	U/L			N
Alanine aminotransferase	126	U/L			N
Aspartate aminotransferase	92	U/L			N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	PREDNISOLON [PREDNISOLONE]		Oral	UNK	Polyarthritis	Feb-2018		



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17439574

Reporter Source:

Study Report?: No

Sender Organization: SANOFI AVENTIS

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17498908

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: USA Event Date: 26-Feb-2020 Outcomes: DE,HO, Application Type: NDA

FDA Rcvd Date: 11-Mar-2020 Mfr Rcvd Date: 06-Mar-2020 Mfr Control #: NVSC2020US060102 Application #: 204114

Patient Information:

Age: 59 YR Sex: Female Weight: 51 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	TRAMETINIB		2 MG/QD	Oral	2 mg, QD	Pancreatic carcinoma	17-Jan-2020	
2	HYDROXYCHLOROQUINE SULFATE		600 MG/BID	Oral	600 mg, BID	Pancreatic carcinoma	17-Jan-2020	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	TRAMETINIB	41 Day	NA	NA				NOVARTIS	
2	HYDROXYCHLOROQUINE SULFATE	41 Day	NA	NA					

Event Information:

Preferred Term (MedDRA Ⓜ Version: 23.0) ReC

Respiratory failure NA

Event/Problem Narrative:

Case number# NVSC2020US060102, is a report initially received from an investigator on 01 Mar 2020 from a clinical study CTMT212A0US04T. This report refers to a 59 years old female subject (center ID: (b) (6) subject ID: (b) (6)) enrolled in (b) (6) (b) (6)

The subject's medical history included pancreatic cancer with lung metastases and Pleural effusion. Concomitant medication was not reported. On (b) (6), the subject started study medication TRAMETINIB at a dose of (b) (6) mg, QD (oral) and study medication hydroxychloroquine at a dose of (b) (6) mg, BID (oral). Investigator reported that, the subject turned to home following her cycle (b) (6) day (b) (6) visit on (b) (6) to comply with requirements, but planned to return for her cycle (b) (6) day (b) (6). On (b) (6), the subject developed respiratory failure grade 4 and 5 (respiratory failure). On same date, the subject was hospitalized for the event of respiratory failure with breathing difficulty. On an unknown date, the subject underwent pleural catheter placement. On (b) (6) the subject's husband informed that her



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17498908

condition had declined quickly and subject had been admitted to intensive care. On (b) (6) the subject was discharged from hospital. On same date, the subject's husband informed she passed away in her sleep. The cause of death was respiratory insufficiency. It was unknown if an autopsy was performed. The event respiratory failure was considered as serious (fatal and hospitalization) by the investigator.

The causality of respiratory failure with TRAMETINIB and hydroxychloroquine was reported as not suspected.

Follow up received on 06 Mar 2020: Added medical history (pancreatic cancer with lung metastases and Pleural effusion), updated cause of death (respiratory failure or respiratory insufficiency) and clinical course.

Follow up to open (prior to circulation of previous report) received on 06 Mar 2020: Updated dose details of study medication (TRAMETINIB and hydroxychloroquine), updated hospitalization details (admission on (b) (6) and discharged on (b) (6)) and updated causality of the event to study medication from (not assessable to not suspected).

Listedness information:-

1. Product --> hydroxychloroquine sulfate, Event --> respiratory failure, Causality --> Not Suspected

Sheet Name --> IB

Listedness --> Unknown.

2. Product --> TRAMETINIB, Event --> respiratory failure, Causality --> Not Suspected

Sheet Name --> IB

Listedness --> Unknown.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Catheter placement				
Metastases to lung			NO	
Pleural effusion			NO	
Medical History Product(s)	Start Date	End Date	Indications	Events



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17498908

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: NOVARTIS

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17507539

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** ESP **Event Date:** 18-Feb-2020 **Outcomes:** HO,LT, **Application Type:** ANDA

FDA Rcvd Date: 06-Mar-2020 **Mfr Rcvd Date:** 28-Feb-2020 **Mfr Control #:** ES-ACCORD-175043 **Application #:** 040716

Patient Information:

Age: 44 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	METHOTREXATE		10 MG/	Subcutaneous		Schnitzler's syndrome	04-Feb-2020	18-Feb-2020
2	Dolquine		200 MG/	Oral	strength: 200 mg, 30 tablets	Schnitzler's syndrome	01-Oct-2019	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	METHOTREXATE		NA	NA				ACCORD	
2	Dolquine		Unk	NA					

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
Bone marrow failure	NA
Drug interaction	NA
Off label use	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17507539

Event/Problem Narrative:

AGEMED Health Authority report from a physician via the Regulatory Agency (ES-AEMPS-604607) concerns. A 44 years old adult male patient who experienced medullary aplasia and drug interaction while receiving Subcutaneous methotrexate (10 mg) from 04-Feb-2020 to 18-Feb-2020(15 Days) for schnitzler's syndrome and Oral dolquine (Coated tablets and 200 mg) (strength: 200 mg, 30 tablets) from 01-Oct-2019 for schnitzler's syndrome.

The patient received methotrexate (Batch no: unknown) from 04-Feb-2020 to 18-Feb-2020 and dolquine (Batch no: unknown) from 01-Oct-2019. Patient experienced grade iv medullary aplasia from (b) (6) and drug interaction. At the time of reporting the action taken with methotrexate was reported as drug withdrawn and dolquine was reported as unknown. The outcome of medullary aplasia was reported as unknown and drug interaction was reported as unknown.

The reporter considered the case to be serious as the event was involved or prolonged inpatient hospitalization and life threatening.

Off label use (schnitzler's syndrome) has been considered as an additional event with methotrexate according to EU (CCSI).

Medical review comment:

The causality is assessed as possible for the events medullary aplasia with methotrexate based on reasonable temporal association.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17507539

Reporter Source:

Study Report?: No

Sender Organization: ACCORD

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17519651

Case Information:

Case Type: EXPEDITED (15-DAY)
eSub: Y
HP:
Country: ESP
Event Date: 14-Feb-2020
Outcomes: HO,LT,
Application Type: ANDA
FDA Rcvd Date: 10-Mar-2020
Mfr Rcvd Date: 03-Mar-2020
Mfr Control #: ES-TEVA-2020-ES-1196061
Application #: 065457

Patient Information:

Age: 30 YR
Sex: Female
Weight:

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	MICOFENOLATO DE MOFETILO (7330LM)		500 MG/	Oral	500 mg 12 Hours	Systemic lupus erythematosus	19-Jul-2019	18-Feb-2020
2	COLCHIMAX (COLCHICINE/DICYCLOVERINE HYDROCHLORIDE)		.5 MG/	Oral	0.5 mg 24 Hours	Serositis	16-May-2019	18-Feb-2020
3	DOLQUINE 200 MG COMPRIMIDOS, 30 COMPRIMIDOS		200 MG/	Oral	200 mg 12 Hours	Systemic lupus erythematosus	16-Jan-2019	18-Feb-2020

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	MICOFENOLATO DE MOFETILO (7330LM)	211 Day	Yes	NA	Unknown			TEVA	
2	COLCHIMAX (COLCHICINE/DICYCLOVERINE HYDROCHLORIDE)	275 Day	Yes	NA	Unknown				
3	DOLQUINE 200 MG COMPRIMIDOS, 30 COMPRIMIDOS	395 Day	NA	NA	Unknown				

Event Information:

Preferred Term (MedDRA @ Version: 23.0) **ReC**
Agranulocytosis NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17519651

Event/Problem Narrative:

03-Mar-2020, Spontaneous, Health authority Serious report . (Report duplicates - AGEMED: ES-AEMPS-604617)
 A Physician reported the case of a 30-Years-old Female patient who received MICOFENOLATO DE MOFETILO (7330LM) (MYCOPHENOLATE MOFETIL, Product cannot be excluded as a Teva product), COLCHIMAX (COLCHICINE, DICYCLOVERINE HYDROCHLORIDE, not Teva's product), DOLQUINE 200 mg COMPRIMIDOS, 30 comprimidos (HYDROXYCHLOROQUINE SULFATE, not Teva's product).
 The patient took MICOFENOLATO DE MOFETILO (7330LM) for LUPUS ERYTHEMATOSUS SYSTEMIC (MYCOPHENOLATE MOFETIL, Oral, from 19-Jul-2019, until 18-Feb-2020, 500 mg 12 Hours) batch: Unknown, COLCHIMAX for SEROSITIS (COLCHICINE; DICYCLOVERINE HYDROCHLORIDE, Oral, from 16-May-2019, until 18-Feb-2020, 0.5 mg 24 Hours) batch: Unknown, DOLQUINE 200 mg COMPRIMIDOS, 30 comprimidos for LUPUS ERYTHEMATOSUS SYSTEMIC (HYDROXYCHLOROQUINE SULFATE, Tablet, Oral, from 16-Jan-2019, until 18-Feb-2020, 200 mg 12 Hours) batch: Unknown.
 While on the suspect medication, the patient experienced AGRANULOCYTOSIS(Serious , since (b) (6) until (b) (6)) .
 At the time of the report the outcome of the AE was: AGRANULOCYTOSIS:Recovered/resolved.
 Action taken with suspect drugs: MICOFENOLATO DE MOFETILO (7330LM) - Drug discontinued; COLCHIMAX - Drug discontinued; DOLQUINE 200 mg COMPRIMIDOS, 30 comprimidos - Dosage maintained.

The patient's medical history was not reported.
 The patient's concomitant medication included RITUXIMAB (2814A)(RITUXIMAB; Unknown, since 10-Jul-2019, until 30-Jul-2019, for LUPUS ERYTHEMATOSUS SYSTEMIC).
 The patient's past medication were unspecified.
 Lab tests were not reported.
 This case was considered serious based on the following criteria: (Life Threatening, Hospitalization Required)
 Because this is a spontaneous case, regulatory distribution will be handled as though it is a related case.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17519651

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	RITUXIMAB (2814A)		Unknown		Systemic lupus erythematosus	10-Jul-2019	30-Jul-2019	220 DAY

Reporter Source:

Study Report?: No

Sender Organization: TEVA

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17548310

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CHN **Event Date:** 03-Feb-2020 **Outcomes:** DS,

Application Type: NDA

FDA Rcvd Date: 17-Mar-2020 **Mfr Rcvd Date:** 11-Mar-2020 **Mfr Control #:** CN-ABBVIE-20K-035-3317442-00

Application #: 021906

Patient Information:

Age: 82 YR

Sex: Male

Weight: 58 KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	ALUVIA 200/50		2 DF/BID	Oral		Pneumonia viral	03-Feb-2020	11-Feb-2020
2	ALUVIA 200/50					CORONAVIRUS INFECTION		
3	CHLOROQUINE PHOSPHATE		2 DF/BID	Oral		CORONAVIRUS INFECTION	08-Feb-2020	11-Feb-2020
4	CHLOROQUINE PHOSPHATE					Pneumonia viral		
5	ROSUVASTATIN CALCIUM		1 DF/QD	Oral		Hyperlipidemia	03-Feb-2020	11-Feb-2020

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	ALUVIA 200/50	8 Day	Yes	NA	1109686				
2	ALUVIA 200/50	8 Day	Yes	NA	1109686				
3	CHLOROQUINE PHOSPHATE	3 Day	Yes	NA	12190901				
4	CHLOROQUINE PHOSPHATE	3 Day	Yes	NA	12190901				
5	ROSUVASTATIN CALCIUM	8 Day	Yes	NA	KD6220				

Event Information:

Preferred Term (MedDRA ® Version: 23.0)

ReC

Blood bilirubin increased

NA

Hepatocellular injury

NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17548310

Off label use	NA
Therapeutic response unexpected	NA
Total bile acids increased	NA

Event/Problem Narrative:

Spontaneous report from CHINA, PRC by a physician of an 82 year old male with events of HEPATOCELLULAR DAMAGE and TOTAL BILE ACIDS INCREASED and non-serious OFF LABEL USE, UNEXPECTED THERAPEUTIC BENEFIT and BILIRUBIN ELEVATED with ALUVIA 200/50 (LOPINAVIR/RITONAVIR). The patient had a relevant medical history of PNEUMONIA ASSOCIATED WITH CORONAVIRUS, PNEUMONIA ASSOCIATED WITH CORONAVIRUS, HYPERTENSION, CORONARY ARTERY ATHEROSCLEROSIS, HYPERLIPIDEMIA, DIABETES and BRONCHITIS.

