FDA Adverse Event Reporting System (FAERS)

FOIA Case Report Information

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.

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:

17644417 17646286 17646292 17685979

Run by: **STEPPERH**

Date - Time: **16-JUL-2020 12:02 PM**

Total number of cases (Esub): **4**

Total number of inactive cases: **0**

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17644417

Case Information:

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

FDA Rcvd Date: 08-Apr-2020 **Mfr Rcvd Date:** 01-Apr-2020 **Mfr Control #:** US-ADVANZ PHARMA-202003002359 **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				UNK			
2	azithromycin				UNK			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine		NA	NA				CONCORDIA	
2	azithromycin		NA	NA					

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
Sudden death	NA
Ventricular fibrillation	NA

Case ID: 17644417

Event/Problem Narrative:

Case number 202003002359 is a spontaneous case (reference ID: 1-2184819976 (1)) sent by physician on 01/Apr/2020.

This is one of the linked case and linked to 202003002360 and 202003002361.

Information was received via other source under principles of good pharmacovigilance practices regarding a patient of an unknown demographics who experienced ventricular fibrillation and sudden death from receiving hydroxychloroquine and azithromycin following treatment with Hydroxychloroquine and Azithromycin.

The patient's medical history and the historical medications was not reported.

The patient's co-morbid conditions was not reported.

The patient's concomitant medications were not reported.

The patient's laboratory tests were not reported.

Cause of death included sudden death from receiving hydroxychloroquine and azithromycin.

Reporter assessed this weekend 3 patients for ventricular fibrillation and sudden death from receiving hydroxychloroquine and azithromycin. The evidence for any therapy against COVID was so far limited based on small, non-randomized studies. Reporter advised to gave hydroxychloroquine and /or azitre, please, it was on the recommendation of an infectologist or internist and make sure that all patients had a previous electrocardiogram and the following two days after its administration. Both medications prolong QT and promote ventricular arrhythmias. Did not gave it with corrected base QT greater than 450 ms, and discontinue use if the QT was prolonged more than 25% baseline. If necessary, asked for help to had someone evaluate the electrocardiograms.

At the time of this report, the outcome of the event ventricular fibrillation was unknown and fatal for sudden death from receiving hydroxychloroquine and azithromycin. The action taken with Hydroxychloroquine and Azithromycin was unknown.

De-challenge and re-challenge result was not applicable for the event with respect to Hydroxychloroquine and Azithromycin.

This case is considered to be serious due to seriousness criteria death and other important medical significant for the event sudden death from receiving hydroxychloroquine and azithromycin and other medically significant for ventricular fibrillation.

The reporter did not provide any causality assessments.

Query mail was sent to other source regarding onset date of event and start date of company suspect drug. So that estimated date can be

Case ID: 17644417

calculated.

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

Reporter Source:

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

Case ID: 17644417

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17646286

Case Information:

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

FDA Rcvd Date: 08-Apr-2020 **Mfr Rcvd Date:** 01-Apr-2020 **Mfr Control #:** US-ADVANZ PHARMA-202003002360 **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				UNK			
2	azithromycin				UNK			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine		NA	NA				CONCORDIA	
2	azithromycin		NA	NA					

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
Sudden death	NA
Ventricular fibrillation	NA

Case ID: 17646286

Event/Problem Narrative:

Case number 202003002360 is a spontaneous case (reference ID: 1-2184819976 (2)) sent by physician on 01/Apr/2020.

This is one of the linked case and linked to the case 202003002359 and 202003002361.

Information was received via other source under principles of good pharmacovigilance practices regarding a patient of an unknown demographics who experienced ventricular fibrillation and sudden death from receiving hydroxychloroquine and azithromycin, following treatment with Hydroxychloroquine and Azithromycin.

The patient's medical history and the historical medications was not reported.

The patient's co-morbid conditions was not reported.

The patient's concomitant medications were not reported.

The patient's laboratory tests were not reported.

The patient's cause of death included sudden death from receiving hydroxychloroquine and azithromycin.

Reporter assessed this weekend three patients for ventricular fibrillation and sudden death from receiving hydroxychloroquine and azithromycin. The evidence for any therapy against COVID was so far limited based on small, non-randomized studies. Reporter advised to gave hydroxychloroquine and /or azitre on the recommendation of an infectologist or internist and make sure that all patients had a previous electrocardiogram and the following two days after its administration. Both medications prolong QT and promote ventricular arrhythmias. Did not gave it with corrected base QT greater than 450 ms, and discontinued the use if the QT was prolonged more than 25% baseline. If necessary, asked for help to had someone evaluate the electrocardiograms.