Case received on 11 Mar 2020 from China Health Authority with reference number 3302011038907202000048.

On (b) (6) the patient experienced OFF LABEL USE. On (b) (6) the patient experienced BILIRUBIN ELEVATED. On (b) (6) (b) (6) the patient experienced HEPATOCELLULAR DAMAGE and TOTAL BILE ACIDS INCREASED. On (b) (6) the OFF LABEL USE resolved. On (b) (6) the patient experienced UNEXPECTED THERAPEUTIC BENEFIT. ROSUVASTATIN CALCIUM and CHLOROQUINE PHOSPHATE were also considered suspect.

On (b) (6) the patient was discharged after got recovered from Pneumonia associated with Coronavirus.

The patient was treated with URSODEOXYCHOLIC ACID, COMPOUND GLYCYRRHIZIN, BICYCLOL and SODIUM CHLORIDE.

Causality for ALUVIA 200/50(LOPINAVIR/RITONAVIR)

The reporter's causality for the event(s) of HEPATOCELLULAR DAMAGE and TOTAL BILE ACIDS INCREASED with ALUVIA 200/50(LOPINAVIR/RITONAVIR) was a reasonable possibility. The reporter's causality for the event(s) of OFF LABEL USE, UNEXPECTED THERAPEUTIC BENEFIT and BILIRUBIN ELEVATED was not provided.

Relevant Laboratory & Other Diagnostic Tests

(b) (6)	ALT: 24 IU/L
(b) (6)	ALT: 16 IU/L
(b) (6)	ALT: 156 IU/L
(b) (6)	ALT: 275 IU/L



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17548310

(b) (6)
ALT: 21 IU/L
AST: 24 IU/L
AST: 19 IU/L
AST: 91 IU/L
AST: 119 IU/L
AST: 25 IU/L
DIRECT BILIRUBIN: 2.8 MCMOL/L
DIRECT BILIRUBIN: 21.4 MCMOL/L
DIRECT BILIRUBIN: 30.2 MCMOL/L
DIRECT BILIRUBIN: 19.1 MCMOL/L
DIRECT BILIRUBIN: 7.1 MCMOL/L
GGT: 121 IU/L
GGT: 86 IU/L
GGT: 362 IU/L

Unknown date INR: normal

Unknown date PT: normal

(b) (6)
TOTAL BILE ACIDS: 3.0 MCMOL/L
TOTAL BILE ACIDS: 4.0 MCMOL/L
TOTAL BILE ACIDS: 10.7 MCMOL/L
TOTAL BILE ACIDS: 8.5 MCMOL/L
TOTAL BILE ACIDS: 9.3 MCMOL/L
TOTAL BILIRUBIN: 6.7 MCMOL/L
TOTAL BILIRUBIN: 30 MCMOL/L
TOTAL BILIRUBIN: 40.4 MCMOL/L
TOTAL BILIRUBIN: 26.1 MCMOL/L
TOTAL BILIRUBIN: 10.3 MCMOL/L
YGT: 467 IU/L
YGT: 110 IU/L

Change History

On 11 Mar 2020, received updates to laboratory/diagnostic procedures and narrative description.

Relevant Medical History:

Patient Medical History

PNEUMONIA ASSOCIATED WITH CORONAVIRUS (Stopped 2020)



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17548310

HYPERTENSION
CORONARY ARTERY ATHEROSCLEROSIS
HYPERLIPIDEMIA
DIABETES
BRONCHITIS
ADYNAMIA
APPEITE IMPAIRED

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Adynamia			
Appetite impaired			
Bronchitis			
CORONAVIRUS INFECTION		2020	
Coronary artery atherosclerosis			
Diabetes			
Hyperlipidemia			
Hypertension			
Pneumonia viral		2020	

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Alanine aminotransferase	156	IU/L			N
Alanine aminotransferase	275	IU/L			N
Gamma GT	467	IU/L			N
Prothrombin time					N
GGT	86	IU/L			N
Total bile acids	10.7	MCMOL/L			N
Bilirubin direct	30.2	MCMOL/L			N
Bilirubin total	26.1	MCMOL/L			N



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17548310

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Aspartate aminotransferase	119	IU/L			N
Gamma GT	110	IU/L			N
Total bile acids	9.3	MCMOL/L			N
Alanine aminotransferase	24	IU/L			N
Total bile acids	3.0	MCMOL/L			N
Bilirubin direct	21.4	MCMOL/L			N
Aspartate aminotransferase	91	IU/L			N
GGT	362	IU/L			N
Bilirubin direct	19.1	MCMOL/L			N
Bilirubin direct	7.1	MCMOL/L			N
Aspartate aminotransferase	25	IU/L			N
Aspartate aminotransferase	24	IU/L			N
Total bile acids	4.0	MCMOL/L			N
INR					N
Bilirubin total	30	MCMOL/L			N
Alanine aminotransferase	21	IU/L			N
Bilirubin direct	2.8	MCMOL/L			N
Aspartate aminotransferase	19	IU/L			N
Bilirubin total	40.4	MCMOL/L			N
Bilirubin total	10.3	MCMOL/L			N
Bilirubin total	6.7	MCMOL/L			N
GGT	121	IU/L			N
Alanine aminotransferase	16	IU/L			N
Total bile acids	8.5	MCMOL/L			N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: ABBVIE

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17560170

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: CHN Event Date: 08-Feb-2020 Outcomes: DS,HO, Application Type: ANDA

FDA Rcvd Date: 19-Mar-2020 Mfr Rcvd Date: 11-Mar-2020 Mfr Control #: NVSC2020CN074307 Application #: 079171

Patient Information:

Age: 82 YR Sex: Male Weight: KG

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	ROSUVASTATIN CALCIUM		1 DF/QD	Oral	1 DF, QD	Hyperlipidaemia	03-Feb-2020	11-Feb-2020
2	CHLOROQUINE PHOSPHATE		2 DF/BID	Oral	2 DF, BID	Product used for unknown indication		12-Feb-2020
3	LOPINAVIR,RITONAVIR		2 DF/BID	Oral	2 DF, BID	Product used for unknown indication		12-Feb-2020

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	ROSUVASTATIN CALCIUM	6 Day	Yes	NA	KD6220			NOVARTIS	
2	CHLOROQUINE PHOSPHATE		Yes	NA					
3	LOPINAVIR,RITONAVIR		Yes	NA					

Event Information:

Preferred Term (MedDRA ® Version: 23.0)	ReC
Asthenia	NA
Coronavirus infection	NA
Decreased appetite	NA
Hepatocellular injury	NA
Total bile acids increased	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17560170

Event/Problem Narrative:

Case number# NVSC2020CN074307, is an initial spontaneous report received from a health care professional on 11 Mar 2020 from Adr (3302011038907202000048). This report refers to an 83-year-old male patient. Historical conditions were not reported. Current conditions included Viral pneumonia, Hypertension, Coronary artery atherosclerosis, Diabetes and Bronchitis. Concomitant medication was not reported. The patient received rosuvastatin calcium (manufacturer unknown) film-coated tablet (batch/lot number: KD6220) for the treatment of hyperlipemia from 03 Feb 2020 to 11 Feb 2020 at a dose of 1 DF, QD (oral).

The patient received lopinavir,ritonavir (manufacturer unknown) film-coated tablet for the treatment of an unknown indication from an unknown start date to 12 Feb 2020 at a dose of 2 DF, BID (oral).

The patient received chloroquine phosphate (manufacturer unknown) tablet for the treatment of an unknown indication from an unknown start date to 12 Feb 2020 at a dose of 2 DF, BID (oral).

On (b) (6) (b) (6) days after the first dose of the suspect drug, the patient developed hepatocellular damage (hepatocellular injury). The treatment medication dicyclohydrin tablets 50mg (oral), thrice daily was given to the patient. On (b) (6) the patient was discharged because the patient was cured from COVID-19 and after the patient developed abnormal liver function, no increase of PT or INR was found in blood coagulation function. The patient was hospitalized on an unknown date for the event of hepatocellular injury.

The following significant lab tests were recorded:

On (b) (6) ALT was 21 IU (the normal range was not reported), AST was 25 (the normal range was not reported), ?-GT was 110 IU (the normal range was not reported), liver function examination was db21.4 mol (the normal range was not reported), liver function examination was tb40.4 mol (the normal range was not reported) and Total bile acid was 9.3 mol (the normal range was not reported).

Treatment with rosuvastatin calcium was stopped on (b) (6) after the patient experienced hepatocellular injury, corona virus infection, total bile acids increased, decreased appetite and asthenia. Treatment with lopinavir,ritonavir was stopped on (b) (6) after the patient experienced hepatocellular injury, corona virus infection, total bile acids increased, decreased appetite and asthenia. Treatment with chloroquine phosphate was stopped on (b) (6) after the patient experienced hepatocellular injury, corona virus infection, total bile acids increased, decreased appetite and asthenia. On an unknown date, the patient developed symptoms of inappetence and adynamia due to covid-19 (corona virus infection), total bile acids increased, inappetence (decreased appetite) and adynamia (asthenia). Bilirubin, liver enzyme and total bile acid were higher than before. The patient was hospitalized on an unknown date for the event of corona virus infection. The patient was hospitalized on an unknown date for the event of total bile acids increased. The patient was hospitalized on an unknown date for the event of decreased appetite. The patient was hospitalized on an unknown date for the event of asthenia.

The following significant lab tests were recorded:

On an unknown date, ALT was 24 IU (the normal range was not reported), ALT was 161 IU (the normal range was not reported), ALT was 156 IU (the normal range was not reported), AST was 24 (the normal range was not reported), AST was 191 (the normal range was not reported), AST was 91 (the normal range was not reported), Bilirubin was increased (the normal range was not reported), ?-GT was 121 IU (the normal range was not reported), ?-GT was 86 IU (the normal range was not reported), ?-GT was 362 IU (the normal range was not reported), liver function examination was tb6.7 mol (the normal range was not reported), liver function examination was db2.8 mol (the normal range was not reported), liver function examination was tb30 mol (the normal range was not reported), liver function examination was db30.2 mol (the normal range was not reported), Total bile acid was 3.0 mol (the normal range was not reported), Total bile acid was 4 mol (the normal range was not reported) and Total bile acid was 10.7 mol (the normal range was not reported).

The patient was treated with Normal Saline (sodium chloride) for treatment of relieve jaundice and protect liver, Compound Glycyrrhizin



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17560170

(glycine, glycyrrhizic acid, methionine) for treatment of relieve jaundice and liver protection, ursodeoxycholic acid for treatment of relieve jaundice and liver protection and bicyclol for treatment of liver protection. Treatment was received for the events hepatocellular injury and corona virus infection. The patient fully recovered from corona virus infection on an unknown date, decreased appetite on an unknown date and asthenia on an unknown date. The outcome of the events hepatocellular injury and total bile acids increased was reported as condition improving. The diagnosed events hepatocellular injury (disability), corona virus infection (disability), total bile acids increased (disability), decreased appetite (disability) and asthenia (disability) were considered serious by the health care professional. The causality of hepatocellular injury, corona virus infection, total bile acids increased, decreased appetite and asthenia with rosuvastatin calcium was reported as suspected. The causality of hepatocellular injury, corona virus infection, total bile acids increased, decreased appetite and asthenia with lopinavir,ritonavir was reported as suspected. The causality of hepatocellular injury, corona virus infection, total bile acids increased, decreased appetite and asthenia with chloroquine phosphate was reported as suspected.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Arteriosclerosis coronary artery			YES
Bronchitis			YES
Diabetes mellitus			YES
Hypertension			YES
Pneumonia viral			YES

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Gamma-glutamyltransferase	86	IU			Y
Liver function test	DB2.8	mol			Y
Total bile acids	3.0	mol			Y
Alanine aminotransferase	24	IU			Y
Blood bilirubin					Y
Gamma-glutamyltransferase	121	IU			Y



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17560170

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Total bile acids	9.3	mol			Y
Liver function test	DB30.2	mol			Y
Alanine aminotransferase	156	IU			Y
Liver function test	TB40.4	mol			Y
Total bile acids	4	mol			Y
Alanine aminotransferase	161	IU			Y
Alanine aminotransferase	21	IU			Y
Gamma-glutamyltransferase	362	IU			Y
Liver function test	DB21.4	mol			Y
Total bile acids	10.7	mol			Y
Liver function test	TB6.7	mol			Y
Liver function test	TB30	mol			Y
Aspartate aminotransferase					Y
Aspartate aminotransferase					Y
Gamma-glutamyltransferase	110	IU			Y

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: NOVARTIS

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17563703

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** CAN **Event Date:** Feb-2020 **Outcomes:** OT, **Application Type:** BLA

FDA Rcvd Date: 21-Mar-2020 **Mfr Rcvd Date:** 17-Mar-2020 **Mfr Control #:** CA-ABBVIE-20K-028-3328160-00 **Application #:** 125057

Patient Information:

Age: 59 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	HUMIRA 40MG/0.8ML		40 MG/QOW	Subcutaneous		Psoriatic arthritis	06-Dec-2017	
2	METHOTREXATE			Unknown		Drug use for unknown indication		
3	PLAQUENIL			Unknown		Drug use for unknown indication		
4	TYLENOL			Unknown		Drug use for unknown indication		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	HUMIRA 40MG/0.8ML		NA	NA	1123201				
2	METHOTREXATE		Unk	NA	UNKNOWN				
3	PLAQUENIL		Unk	NA	UNKNOWN				
4	TYLENOL		Unk	NA	UNKNOWN				

Event Information:

Preferred Term (MedDRA @ Version: 23.0)	ReC
Fatigue	NA
Headache	NA
Pneumothorax	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17563703

Event/Problem Narrative:

Solicited report from CANADA by a consumer of a 59 year old male with events of PNEUMOTHORAX and non-serious TIRED and HEADACHES with HUMIRA 40MG/0.8ML (ADALIMUMAB). There was no reported medical history.

On unknown dates, the patient experienced TIRED and HEADACHES. In February 2020, the patient experienced PNEUMOTHORAX. On an unknown date, HEADACHES resolved. TYLENOL (PARACETAMOL), METHOTREXATE and PLAQUENIL (HYDROXYCHLOROQUINE PHOSPHATE) were also considered suspect.

The patient was very tired at night and his physician told him that it was related to his Methotrexate. He had headaches every night at 5:30 PM until his physician stopped his Plaquenil and Tylenol, he did not have any more headaches. They found a stain in the lung in mid Feb 2020 and the physician sent him to see a pulmonologist and the pulmonologist told him that it was a pneumothorax. He was asking if with the corona virus if he was more at risk because of the HUMIRA.

Causality for HUMIRA 40MG/0.8ML(ADALIMUMAB)

The reporter's causality for the event(s) of PNEUMOTHORAX, TIRED and HEADACHES was not provided. AbbVie's opinion is that there is no reasonable possibility that the events of PNEUMOTHORAX, TIRED and HEADACHES are related to HUMIRA 40MG/0.8ML(ADALIMUMAB).

Change History

On 17 Mar 2020, received updates to reporter opinion of causality and narrative description.

Relevant Medical History:

Not reported.

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	Start Date	End Date	Indications	Events



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17563703

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No

Sender Organization: ABBVIE

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17579865

Event/Problem Narrative:

17-Mar-2020, Spontaneous, Health authority Serious report. (Report duplicates - AFSSAPS: FR-AFSSAPS-AM20200358)
A Physician reported the case of a 45-Years-old Female patient who received PLAQUENIL 200 mg, comprime pellicule (HYDROXYCHLOROQUINE PHOSPHATE, not Teva's product), LEVOFLOXACINE (LEVOFLOXACIN, Product cannot be excluded as a Teva product), IDEOS (COLECALCIFEROL, CALCIUM CARBONATE, not Teva's product), ACARIZAX (ALLERGENS, HOUSE DUST & MITE, not Teva's product).
The patient took LEVOFLOXACINE for PLEURISY (LEVOFLOXACIN, Oral, from 04-Feb-2020, until 17-Feb-2020, 1000 mg) batch: Unknown, PLAQUENIL 200 mg, comprime pellicule for CUTANEOUS LUPUS ERYTHEMATOSUS (HYDROXYCHLOROQUINE PHOSPHATE, Coated tablet, Oral, from 17-Feb-2020, until 21-Feb-2020, 2 Dosage forms) batch: Unknown, IDEOS for VITAMIN D SUPPLEMENTATION (COLECALCIFEROL; CALCIUM CARBONATE, Oral, from 17-Feb-2020, until 21-Feb-2020, 2 Dosage forms) batch: Unknown, ACARIZAX for ALLERGY (ALLERGENS, HOUSE DUST & MITE, Oral, until 21-Feb-2020) batch: Unknown.
While on the suspect medications, the patient experienced HEPATIC CYTOLYSIS(Serious , since 21-Feb-2020) .
At the time of the report the outcome of the AE was: HEPATIC CYTOLYSIS:Recovering/resolving.
Action taken with suspect drug: LEVOFLOXACINE - Not Applicable; PLAQUENIL 200 mg, comprime pellicule - Drug discontinued; IDEOS - Drug discontinued; ACARIZAX - Drug discontinued.
The patient had medical history of CUTANEOUS LUPUS ERYTHEMATOSUS(Unknown if Continuing), LUPUS PLEURISY(Unknown if Continuing).
The patient's concomitant medication included LUTENYL(NOMEGESTROL ACETATE); CORTANCYL(PREDNISONE).
The patient's past medication were unspecified.
Lab tests
27-Feb-2020, ALANINE AMINOTRANSFERASE: 232 UI/L < 50
04-Feb-2020, Alkaline phosphatase: 57 U/L(46 -116)
27-Feb-2020, Alkaline phosphatase: 133 U/L(46 -116)
27-Feb-2020, GGT: 314 UI/L < 38
22-Feb-2020, ASAT: 208 UI/L < 35
22-Feb-2020, ALANINE AMINOTRANSFERASE: 797 UI/L < 50
27-Feb-2020, ASAT: 42 UI/L < 35
22-Feb-2020, GGT: 598 UI/L < 38
21-Feb-2020, ASAT: 473 UI/L < 35
21-Feb-2020, GGT: 797 UI/L < 38
21-Feb-2020, ALANINE AMINOTRANSFERASE: 1188 UI/L < 50
04-Feb-2020, ASAT: 34 UI/L < 35
22-Feb-2020, ALKALINE PHOSPHATASE: 254 U/L(46 -116)
04-Feb-2020, ALANINE AMINOTRANSFERASE: 28 UI/L < 50
21-Feb-2020, ALKALINE PHOSPHATASE: 305 U/L(46 -116)
04-Feb-2020, GGT: 19 UI/L < 38

This case was considered serious based on the following criteria: (Other Serious (Important Medical Events))



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17579865

Because this is a spontaneous case, regulatory distribution will be handled as though it is a related case.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Cutaneous lupus erythematosus			UNKNOWN
Lupus pleurisy			UNKNOWN

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
ASAT	42	Unknown			N
Alkaline phosphatase	57	U/L	46	116	N
GGT	314	Unknown			N
ALANINE AMINOTRANSFERASE	1188	Unknown			N
GGT	797	Unknown			N
ALKALINE PHOSPHATASE	254	U/L	46	116	N
ALANINE AMINOTRANSFERASE	797	Unknown			N
ASAT	473	Unknown			N
GGT	19	Unknown			N
ALKALINE PHOSPHATASE	305	U/L	46	116	N
Alkaline phosphatase	133	U/L	46	116	N



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17579865

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
ASAT	208	Unknown			N
ALANINE AMINOTRANSFERASE	28	Unknown			N
ASAT	34	Unknown			N
GGT	598	Unknown			N
ALANINE AMINOTRANSFERASE	232	Unknown			N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	CORTANCYL							
2	LUTENYL							

Reporter Source:

Study Report?: No

Sender Organization: TEVA

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17581930

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** ESP **Event Date:** 18-Feb-2020 **Outcomes:** HO,LT, **Application Type:** ANDA

FDA Rcvd Date: 25-Mar-2020 **Mfr Rcvd Date:** 17-Mar-2020 **Mfr Control #:** ES-MYLANLABS-2020M1030615 **Application #:** 201529

Patient Information:

Age: 44 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	METHOTREXATE		10 MG/wk	Subcutaneous	10 milligram, qw	Schnitzler's syndrome	04-Feb-2020	18-Feb-2020
2	DOLQUINE		200 MG/BID	Oral	200 milligram, bid (12 hours)	Schnitzler's syndrome	01-Oct-2019	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	METHOTREXATE	14 Day	NA	Unk					
2	DOLQUINE	140 Day	Unk	Unk				MYLAN	

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
Bone marrow failure	NA
Drug interaction	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17581930

Event/Problem Narrative:

This Regulatory Authority report was sent to Mylan on 17-Mar-2020 via the Spain Regulatory Authority (Authority Reference No. ES-AEMPS-604607).

This case, received from Physician in Spain, involved a 44-Years-old Male patient who reportedly drug interaction between methotrexate (company suspect) and Dolquine (hydroxychloroquine sulfate) (non-company suspect) and experienced bone marrow failure.

Medical history and concomitant medication were not reported.

Current condition included schnitzler's syndrome.

Non-company suspect medication included Dolquine (hydroxychloroquine sulfate).

01-Oct-2019: The patient initiated hydroxychloroquine sulfate coated tablet at a dose of 200 milligram, bid via oral route for schnitzler's syndrome.

04-Feb-2020: The patient initiated methotrexate injection at a dose of 10 milligram, qw via subcutaneous route for schnitzler's syndrome.

Unknown Date: The patient had drug interaction.

(b) (6) The patient experienced aplastic marrow. Therapy with methotrexate was discontinued.

Unknown date: The patient was hospitalized in response to the event bone marrow failure whereas the event was considered as life-threatening.

Action taken with hydroxychloroquine sulfate was not reported.

The outcome of event bone marrow failure was unknown.

Company Comment:

Serious: Bone marrow failure and drug interaction (non-serious) are unlisted events as per company RSI of methotrexate. Causality has been assessed as possible for events, as contributory role of suspect drug methotrexate cannot be completely excluded considering the temporal association. The patient's concurrent condition and therapy with co-suspect may have contributed to the events in this case.