At the time of this report, the outcome of the event ventricular fibrillation was unknown and fatal for sudden death from receiving hydroxychloroquine and azithromycin. The action taken with Hydroxychloroquine and Azithromycin was unknown.

De-challenge and rechallenge result was not applicable for the event with respect to Hydroxychloroquine and Azithromycin.

This case is considered to be serious due to seriousness criteria death and other important medical significant for the event sudden death from receiving hydroxychloroquine and azithromycin and medically significant for ventricular fibrillation.

The reporter did not provide any causality assessments.

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FOIA Case Report Information

Case ID: 17646286

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

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: 17646292

Case Information:

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

FDA Rcvd Date: 08-Apr-2020 **Mfr Rcvd Date:** 01-Apr-2020 **Mfr Control #:** US-ADVANZ PHARMA-202003002361 **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				UNK			
2	azithromycin				UNK			

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Hydroxychloroquine		NA	NA				CONCORDIA	
2	azithromycin		NA	NA					

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
Sudden death	NA
Ventricular fibrillation	NA

Case ID: 17646292

Event/Problem Narrative:

Case number 202003002361 is a spontaneous case (reference ID: 1-2184819976 (3)) sent by physician on 01/Apr/2020.

This is one of the linked case and linked to the case 202003002359 and 202003002360.

Information was received via other source under principles of good pharmacovigilance practices regarding a patient of an unknown demographics who experienced ventricular fibrillation and sudden death from receiving hydroxychloroquine and azithromycin following treatment with Hydroxychloroquine and Azithromycin.

The patient's medical history and the historical medications was not reported.

The patient's co-morbid conditions was not reported.

The patient's concomitant medications were not reported.

The patient's laboratory tests were not reported.

The patient's cause of death included sudden death from receiving hydroxychloroquine and azithromycin.

Reporter assessed this weekend 3 patients for ventricular fibrillation and sudden death from receiving hydroxychloroquine and azithromycin. The evidence for any therapy against COVID was so far limited based on small, non-randomized studies. Reporter advised to gave hydroxychloroquine and /or azitre on the recommendation of an infectologist or internist and make sure that all patients had a previous electrocardiogram and the following two days after its administration. Both medications prolong QT and promote ventricular arrhythmias. Did not gave it with corrected base QT greater than 450 ms, and discontinued the use if the QT was prolonged more than 25% baseline. If necessary, asked for help to had someone evaluate the electrocardiograms.

At the time of this report, the outcome of the event ventricular fibrillation was unknown and fatal for sudden death from receiving hydroxychloroquine and azithromycin. The action taken with Hydroxychloroquine and Azithromycin was unknown.

De-challenge and re-challenge result was not applicable for the event with respect to Hydroxychloroquine and Azithromycin.

This case is considered to be serious due to seriousness criteria death and other important medical significant for the event sudden death from receiving hydroxychloroquine and azithromycin and medically significant for ventricular fibrillation.

The reporter did not provide any causality assessments.

A query mail was sent to the business partner regarding the onset date of event and start date of suspect drug. So that estimated date can be

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calculated.

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

Reporter Source:

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

Case ID: 17646292

Literature Text:

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17685979

Case Information:

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

FDA Rcvd Date: 15-Jun-2020 **Mfr Rcvd Date:** 04-Jun-2020 **Mfr Control #:** US-ALEXION-A202005121 **Application #:** 125166

Patient Information:

Age: 44 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name	Compounded Drug ?	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	SOLIRIS 300mg		900 MG/	Intravenous (not otherwise specified)	900 mg	COVID-19 treatment	23-Mar-2020	
2	HYDROXYCHLOROQUINE			Unknown	UNK	Systemic lupus erythematosus		28-Mar-2020
3	SOLIRIS 300mg		900 MG/	Intravenous (not otherwise specified)	900 mg		02-Apr-2020	
4	SOLIRIS 300mg		900 MG/	Intravenous (not otherwise specified)	900 mg	Off label use	27-Mar-2020	

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	SOLIRIS 300mg		Unk	NA				ALEXION	
2	HYDROXYCHLOROQUINE		NA	NA					
3	SOLIRIS 300mg		Unk	NA				ALEXION	
4	SOLIRIS 300mg		Unk	NA				ALEXION	

Event Information:

Preferred Term (MedDRA Version: 23.0)	ReC
COVID-19	NA
Normocytic anaemia	NA

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Off label use	NA

Event/Problem Narrative:

This is an off label use report, received from a physician via an Alexion employee on 05Apr2020 which described an off label use of Soliris (eculizumab) for the indication of Corona Virus infection (COVID-19). No adverse events were reported.