Relevant Medical History:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17581930

Disease/Surgical Procedure

Schnitzler's syndrome

Start Date

End Date

Continuing?

YES

Medical History Product(s)

Start Date

End Date

Indications

Events

Relevant Laboratory Data:

Test Name

Result

Unit

Normal Low Range

Normal High Range

Info Avail

Concomitant Products:

Product Name

**Dose/
Frequency**

Route

Dosage Text

Indications(s)

Start Date

End Date

**Interval 1st
Dose to Event**

Reporter Source:

Study Report?: No

Sender Organization: MYLAN

**503B Compounding
Outsourcing Facility?:**

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17581969

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** **Country:** ESP **Event Date:** 14-Feb-2020 **Outcomes:** HO,LT, **Application Type:** ANDA

FDA Rcvd Date: 25-Mar-2020 **Mfr Rcvd Date:** 17-Mar-2020 **Mfr Control #:** ES-MYLANLABS-2020M1030618 **Application #:** 065520

Patient Information:

Age: 30 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	MYCOPHENOLATE MOFETIL		500 MG/BID	Oral	500 milligram, bid	Systemic lupus erythematosus	19-Jul-2019	18-Feb-2020
2	DOLQUINE		200 MG/BID	Oral	200 milligram, bid	Systemic lupus erythematosus	16-Jan-2019	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	MYCOPHENOLATE MOFETIL	210 Day	Yes	Unk					
2	DOLQUINE	394 Day	NA	NA				MYLAN	

Event Information:

Preferred Term (MedDRA @ Version: 23.0) **ReC**
Agranulocytosis NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17581969

Event/Problem Narrative:

This Regulatory Authority report was sent to Mylan on 17-Mar-2020 via the Spain regulatory Authority (Authority No: ES-AEMPS-604617).

This case, received from Physician in Spain, involved a 30-Years-old Female patient who reportedly experienced agranulocytosis while receiving mycophenolate mofetil.

Medical history were not reported.

Current condition included systemic lupus erythematosus, serositis.

Concomitant medications were rituximab.

Non-company suspect medication included Dolquine (hydroxychloroquine sulfate) and Colchimax.

16-Jan-2019: The patient initiated hydroxychloroquine sulfate tablet at a dose of 200 milligram bid via oral route (Batch/Lot number unknown, Expiration date unknown) for lupus erythematosus systemic.

16-May-2019: The patient initiated colchimax unknown formulation at a dose of 0.5 milligram qd via oral route (Batch/Lot number unknown, Expiration date unknown) for serositis.

19-Jul-2019: The patient initiated mycophenolate mofetil unknown formulation at a dose of 500 milligram bid via oral route (Batch/Lot number unknown, Expiration date unknown) for lupus erythematosus systemic.

(b) (6) The patient experienced agranulocytosis.

Unknown date: The patient was hospitalized in response to the event agranulocytosis and the event was life-threatening.

(b) (6) Therapy with mycophenolate mofetil and colchimax was discontinued. The patient took last dose of hydroxychloroquine sulfate.

No action was taken for hydroxychloroquine sulfate.

(b) (6) The event agranulocytosis resolved.

Company Comment:

Serious: Agranulocytosis is a listed event as per company RSI of mycophenolate mofetil. Causality of the reported event assessed as possible, as contributory role of suspect drug cannot be completely excluded considering the known safety profile of the drug. Non-company suspect medication confounds causality.



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17581969

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Serositis			YES
Systemic lupus erythematosus			YES

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	RITUXIMAB		Unknown	UNK	Systemic lupus erythematosus	10-Jul-2019	30-Jul-2019	219 DAY

Reporter Source:

Study Report?: No

Sender Organization: MYLAN

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17583875

Case Information:

Case Type: EXPEDITED (15-DAY)
eSub: Y
HP:
Country: CAN
Event Date: 10-Jan-2020
Outcomes: OT,
Application Type: BLA
FDA Rcvd Date: 26-Mar-2020
Mfr Rcvd Date: 09-Jan-2020
Mfr Control #: CA-ROCHE-2523564
Application #: 103705

Patient Information:

Age: 62 YR
Sex: Female
Weight:

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	RITUXAN		1000 MG//wk	Intravenous (not otherwise specified)	1 every week for 4 dose	IMMUNE THROMBOCYTOPENIC PURPURA	09-Jan-2020	
2	LEFLUNOMIDE		10 MG/	Unknown		Product used for unknown indication	21-Apr-2016	21-Aug-2017
3	PLAQUENIL [HYDROXYCHLOROQUIN E SULFATE]		400 MG/	Unknown		Product used for unknown indication	23-Apr-2015	13-Sep-2019
4	RITUXAN		680 MG//wk	Intravenous (not otherwise specified)			16-Jan-2020	30-Jan-2020
5	RITUXAN			Unknown		Neoplasm malignant	2015	
6	SULFASALAZINE		500 MG/BID	Unknown		Product used for unknown indication	07-Sep-2016	13-Sep-2019

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	RITUXAN		Yes	NA	H0280B28,H0967 B01,H0280B30				
2	LEFLUNOMIDE		Unk	NA	UNKNOWN				
3	PLAQUENIL [HYDROXYCHLOROQUIN E SULFATE]		Unk	NA	UNKNOWN				
4	RITUXAN		Unk	NA	ASKED BUT UNKNOWN				
5	RITUXAN		Yes	NA	H0280B28,H0967 B01,H0280B30				



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17583875

Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)		Start Date	End Date
Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC	
6 SULFASALAZINE		Unk	NA	UNKNOWN					

Event Information:

Preferred Term (MedDRA Version: 23.0)

ReC

Blood pressure diastolic abnormal	NA
Bone marrow toxicity	NA
C-reactive protein increased	NA
Intentional product use issue	NA
Neuropathy peripheral	NA
Off label use	NA
Paraesthesia	NA
Rash	NA
Thrombocytopenia	NA

Event/Problem Narrative:

AER 2523564 is a patient support program case, received on 09/Jan/2020 from an other health care professional (nursing) via consumer in Canada. It concerns a female patient (age not reported) (patient number: (b) (6)) who was intentionally treated with rituximab (Rituxan IV) for an unapproved indication (off label use) and experienced episode of low and fluctuating diastolic blood pressure, felt occasional pins and needles on both arms and legs, thrombocytopenia, bone marrow toxicity, rash, peripheral neuropathy and high C reactive protein while participating in (b) (6) and treated with rituximab (for unknown) with chemotherapy, Leflunomide, hydroxychloroquine sulfate (Plaquenil) and Sulfasalazine

The patient's past drugs included penicillin. Concurrent conditions included allergy to penicillin. Concomitant medications included paracetamol (Acetaminophen), diphenhydramine and pregabalin (Lyrica), synthroid and Thyroid pill. No medical history was reported.

On /Jan/2014, she was diagnosis with follicular lymphoma with cervical and abdominal lymphadenopathy as well as bone marrow involvement. They were treated with rituximab for ITP (Immune thrombocytopenic purpura) and there is no evidence of recurrent progression



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17583875

radiographically with respect to the lymphoma. Discontinued all DMARDs due to significant issues with thrombocytopenia. On an unspecified date, in 2015, the patient received rituximab (lot number: asked but unknown) (dosing regimen: not reported) with chemotherapy for cancer (NOS). On (b) (6) she received hydroxychloroquine sulfate, (b) (6) mg (route and frequency not reported). On (b) (6) she received leflunomide, (b) (6) mg (route and frequency not reported). On (b) (6) she received sulfasalazine (lot number: unknown) (b) (6) mg (b) (6) (route not reported) for unknown indication. On 21/Aug/2017, leflunomide stopped due to peripheral neuropathy. On 13/Sep/2019, sulfasalazine and hydroxychloroquine sulfate stopped due to thrombocytopenia and risk of bone marrow toxicity. On (b) (6), she started therapy with intravenous rituximab infusion (lot number: H0280B28, H0967B01, H0280B30 with expiry date: 01/Feb/2021, 01/Oct/2021) at (b) (6) mg (frequency: not reported) for idiopathic thrombocytopenic purpura (Off label use). This was considered as use of rituximab for an unapproved indication. On (b) (6) she started therapy with intravenous rituximab, (b) (6) mg, (b) (6). On an unspecified date, she experienced low and fluctuating diastolic blood pressure during infusion: at 08:00 (pre infusion) it was 115/64; at 08:45 (infusion started); at 09:15 it was 110/65; at 09:45 it was 103/68; at 10:15 it was 108/73; at 10:45 it was 96/55; at 11:15 it was 107/52; at 11:45 it was 113/79; at 12:15 it was 102/69 and at 12:45 (infusion completed) it was 110/72. On 16/Jan/2020, she presented with first episode of low as well as fluctuating diastolic blood pressure during infusion (lot number HO280B30 with expiry date 01/Oct/2021): at 08:00 106/73; at 08:15 (infusion started); at 08:30 106/73; at 09:00 106/57; at 09:30 90/53; at 10:00 97/64; at 10:30 93/57; at 11:00 97/55; at 11:20 (infusion completed). Baseline values were 115/64. It was reported that a day after infusion on 10/Jan/2020, she felt occasional pins and needles, just one like pick at a time on both arms and legs. Symptoms lasted a couple of days and On 12/Jan/2020, it resolved on own. On 23/Jan/2020, her ECOG (Electrocochleography) score was reported as 1 (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work). Baseline ECOG was 1. Previous Rituxan Infusion was on 16/Jan/2020. On 30/Jan/2020, post infusion report received from infusion nurse. Infusion nurse reported that her ECOG score reported as 1 (Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g, light house work, office work). Baseline ECOG was 1. She was yet to receive tocilizumab for indication seronegative inflammatory arthritis, which was an off label indication. The reason for the switch from rituximab HA was unknown. On 14/Feb/2020, she has recent consult from swollen joint count 6, tender joint count 12 plus all MTP (metatarsophalangeal joints) in feet. She seronegative but has erosive inflammatory arthritis. Therapy with rituximab was withdrawn.

At the time of this report, the outcome of event episode of low and fluctuating diastolic blood pressure was reported, thrombocytopenia, bone marrow toxicity, rash, peripheral neuropathy and high C reactive protein as unknown.

The reporter did not report the causality of event episode of low and fluctuating diastolic blood pressure, felt occasional pins and needles on both arms and legs, thrombocytopenia, bone marrow toxicity, rash, peripheral neuropathy and high C reactive protein with rituximab.

The company assessed the causality of event episode of low and fluctuating diastolic blood pressure, felt occasional pins and needles on both arms and legs, thrombocytopenia, bone marrow toxicity, rash, peripheral neuropathy and high C reactive protein as not related with rituximab.

The company assessed the causality of event thrombocytopenia as not related with rituximab IV as it is reported that thrombocytopenia was related to DMARDs. The company assessed the causality of event peripheral neuropathy and bone marrow toxicity as related with rituximab



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17583875

IV based on reasonable temporal association with therapy and was a known pattern of response

The company assessed of thrombocytopenia, bone marrow toxicity and peripheral neuropathy as medically significant.

No further information was provided.

This case is cross-referenced with AER 2503350 (same patient).

Additional information was received on 16/Jan/2020. The following information was added to the case (ROC13222370): New event first episode of low and fluctuating diastolic blood pressure, felt occasional pins and needles on both arms and legs added. Event description updated.

Additional information was received on 23/Jan/2020. The following information was added to the case: Primary reporter added, batch number HO280B30 and expiry date: 01/Feb/2021 added, event description updated, dosing regimen of rituximab IV added.

Additional information was received on 30/Jan/2020. The following information was added to the case (ROC13224368): Event description was updated, narrative updated.

Additional information was received on 03/Mar/2020 and following information was added: Secondary reporter, event description and therapy start date of rituximab updated to 16/Jan/2020 from 09/Jan/2020.

Additional information was received on 12/Mar/2020 and following information was added case (ROC132290781): New primary reporter, secondary reporter, new event (thrombocytopenia, bone marrow toxicity, rash, peripheral neuropathy and high C reactive protein), new suspect (leflunomide, hydroxychloroquine sulfate (Plaquenil) and sulfasalazine), suspect rituximab dosing regimen updated (end date: 30/Jan/2020), new lab test (swollen joint count , tender joint count, C-reactive protein and X ray) and Concomitant medications (synthroid) was added. Event description updated.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Drug hypersensitivity			YES



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17583875

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
X-ray					N
Tender joint count					N
C-reactive protein					N
Blood pressure measurement					N
Swollen joint count					N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	ACETAMINOPHEN	650 MG/	Oral		Premedication	09-Jan-2020		
2	DIPHENHYDRAMINE	50 MG/	Oral		Premedication	09-Jan-2020		
3	LYRICA							
4	SYNTHROID							

Reporter Source:

Study Report?: No

Sender Organization: ROCHE

503B Compounding
Outsourcing Facility?:

Literature Text:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17601685

Case Information:

Case Type: EXPEDITED (15-DAY) eSub: Y HP: Country: FRA Event Date: 2011 Outcomes: OT, Application Type: NDA

FDA Rcvd Date: 31-Mar-2020 Mfr Rcvd Date: 18-Mar-2020 Mfr Control #:FR-ADVANZ PHARMA-202003002044 Application #: 009768

Patient Information:

Age: Sex: Weight:

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		2 DF/	Unknown	2 Dosage Form, bid (one in morning and one in evening, film-coated tablet)	Systemic lupus erythematosus	1999	
2	AMOXLCILLIN TRIHYDRATE/POTASSIUM CLAVULANATE					CORONA VIRUS INFECTION		
3	AMOXLCILLIN TRIHYDRATE/POTASSIUM CLAVULANATE			Unknown	UNK	Paronychia		
4	AMOXLCILLIN TRIHYDRATE/POTASSIUM CLAVULANATE					Pneumonia legionella		
5	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		3 DF/	Unknown	3 Dosage Form (Film-coated tablet)	CORONA VIRUS INFECTION		
6	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil					Pneumonia legionella		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		Unk	NA				CONCORDIA	
2	AMOXLCILLIN TRIHYDRATE/POTASSIUM CLAVULANATE		Unk	NA					
3	AMOXLCILLIN TRIHYDRATE/POTASSIUM CLAVULANATE		Unk	NA	Unknown				



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17601685

Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text		Indications(s)		Start Date	End Date
Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler		OTC
4 AMOXCILLIN TRIHYDRATE/POTASSIU M CLAVULANATE		Unk	NA						
5 Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		Unk	NA	Unknown			CONCORDIA		
6 Hydroxychloroquine sulfate (Authorized Generic),Plaquenil		Unk	NA				CONCORDIA		

Event Information:

Preferred Term (MedDRA ® Version: 23.0)

ReC

Blood pressure abnormal	NA
Breast cancer metastatic	NA
Burning sensation	NA
Constipation	NA
Dementia Alzheimer's type	NA
Expired product administered	NA
Gait disturbance	NA
Intentional product misuse	NA
Malaise	NA
Off label use	NA
Paronychia	NA
Skin plaque	NA
Systemic lupus erythematosus	NA
Toe amputation	NA



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17601685

Event/Problem Narrative:

Case number 202003002044 is a business partner report (reference ID: 2020SA072343) sent by consumer on 18/Mar/2020.

Case Description: Initial information received on 18-Mar-2020 from France regarding an unsolicited valid serious case from a patient.

This case involves a 77 years old female patient who reported she went to (b) (6) for her cancer, metastatic cancer, breast cancer, she has a blue scar of alzheimer, relapse of lupus, she had a burning sensation all over her body that prevented her from walking, she had a burning sensation all over her body that prevented her from walking, toe infection that failed to lead to amputation, she is constipated like a stone, blood pressure increased, she felt malaise unwell, toe infection that failed to lead to amputation, returned home with coronavirus and took plaquenil, by reflex she took in the morning and evening and when she realized its effectiveness she even switched to 3 tablets used the plaquenil she had left in her pharmacy, some of which were expired in december 2019, while she was treated with hydroxychloroquine sulfate [Plaquenil] and amoxicillin trihydrate, potassium clavulanate [Clamoxil].

The patient's past medical history included Malaria and Rheumatism. She had never smoked or drunk alcohol in her life. For her, quinine (past drug) was the holy grail, relieves her of these rheumatisms. The patient's family history was not provided.

Concomitant medications included lercanidipine hydrochloride (Lercan) for Blood pressure increased; and quinine (quinine).

In 1999, the patient started taking hydroxychloroquine sulfate (strength: 200 mg, film coated tablet) at dose of 2 tablets twice a day (in morning and evening) for Systemic lupus erythematosus, suspected Corona virus infection and suspected legionella.

On an unknown date, the patient started taking amoxicillin trihydrate/potassium clavulanate at unknown strength, formulation, dosage, frequency, route (with an unknown batch number and expiry date) for toe infection, suspected Corona virus infection and suspected legionella.

Patient had problems when she took lercan with aromasine for her Metastatic cancer in 2011. On 13-Dec-2019 (latency: unknown), the patient reported she went to (b) (6) for her cancer, and her oncologist noticed that she had plaques. She informed him about her Lupus. On her way home, she stoned taking her plaquenil to treat relapse of Lupus (onset: 13-Dec-2019 and latency: approximately 10 years). On (b) (6) she returned by plane to (b) (6) that is probably also connected with to Italy (b) (6). She returned home with the coronavirus. She remained isolated at home without possibility to move: "completely bedridden". Therefore, she did not give any sign of life for 8 days and was not tested for the coronavirus. She was treated with the means of the edge and in particular with her plaquenil and clamoxil (intentional product misuse). By reflex she took it in morning and evening and when she realized the effectiveness, she even went to 3 tablets (intentional product misuse). When she took the plaquenil her fever went down. It went to 38- 38.5 degree celsius, whereas on the first day it was rather at 41 degree celsius. She used the plaquenil she had left in her pharmacy, some of which were expired in December 2019 (expired product administered; onset and latency: unknown).

On 28-Jan-2020 (latency: approximately 10 years), she had a burning sensation all over her body that prevented her from walking. She was almost sitting there so she could breathe. If she had had ventolin she would have used it. She had a lot of sputum cough. She has never been sick like that and "she has a lot of point of comparison in her life even her worst malaria attack wasn't as terrible". If it wasn't the coronavirus,



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17601685

then she thinks it was a very serious case of legionellosis. She takes her lupus treatment only during manifestations/ episodes of her lupus and from January to March, but this year she didn't see the months of January to March because she was concerned about her cancer. She accepts that her doctor will be contacted again by the PV. The prescribed dosage is 1 tablet of 200mg per day. The clamoxil she took was a leftover! remnant from a previous prescription she had had for a toe infection (onset and latency: unknown) that failed to lead to amputation. She didn't even have diarrhea despite taking the medication for several days. In the end she would have liked to have had diarrhea because she is "constipated like a stone" (onset and latency: unknown). It is not clear if the constipation is persistent or not. She is taking lercan 10mg for her blood pressure (onset and latency: unknown). She takes it well away from the plaquenil She felt malaise/unwell (onset and latency: unknown) and would have fallen into a coma after her lunch and woke up the next night on the floor. Because she has a "blue scare" of Alzheimer's (onset and latency: unknown), she documented all of it in her journal. She doesn't understand why if this drug is effective it is not given to the patients because if she was alive now it is thanks to the plaquenil. She was waiting to find out if she is in remission from her breast cancer. She was being monitored.

Relevant laboratory test results included: Body temperature - On an unknown date: 41degree celsius; on an unknown date: 38-38.5 degree celsius

Action taken: not applicable for intentional product misuse, off label use and expired product administered and unknown for rest all events for both suspects

Corrective: Amoxicillin (Clamoxil) for toe infection; lercanidipine hydrochloride (Lercan) for blood pressure; exemestane (Aromasine) for cancer; amputation for toe infection.

Outcome: not applicable for intentional product misuse and expired product administered; unknown for rest all events.

Seriousness: Medically significant for Metastatic neoplasm, skin plaques, Alzheimer's disease, Systemic lupus erythematosus.

This suspected adverse reaction report is submitted and classified as a medication error solely and exclusively to ensure the marketing authorization holder's compliance with the requirements set out in Directive 2001/83/EC and module VI of the Good Pharmacovigilance Practices. The classification as a medical error is in no way intended, nor should it be interpreted or construed as an allegation or claim made by the marketing authorization holder that any third party has contributed to or is to be held liable for the occurrence of this medication error.

Query mail was sent to the business partner regarding event onset date, so that estimated date could be calculated.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17601685

Abstains from alcohol
 Blood pressure increased
 CORONA VIRUS INFECTION
 Malaria
 Non-tobacco user
 Paronychia
 Pneumonia legionella
 Rheumatic disorder
 Systemic lupus erythematosus

Medical History Product(s)	Start Date	End Date	Indications	Events
quinine				

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Body temperature	38-38.5	degree Celsius			N
Body temperature	41	degree Celsius			N

Concomitant Products:

#	Product Name	Dose/Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	Lercan	10 MG/		10 mg	Blood pressure increased	2011		
2	quinine			UNK				

Reporter Source:

Study Report?: No Sender Organization: ADVANZ PHARMA 503B Compounding Outsourcing Facility?:



FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17601685

Literature Text:

Printer: CDPEDQ5

User: STEPPERH

Date - Time: 11-May-2020 03:24 PM

Total Number of Cases (Non-Esub): 9

Total Number of Pages: 51

Print Job Number: 22101

Disclaimers:

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

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

Processed Case Id's for Images:

17292381 17407178 17591609 17597821 17598592 17605416 17605425 17605439
17611030

Failed Case Id's for Images:

Total Failed Cases: 0

U.S. Department of Health and Human Services

For VOLUNTARY reporting of adverse events, product problems and product use errors

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 See PRA statement on reverse.

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Page 1 of 3

FDA USE ONLY	
Triage unit sequence #	
FDA Rec. Date	

AE Record ID: AE00259500

A. PATIENT INFORMATION

1. Patient Identifier (b) (6) 2. Age Year(s) Month(s) Week(s) Days(s)

3. Sex Female Male 4. Weight lb kg

5.a. Ethnicity (Check single best answer) Hispanic/Latino Not Hispanic/Latino

5.b. Race (Check all that apply) Asian American Indian or Alaskan Native Black or African American White Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply *

Adverse Event Product Problem (e.g., defects/malfunctions)

Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply) *If Non-Serious check nothing

Death Include date (dd-mmm-yyyy) Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Required intervention to prevent permanent impairment/damage (Devices)

Disability or Permanent Damage Congenital Anomaly/Birth Defects

3. Date of Event (dd-mmm-yyyy) 01-Jan-2020 4. Date of this Report (dd-mmm-yyyy) 01-Jan-2020

5. Describe Event, Problem or Product Use Error

In the past, patient had taken and discontinued plaquenil due to headache or stomachache. she was not sure of which reaction and what dates it was

6. Relevant Tests/Laboratory Data, including Dates

7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)

Yes No Returned to Manufacturer on (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)

#1 - Name and Strength PLAQUENIL TAB 200MG	#1 - NDC # or Unique ID 00024156210
#1 - Manufacturer/Compounder	#1 - Lot # not available
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot #

3. Dose or Amount Frequency Route

#1 200mg	Other	Oral
#2		

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)

#1 unknown - unknown

9. Event Abated After Use Stopped or Dose Reduced?

#1 Yes No Doesn't apply

5. Diagnosis or Reason for Use (indication)

#1

10. Event Reappeared After Reintroduction?

#1 Yes No Doesn't apply

6. Is the Product Compounded? 7. Is the Product Over-the-Counter?

#1 ☐ Yes ☒ No	#1 ☐ Yes ☒ No
#2 Yes No	#2 Yes No

8. Expiration Date (dd-mmm-yyyy)

#1 #2

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Common Device Name 2b. Procode

3. Manufacturer Name, City and State

4. Model # Lot # 5. Operator of Device

Catalog # Expiration Date (dd-mmm-yyyy)

Serial # Unique Identifier (UDI) #

Health Professional Lay User/Patient Other

6. If Implanted, Give Date (dd-mmm-yyyy) 7. If Explanted, Give Date (dd-mmm-yyyy)

8. Is this a single-use device that was reprocessed and reused on a patient? Yes No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)

G. REPORTER: (See confidentiality section on back)

1. Name and Address

Full Name

Address:

City: State/Province/Region:

Country: USA ZIP/Postal Code:

Phone #: Email:

2. Health Professional? Yes No

3. Occupation

4. Also Reported to: Manufacturer/Compounder User Facility Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box:

PLEASE TYPE OR USE BLACK INK

AE Record ID: AE00259500

Manufacturer Program ID Not Available
(if applicable)

Addendum

MedWatch Adverse Event Reporting Program

Voluntary Reporting

Page 3 of 3

Prescriber Information

Prescriber Name	
Street Address	
City	
State	
Zip	
Phone	
Fax	

Report submitted by:

(b) (6)

Report submitted date:

01-Jan-2020

Vendor E-mail address:

(b) (6)

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	11-Feb-2020	CTU Received Date	11-Feb-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b) (6)
Age	28 Year(s)
Date of Birth	
Gender	Female
Weight	98 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☒ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	☒ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☒ Life Threatening ☒ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage

Date of Death		
Date of Event	03-Feb-2020	
Date of this Report	11-Feb-2020	

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: The patient took hydroxychloroquine for the first time. She was found down with a suspected seizure (b) (6) When she presented to the ED, she was found to be hypoglycemic

Relevant Test/Laboratory Data 1 of 1

Test Name	RANDOM GLUCOSE	Test Date	(b) (6)
Test Result	27	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

patient is not diabetic

Other Relevant History, Including Preexisting Medical Conditions

Patient has polycystic kidney disease, newly diagnosed scleroderma; on dialysis

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 6

Suspect	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	Yes
Type	Drug/Biologic
Product Name	hydroxychloroquine
Strength	200 mg milligram(s) If Other
Manufacturer/Compounder	
NDC# or Unique ID	
Product Type(check all that apply)	☐ OTC

	☐ Compounded ☒ Generic ☐ Biosimilar	
Event Abated After Use Stopped or Dose Reduced?	Yes	
Event Reappeared after Reintroduction ?	Doesn't Apply	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency	Other	If Other	first dose
Route		If Other	
Dosage Form			
Start	03-Feb-2020		
Stop	03-Feb-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

Scleroderma

D. PRODUCT(S) 2 of 6

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	metoprolol		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	

Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication)			1 of 1

D. PRODUCT(S) 3 of 6

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	carvedilol		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication)			1 of 1

D. PRODUCT(S) 4 of 6

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	vitamin B12		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 5 of 6

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			

Type	Drug/Biologic		
Product Name	Vitamin D		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 6 of 6

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	Lisinopril		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		

Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	

Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION	

G. REPORTER 1 of 1

Primary?	Yes	
Reporter is Patient?		
Title		
Last Name	(b) (6)	
Middle Name		
First Name	(b) (6)	
Address		
City	(b) (6)	
State/Province/Region	(b) (6)	
Country	UNITED STATES	If Other
ZIP/Postal Code	(b) (6)	
Phone		
Email	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Health Professional?	Yes	
Occupation	Pharmacist	If Other
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	26-Mar-2020	CTU Received Date	26-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b) (6)
Age	65 Year(s)
Date of Birth	
Gender	Male
Weight	105.3 kg
Ethnicity (Check single best answer)	
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	☒ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☒ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage

Date of Death	
Date of Event	17-Mar-2020
Date of this Report	26-Mar-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Per pharmacist internal report: QTc on (b) (6) was 482 but increased to 570 on (b) (6) with hydroxychloroquine so therapy was changed to darunavir / cobicistat (800/150 mg - 1 tablet - daily) Patient admitted on (b) (6) Transferred to ICU on (b) (6) Received plaquenil: 400 mg - (b) (6) at 1847 400 mg - (b) (6) at 0844 200 mg - (b) (6) at 1716 200 mg - (b) (6) at 0913 Additional patient information: Does take sertraline 25 mg daily (home med), utilizes hemodialysis, Haldol 1 mg IV was administered on (b) (6) at 0741 and 2 mg IV was given (b) (6) at 2152 (order was prn agitation q4 hrs) As of (b) (6) - patient is still admitted in ICU

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 1

Suspect	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	Yes
Type	Drug/Biologic
Product Name	plaquenil
Strength	If Other
Manufacturer/Compounder	
NDC# or Unique ID	

Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	

Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes	
Reporter is Patient?		
Title		
Last Name	(b) (6)	
Middle Name		
First Name	(b) (6)	
Address	(b) (6)	
City	(b) (6)	
State/Province/Region	(b) (6)	
Country	UNITED STATES	If Other
ZIP/Postal Code	(b) (6)	
Phone	(b) (6)	
Email	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Health Professional?	Yes	
Occupation	Pharmacist	If Other
Also Reported to	☐ Manufacturer/Compounder ☒ User Facility ☐ Distributor/Importer	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Urgent		
Override Auto Calculation Rule	No		
FDA Received Date	29-Mar-2020	CTU Received Date	29-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	☒ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	28-Mar-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☒ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)	
I take hydroxychloroquine 200 mgs twice a day, yesterday on 3/28/2020 after taking my morning dose, I started having chest problems. It was not the first time having them, I've also starting developing eye problems over the last 2 weeks. I had heart attacks in 2017 and had 3 stents placed in my heart.	

Relevant Test/Laboratory Data				1 of 1
Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments

I will be contacting my arthritis doctor on 3/30/2020 and inform her of the problems, I do not know if its totally the hydroxychloroquine or if it's the new medication orenicia that I recently started on 3/8/2020.

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 2

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Drug
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Hydroxychloroquine
Name of the company that makes (or compounds) the product	Unknown
Product Type(check all that apply)	☐ Over-the-Counter ☒ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar
Strength	200 mg milligram(s) If Other
NDC number	Unknown
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes
Did the problem return if the person started taking or using the product again?	Doesn't Apply

Drug Therapy 1 of 1

Expiration date	27-Feb-2021
Lot number	Unknown
Dosage Form	
Quantity	Other If Other 1 Tablet(s)
Frequency	Twice a day If Other
How was it taken or used	Oral If Other
Date the person first started taking or using the product	28-Jun-2019
Date the person stopped taking or using the product	28-Mar-2020
Give best estimate of duration	

Is therapy still on-going?	Yes
Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1	
Rheumatoid arthritis	

Section C - About the Products 2 of 2

Suspect	Yes
Primary?	
Type	Drug/Biologic
This report is about	Drug
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Orencia
Name of the company that makes (or compounds) the product	(b) (6)
Product Type(check all that apply)	☐ Over-the-Counter ☒ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar
Strength	125 mg milligram(s) If Other
NDC number	000-2188-51
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
Did the problem return if the person started taking or using the product again?	Doesn't Apply

Drug Therapy 1 of 1

Expiration date	27-Feb-2021
Lot number	Abj7291
Dosage Form	
Quantity	Other If Other 1 Injection(s)
Frequency	Other If Other Once a week
How was it taken or used	Intramuscular If Other
Date the person first started taking or using the product	27-Feb-2020
Date the person stopped taking or using the product	26-Mar-2020
Give best estimate of duration	
Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

Rheumatoid arthritis	

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Male
Age (specify unit of time for age)	61 Year(s)
Date of Birth	
Weight	86.4 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☒ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

High blood pressure, 3 stints in my heart, type 2 diabetic, asthma, copd, nerve damage in neck and both arms, and migraines

Please list all allergies (such as to drugs, foods, pollen or others)

Penicillin

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

5 cigarettes a day, no alcohol use, no street drugs

List all current prescription medications and medical devices being used.

To many to list, but heart meds, diabetes meds, inhalers, and a med for migraines.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

Today's date	29-Mar-2020	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	29-Mar-2020	CTU Received Date	29-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem	
What kind of problem was it? (Check all that apply)	☐ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☒ Had problems after switching from one product maker to another maker
Date the problem occurred	29-Mar-2020
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☒ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4. Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I used to have name brand plaquenil for systemic connective disease. It was on hold mid February then switched to generic. I received a white oblong pill that said AC38 which is from Dr. Reddy's pharm. my problem I started the pill a few weeks ago and as time is going on I have increasingly been experiencing joint pain and this morning my entire body was stiff and joints are sore. I am complaining because either the med has less efficacy or it is a placebo that was given due to shortage. I would have rather been told it was a shortage so I could get something else on top like prednisone. I do not want biologics yet and I did need them because I was stable on plaquenil. I thought generics were supposed to be just as effective as name brand! I will be saving a pill or 2 for testing if the FDA needs it.

Relevant Test/Laboratory Data				1 of 1
Test Name		Test Date		
Test Result		Test Unit		
Low Test Range		High Test Range		

More Information Available?	

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report is about	Drug
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Hydroxychloroquine 200mg tab
Name of the company that makes (or compounds) the product	Dr. reddy's lab
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☒ Generic ☐ Biosimilar
Strength	If Other
NDC number	
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No
Did the problem return if the person started taking or using the product again?	No

Drug Therapy 1 of 1

Expiration date	
Lot number	
Dosage Form	
Quantity	If Other
Frequency	If Other
How was it taken or used	If Other
Date the person first started taking or using the product	04-Mar-2020
Date the person stopped taking or using the product	

Give best estimate of duration	
Is therapy still on-going?	Yes
Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1	
Systemic connective tissue disease	

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Gender	Female
Age (specify unit of time for age)	39 Year(s)
Date of Birth	
Weight	83.25 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☒ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

Iron deficiency, vitamin d deficiency, systemic connective disease, GERD, osteoarthritis, allergies

Please list all allergies (such as to drugs, foods, pollen or others)

Cats, mold, pollen, dilaudid

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

None

List all current prescription medications and medical devices being used.

Omeprazole, hydroxychloroquine, clarinex

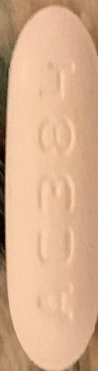
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

turmeric, iron, MVI, vitaminD3, Aleve prn Tylenol prn, pseudoephedrine Cvs brand and guaifenesin Cvs brand prn

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	(b) (6)
City	(b) (6)
State/Province	(b) (6)
Country	UNITED STATES
ZIP or Postal code	(b) (6)
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	
Department	
Reporter Speciality	

Today's date	29-Mar-2020	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	



All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Urgent		
Override Auto Calculation Rule	No		
FDA Received Date	31-Mar-2020	CTU Received Date	31-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	(b) (6)

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b) (6)
Age	41 Year(s)
Date of Birth	
Gender	Male
Weight	143 kg
Ethnicity (Check single best answer)	Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	☒ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☒ Death ☐ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	(b) (6)

Date of Event	29-Mar-2020
Date of this Report	31-Mar-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient with no PMH admitted to ICU with COVID19 pneumonia, intubated, in ARDS and renal failure. Received 5 days of hydroxychloroquine (200 mg TID) last dose on (b) (6). He also received 7 days of ceftriaxone 2 g IV q 24 hours and doxycycline 100 mg BID for community acquired pneumonia. Prior to starting hydroxychloroquine, he had a baseline EKG of 472 on (b) (6). On (b) (6) he went into VTach, then PEA arrest, and was unable to be resuscitated.

Relevant Test/Laboratory Data 1 of 2

Test Name	POTASSIUM	Test Date	(b) (6)
Test Result	5.6	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	MAGNESIUM	Test Date	(b) (6)
Test Result	3.2	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

obesity

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 9

Suspect	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	Yes
Type	Drug/Biologic

Product Name	Hydroxychloroquine		
Strength	200 mg milligram(s)	If Other	
Manufacturer/Compounder			
NDC# or Unique ID	00781140797		
Product Type(check all that apply)	☐ OTC ☐ Compounded ☒ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply		
Event Reappeared after Reintroduction ?	Doesn't Apply		

Drug Therapy 1 of 1

Dose or Amount	200 mg milligram(s)	If Other	
Frequency	3 times a day	If Other	
Route	Oral	If Other	
Dosage Form			
Start			
Stop			
Therapy Duration	5 Day	If Other	
Is therapy still on-going?	No		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 2 of 9

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	Acetaminophen		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			

Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 3 of 9

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	Ceftriaxone		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	

Is therapy still on-going?		
Lot Number		
Expiration Date		

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 4 of 9

Concomitant	Yes	
Does this report involve cosmetic, dietary supplement or food/medical food?		
Primary?		
Type	Drug/Biologic	
Product Name	Cisatricurium	
Strength		If Other
Manufacturer/Compounder		
NDC# or Unique ID		
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar	
Event Abated After Use Stopped or Dose Reduced?		
Event Reappeared after Reintroduction ?		

Drug Therapy 1 of 1

Dose or Amount		If Other
Frequency		If Other
Route		If Other
Dosage Form		
Start		
Stop		
Therapy Duration		If Other
Is therapy still on-going?		
Lot Number		
Expiration Date		

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 5 of 9

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	doxycycline		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 6 of 9

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	fentanyl		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			

Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 7 of 9

Concomitant	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	
Type	Drug/Biologic
Product Name	heparin
Strength	
Manufacturer/Compounder	
NDC# or Unique ID	
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	

Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 8 of 9

Concomitant	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	
Type	Drug/Biologic
Product Name	pantoprazole
Strength	
Manufacturer/Compounder	
NDC# or Unique ID	
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 9 of 9

Concomitant	Yes	
Does this report involve cosmetic, dietary supplement or food/medical food?		
Primary?		
Type	Drug/Biologic	
Product Name	midazolam	
Strength		If Other
Manufacturer/Compounder		
NDC# or Unique ID		
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar	
Event Abated After Use Stopped or Dose Reduced?		
Event Reappeared after Reintroduction ?		

Drug Therapy 1 of 1

Dose or Amount		If Other
Frequency		If Other
Route		If Other
Dosage Form		
Start		
Stop		
Therapy Duration		If Other
Is therapy still on-going?		
Lot Number		
Expiration Date		

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	

City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last Name	(b) (6)
Middle Name	
First Name	(b) (6)
Address	(b) (6)
City	(b) (6)
State/Province/Region	(b) (6)
Country	UNITED STATES If Other
ZIP/Postal Code	(b) (6)
Phone	(b) (6)
Email	(b) (6)
Fax	
Reporter Organization	

Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Pharmacist	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes		

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	30-Mar-2020	CTU Received Date	30-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b) (6)
Age	87 Year(s)
Date of Birth	
Gender	Male
Weight	84.5 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☒ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	☒ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☒ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage

Date of Death	
Date of Event	27-Mar-2020
Date of this Report	30-Mar-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Report from Clinical Pharmacist: QTc increased from 397 on (b) (6) at 2240 to 468 on (b) (6) at 0453, which is a >15% increase leading to increased EKG monitoring. Chart review: Admitted: (b) (6) Expired: (b) (6) Weight: 84.5 kg Height: 69 inches CrCL: 12 mL/min COVID positive test: (b) (6) Home medications: ? Amlodipine 5 mg daily ? Atenolol 100 mg daily ? Atorvastatin 40 mg nightly ? Chlorthalidone 25 mg daily ? Furosemide 20 mg daily prn swelling of legs ? Loratadine 10 mg daily ? Losartan 50 mg dily ? Meclizine 25 mg three a day as prn for dizziness ? TiZANidine 4 mg q6 hrs prn muscle spasms Information from H&P: pleasant 87 y.o. old male with CAD, HTN, history of prostate cancer, CKD stage III who presented to the CHE ED with complaints of malodorous urine. He has had prior hx UTIs. He also complains of mild cough. He denies known ill contacts. He denies myalgias. Further history is limited; pt is a poor historian. ED course: vancomycin, meropenem, 900 ml LR bolus ? Hydroxychlorquine: 400 mg given (b) (6) at 1817, (b) (6) at 0951 ? Hydroxychlorquine: 200 mg given (b) (6) at 1648, (b) (6) at 0936 and 1750, missed both doses on (b) (6) (RN comments state pt on bipap); (b) (6) at 0829 ? One dose of azithromycin 250 mg tablet given (b) (6) at 0830 No treatment of QTc prolongation noted in chart

Relevant Test/Laboratory Data 1 of 1

Test Name	Test Date
Test Result	Test Unit
Low Test Range	High Test Range
More Information Available?	

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 2

Suspect	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	Yes
Type	Drug/Biologic
Product Name	hydrochlorquine

Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start	24-Mar-2020		
Stop	28-Mar-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

COVID-19	

D. PRODUCT(S) 2 of 2

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	azithromycin 250 mg tablet		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start	27-Mar-2020		
Stop	27-Mar-2020		
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION	

G. REPORTER		1 of 1	
Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b) (6)		
Middle Name			
First Name	(b) (6)		
Address	(b) (6)		
City	(b) (6)		
State/Province/Region	(b) (6)		
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b) (6)		
Phone	(b) (6)		
Email	(b) (6)		
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Pharmacist	If Other	
Also Reported to	☐ Manufacturer/Compounder ☒ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No		

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	31-Mar-2020	CTU Received Date	31-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	(b) (6)

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b) (6)
Age	85 Year(s)
Date of Birth	
Gender	Male
Weight	84 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☒ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	☒ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☒ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☐ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	

Date of Event	31-Mar-2020
Date of this Report	31-Mar-2020

Describe Event, Problem or Product Use Error	
Describe Event, Problem, or Product Use Error: Plaquenil along with azithromycin caused wide complex tachycardia in this patient and another patient - both with COVID confirmed dx - wish FDA to retract EUA for this combination for this combination	

Relevant Test/Laboratory Data				1 of 1
Test Name	COVID-19	Test Date	(b) (6)	
Test Result	positive	Test Unit		
Low Test Range		High Test Range		
More Information Available?				

Additional Comments	
pcr positive	

Other Relevant History, Including Preexisting Medical Conditions	
MS-underlying pulmonary fibrosis and CB-hypertension	

C. PRODUCT AVAILABILITY	
Product Available for Evaluation? (Do not send product to FDA)	Yes
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S)			1 of 2
Suspect	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?	Yes		
Type	Drug/Biologic		
Product Name	Plaquenil 400mg load then 200 mg BID		
Strength	400 mg milligram(s)	If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded		

	☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	Yes
Event Reappeared after Reintroduction ?	No

Drug Therapy 1 of 1

Dose or Amount	400 mg milligram(s)	If Other	
Frequency	Other	If Other	Load - then 200mg
Route	Oral	If Other	
Dosage Form			
Start	24-Mar-2020		
Stop	31-Mar-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

covid 19 treatment but family wants the pt to recieve this d

D. PRODUCT(S) 2 of 2

Concomitant	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	azithromycin		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			

Start	24-Mar-2020		
Stop	28-Mar-2020		
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER		1 of 1	
Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b) (6)		
Middle Name			
First Name	(b) (6)		
Address	(b) (6)		
City	(b) (6)		
State/Province/Region	(b) (6)		
Country	UNITED STATES	If Other	
ZIP/Postal Code	(b) (6)		
Phone	(b) (6)		
Email	(b) (6)		
Fax			
Reporter Organization			
Department			
Reporter Speciality			
Health Professional?	Yes		
Occupation	Physician	If Other	
Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No		

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	31-Mar-2020	CTU Received Date	31-Mar-2020
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☒ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact				
Case Reporter	First Name	Last Name	Email Address	Phone
☒	(b) (6)	(b) (6)	(b) (6)	

A. PATIENT INFORMATION	
Patient Identifier (In Confidence)	(b) (6)
Age	61 Year(s)
Date of Birth	
Gender	Male
Weight	95.9 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☒ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM	
Type of Report (check all that apply)	☒ Adverse Event ☐ Product Use/Medication Error ☐ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☒ Life Threatening ☐ Hospitalization (initial or prolonged) ☐ Other Serious or Important Medical Events ☒ Disability or Permanent Damage ☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage

Date of Death		
Date of Event	22-Mar-2020	
Date of this Report	31-Mar-2020	

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Reported on 3.27 by clinical pharmacist -Pt admitted: (b) (6) -BMI: 182.9 -ht: 6 ft -CrCl: 31.3 mL/min -Pt expired on (b) (6) discharge summary states "Patient died while hospitalized for pneumonia, and was found to be COVID19 positive. Preliminary cause of death viral pneumonia from COVID19." -PTA Med List: allopurinol 300 mg daily amiodrone 200 mg every other day amlodipine 10 mg daily aspirin 81 mg daily carvedilol 25 g daily clopidogrel 75 mg daily fluticasone one spray each nostril daily hydralazine 25 mg three times a day hydrocodone/apap 5/325 one table q6 hrs prn pain isosorbide dinitrate 20 mg three times a day levetiracetam 1000 mg twice a day levothyroxine 50 mcg daily metolazone 1.25 mg prn CHF multivitamin daily pravastatin 40 mg dadily ranitidine 150 mg twice a day sertraline 50 mg daily Tamsulosin 0.4 mg daily torsemide 40 mg daily report from clinical pharmacist states "COVID patient QTc of 624 from 541" MAR states: -Plaquenil 400 mg: (b) (6) at 0818 and 1711 -abx: vanc and cefepime

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 1

Suspect	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	Yes
Type	Drug/Biologic
Product Name	plaquenil
Strength	If Other
Manufacturer/Compounder	

NDC# or Unique ID	
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	
If Implanted, Give Date	
If Explanted, Give Date	

Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes	
Reporter is Patient?		
Title		
Last Name	(b) (6)	
Middle Name		
First Name	(b) (6)	
Address	(b) (6)	
City	(b) (6)	
State/Province/Region	(b) (6)	
Country	UNITED STATES	If Other
ZIP/Postal Code	(b) (6)	
Phone	(b) (6)	
Email	(b) (6)	
Fax		
Reporter Organization		
Department		
Reporter Speciality		
Health Professional?	Yes	
Occupation	Pharmacist	If Other
Also Reported to	☐ Manufacturer/Compounder ☒ User Facility ☐ Distributor/Importer	
If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

Printer: CDPEDQ5

User: STEPPERH

Date - Time: 11-May-2020 03:24 PM

Total Number of Cases: 1

Total Number of Pages: 7

Print Job Number: 22100

Disclaimers:

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

Please Note: Even though the attachments cover page may cite a particular image, there may be some exceptions where attachments will print without a case ID identifier because of font or text irregularities. Also similar literature attachments may appear numerous times because they had been submitted under multiple image or electronic case submissions.

Processed Case Id's for Attachments:

17412097

Failed Case Id's for Attachments:

Total Failed Cases: 0

Zydus Pharmaceuticals, Inc.

Adverse Event Worksheet

Case ID#: ZYD-20-AE-179

 Serious Non-serious Expected Unexpected

TMAC receipt date: 2/10/2020

Safety receipt date: 2/10/2020

Product InformationDrug name: hydroxychloroquine sulfate
tablets

Strength: 200 mg

Dose: 200 mg

Frequency: Twice daily

Indication: Rheumatoid arthritis

Lot: Z903866

Exp: 08/31/2021

Drug Start: 02-Feb-2020

Drug Stop: 04-Feb-2020

Confirmed Zydus product? Yes NoSample available? Yes No

Product imprint: UNK

Has patient used this product before? Yes No UnknownExperienced this AE(s) before? Yes No Unknown

Dose: 200 mg twice daily

Start: 02-Feb-2020

Stop: 04-Feb-2020

Reporter Information

Name: (b) (6)

Address: (b) (6)

City, State: (b) (6)

 Phone Fax Email Sales Rep. Other

Phone: (b) (6)

Zip: (b) (6)

Reporter Type: Consumer HCP Other

Relationship to Patient: Daughter

Reported to FDA: Yes No Unknown**Pharmacy Information** Reporter/patient declined to provide pharmacy information

Pharmacy: (b) (6)

Address: (b) (6)

City, State: (b) (6)

Employee: N/A

Phone: (b) (6)

Zip: (b) (6)

Patient Demography

Initials: (b) (6)

Age at time of event: 94 years

DOB: (b) (6)

 Male Female Pregnant Unknown**Concomitant Medications** Not reported N/A

Medication	Dose/frequency	Dates	Indication
albuterol	UNK/twice daily	UNK-Ongoing	UNK
Eliquis	UNK/UNK	UNK-Ongoing	UNK
aspirin	81 mg/ once daily	UNK-Ongoing	UNK
calcium	UNK/UNK	UNK-Ongoing	UNK

Zydus Pharmaceuticals, Inc.

Adverse Event Worksheet

Case ID#: ZYD-20-AE-179

vitamin D	UNK/UNK	UNK-Ongoing	UNK
carvedilol	12.5 mg/ twice daily	UNK-Ongoing	UNK
Claritin	10 mg/ once daily	UNK-Ongoing	UNK
erythromycin ointment	UNK/UNK	UNK-Ongoing	UNK
Evenity	UNK/UNK	UNK-Ongoing	Osteoporosis
Flonase	UNK/UNK	UNK-Ongoing	Sinusitis
folic acid	1 mg/ once daily	UNK-Ongoing	UNK
isosorbide	60 mg/ twice daily	UNK-Ongoing	UNK
levothyroxine	100 mcg/ once daily	UNK-Ongoing	UNK
warfarin	UNK/UNK	UNK-Ongoing	UNK
Plavix	UNK/UNK	UNK-Ongoing	UNK
Lipitor	UNK/UNK	UNK-Ongoing	UNK

Medical History

Rheumatoid arthritis, Osteoporosis, Atrial fibrillation, Sinusitis, Pulmonary fibrosis

Drug Allergies

Acyclovir, amlodipine, penicillin, allopurinol, amoxicillin, clindamycin, doxycycline, Levaquin, spironolactone, Fosamax, furosemide, lisinopril, sulfa, torsemide (Reactions: UNK)

Relevant Tests

(b) (6) Echocardiogram (Results: UNK)

Treatment

(b) (6) administered heparin in hospital

Adverse Event Narrative

On 10-Feb-2020, Zydus Pharmaceuticals was contacted via phone by a daughter on behalf of a currently 94-year-old female consumer (initials: (b) (6) DOB: (b) (6)) regarding adverse events she experienced while taking Zydus hydroxychloroquine sulfate 200 mg tablets. The reporter identified the following lot and expiry (lot: Z903866, exp: 08/31/2021). She agreed to submit a product sample for investigation, and sample retrieval was sent via FedEx on 10-Feb-2020. Her medical history is significant for rheumatoid arthritis, osteoporosis, atrial fibrillation, sinusitis, and pulmonary fibrosis. She has known drug allergies to Acyclovir, amlodipine, penicillin, allopurinol, amoxicillin, clindamycin, doxycycline, Levaquin, spironolactone, Fosamax, furosemide, lisinopril, sulfa, torsemide (reactions: UNK). She concomitantly takes the following medications (therapy dates: UNK - ongoing): albuterol twice daily, Eliquis, aspirin 81 mg once daily, calcium, vitamin D, carvedilol 12.5 mg twice daily, Claritin 10 mg once daily, erythromycin ointment, Evenity for osteoporosis, Flonase for sinusitis, folic acid 1 mg once daily, isosorbide 60 mg twice daily, levothyroxine 100 mcg once daily, warfarin, Plavix, and Lipitor. On 02-Feb-2020, she started therapy with Zydus hydroxychloroquine 200 mg sulfate tablets, one tablet by mouth twice daily for rheumatoid arthritis. On 03-Feb-2020, she began to experience dizziness

Zydus Pharmaceuticals, Inc.

Adverse Event Worksheet

Case ID#: ZYD-20-AE-179

(Dizziness). On ^{(b) (6)} she was hospitalized due to a cardiac event (Acute cardiac event). On ^{(b) (6)} she discontinued therapy with Zydus hydroxychloroquine 200 mg tablets. On an unknown date in ^{(b) (6)} while hospitalized, she was administered heparin. On an unknown date in ^{(b) (6)} while hospitalized, she underwent an echocardiogram (result: UNK). On ^{(b) (6)} she was discharged. Her daughter reports that the rheumatoid arthritis physician stated, 'it is not related to the medication.' On an unknown future date in ^{(b) (6)} her adverse events resolved. At the time of this report, she no longer takes the suspect medication and the outcomes of the adverse events remain resolved. No additional information was provided. External reference number: ZYD-20-AE-179.

AE Term: dizziness (Dizziness: expected)

Serious #: Non-serious Onset Date: 03-Feb-2020 Resolution Date: Feb-2020

Event abated after use stopped or dose reduced? Yes No N/A

Event reappeared after reintroduction? Yes No N/A

AE Term: cardiac event (Acute cardiac event: unexpected)

Serious #: 3 Non-serious Onset Date: 04-Feb-2020 Resolution Date: Feb-2020

Event abated after use stopped or dose reduced? Yes No N/A

Event reappeared after reintroduction? Yes No N/A

Serious Outcome Criteria: (enter number in space above)

1-Fatal 2-Life threatening 3-Hospitalization (initial or prolonged) 4-Significant or Persistent disability
5-Congenital Anomaly 6-Required intervention to prevent permanent impairment damage
7-Important medical event

Prescriber Information

Name: UNK

May we contact: Yes No

Address: UNK

Phone: UNK

Please enter any additional relevant information before signing: N/A

Do you consider these events attributable to ...?

Probably/possibly related Unlikely/Unrelated Related to another medical condition

Document History Original Transcribed

Reporter Signature: ^{(b) (6)}

Date: _____

Drug Safety Associate

Date: 11-Feb-2020

Zydus Pharmaceuticals, Inc.

Adverse Event Worksheet

Case ID#: ZYD-20-AE-179

Sample Retrieval N/A

Initials/Date/Time	Method of Attempt	Comments
(b) (6) 10-Feb-2020	☒ Phone ☐ Email ☐ Letter ☐ Fax	The reporter agreed to submit a product sample for investigation, and sample retrieval was sent via FedEx on 10-Feb-2020.
	☐ Phone ☐ Email ☐ Letter ☐ Fax	
	☐ Phone ☐ Email ☐ Letter ☐ Fax	

*If an address is available, the final attempt MUST be a letter.

Lot Retrieval N/A

Initials/Date/Time	Method of Attempt	Comments
(b) (6) 10-Feb-2020	☒ Phone ☐ Email ☐ Letter ☐ Fax	The reporter identified the following lot and expiry (lot: Z903866, exp: 08/31/2021).
	☐ Phone ☐ Email ☐ Letter ☐ Fax	
	☐ Phone ☐ Email ☐ Letter ☐ Fax	

*If an address is available, the final attempt MUST be a letter.

Follow Up N/A

Initials/Date/Time	Method of Attempt	Comments
	☐ Phone ☐ Email ☐ Letter ☐ Fax	
	☐ Phone ☐ Email ☐ Letter ☐ Fax	
	☐ Phone ☐ Email ☐ Letter ☐ Fax	
	☐ Phone ☐ Email ☐ Letter ☐ Fax	
	☐ Phone ☐ Email ☐ Letter ☐ Fax	

*If an address is available, the final attempt MUST be a letter.

*All 15-day cases MUST be documented with three phone call attempts followed by a written request. If no response is received within one week, a second written request MUST be mailed via FedEx.



February 10, 2020

(b) (6)

Re: Hydroxychloroquine
Reference #: ZYD-20-AE-179

Dear (b) (6)

Thank you for recently contacting Zydus Pharmaceuticals regarding our product, Hydroxychloroquine. We have included a FedEx envelope with paid postage for return of the product sample. **Please insert the product sample in its original bottle into the FedEx envelope and return it for investigation.**

We greatly appreciate your assistance, and you will be notified of the results of the investigation. If you need further assistance, please call (b) (6) option 2, Monday through Friday (9am - 5pm EST).

Sincerely,

(b) (6)

(b) (6)

Drug Safety Associate
Zydus Pharmaceuticals, Inc.

**Office of Regulatory Affairs
Zydus Pharmaceuticals (USA) Inc.**

73 Route 31 North • Pennington, NJ 08534

Ph. 609-730-1900 (Ext: 110) • Fax 609-730-1999 • www.zydususa.com

ORIGIN ID: NCOA (b) (6)
THE MEDICAL AFFAIRS COMPANY
125 TOWNPARK DRIVE, SUITE 190

SHIP DATE: 10FEB20
ACTWGT: 1.00 LB
CAD: 110692431/INET4220

KENNESAW, GA 30144
UNITED STATES US
TO (b) (6)

BILL THIRD PARTY

568J20495FEFA

INV (b) (6) REF (b) (6)
PO DEPT



TUE - 11 FEB 8:00P
STANDARD OVERNIGHT

TRK# (b) (6)
0201

RES (b) (6)

XH CVGA
(b) (6)

(b) (6) US CVG



After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

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ORIGIN ID (b) (6) (b) (6)
(b) (6)

SHIP DATE: 10FEB20
ACTWGT: 3.00 LB
CAD: 110692431/NET4220

UNITED STATES US
TO (b) (6)

ZYDUS PHARMACEUTICALS USA INC.
73-B, ROUTE 31 NORTH

PENNINGTON NJ 08534

INV. (b) (6) REF (b) (6)
PO DEPT

56BL0049EFE4A



RETURNS MON-FRI
PRIORITY OVERNIGHT

TRK# (b) (6)
0221

(b) (6)

(b) (6)
(b) (6) US

1. Select the 'Print' button to print 1 copy of each label.
2. The Return Shipment instructions, which provide your recipient with information on the returns process, will be printed with the label (s)
3. After printing, select your next step by clicking one of the displayed buttons.

Note: To review or print individual labels, select the Label button under each label image above.

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