No additional information was requested as no further information was needed.

Follow up was received from a physician from the literature on 09 Apr 2020. This case was upgraded from non-serious to serious due to the event of normocytic anemia.

Journal: Hudson Medical
Author: Pitts Thomas C
Title: A Preliminary Update to The Soliris To Stop Immune Mediated Death in Covid-19 (SOLID-C19) Compassionate Use Study
Year: 2020 Pages:1-8 Vol: Unk

This is a literature report from United States.

Covid-19 has spread rapidly throughout the world causing widespread injury, and death. While this virus is the provocateur, it is often the patients own disproportionate immune response which likely deals the most devastating (and often fatal) damage. The Membrane Attack Complex (MAC) is a primary mediator of this catastrophic, immune mediated, end organ damage and is formed by the various components of the distal complement (C5-C9).The MAC is ordered to form and attack when C1q, a surveillance component of the complement system, surveys the antigen and calls upon its destruction even if the involvement of the membrane attack complex (MAC) causes the devastating destruction to the end organ within which the virus exists (the lungs). This mechanism has been shown to be a cause such damage in other types of coronaviruses. In the Solid-c19 compassionate use study, Soliris (eculizumab) was being used to modulate the activity of the distal complement by preventing the formation of membrane attack complex (MAC). By modulating this portion of the immune response, mortality can be halted while the patient had time to recover from the virus with supportive medical care. The proximal complement was left intact. The membrane attack complex primary role was to combat certain encapsulated bacteria, thus, its inhibition should stop immune mediated end organ destruction while not hindering viral fighting components of the immune system. This case demonstrates effective targeting of the distal complement to halt catastrophic complement mediated lung damage and acute respiratory distress syndrome (ARDS) in an intubated, covid-19 positive patient who was on hydroxychloroquine chronically for lupus in life-threatening condition.

This report refers to a 44 year old female patient.

Medical history included Covid-19, lupus, possible lupus flare complaining of intermittent fever, cough, generalized myalgias including chest

discomfort when breathing, dyspnea when laying supine, crackles, rhonchi in the left upper lung were noted on physical exam, left midlung disease speculated to be a developing pneumonia, exposed to covid-19 positive patients, worsened dyspnea, lightheadedness, rhonchi, left midlung disease, fever of 38.8 C, admitted to the hospital, worsening dyspnea, fever rose to 39 C, intubated and transferred to the intensive care unit, progression of the bilateral lung disease consistent with acute respiratory distress syndrome (ARDS), superimposed bilateral pulmonary edema, a generalized seizure, hypoxia, desaturation of her oxygen /intermittent desaturations while supine despite mechanical ventilation. Vaccination history included seroB and quadrivalent meningococcal vaccines administered on 23 Mar 2020. Historical drugs included mycophenolate mofetil, prednisone, furosemide, piperacillin/tazobactam and doxycycline. Concomitant medication included norepinephrine, Rocephin (ceftriaxone), ceftriaxone, azithromycin, propofol, fentanyl, and midazolam. Patient allergies were not reported.

Laboratory test results prior to Soliris included: noticed some crackle when she listened to her own lungs, rhonchi in the left upper lung were noted on physical exam, rapid flu and urine test were normal, chest x-ray showed left midlung disease, Covid-19 testing, electrocardiogram was normal, chest x-ray showed mild to moderate bibasilar opacities, oxygen saturation was 88 % during this evaluation on room air and she had a fever of 38.8 C, CT PE (computerized tomography pulmonary embolism) study was obtained and remonstrated the bibasilar opacities and was negative for pulmonary embolism, fever rose to 39 C, at the time of intubation her blood pressure was 84/45, respiratory rate was 43/min, repeat chest x-ray after intubation showed significant progression of the bilateral lung disease consistent with acute respiratory distress syndrome (ARDS), CRP (C reactive protein) at the time of intubation was 33.7, flu and RSV (respiratory syncytial virus)were negative, desaturation of her oxygen, PaO2 was 71, SPO2 rose to 95%, chest Xray obtained remonstrated findings consistent with severe ARDS with superimposed bilateral pulmonary edema and Murray score was 13/16 prior to the first dose.

On 23 Mar 2020, the patient initiated treatment with Soliris (eculizumab) at a dose of 900 mg via intravenous (IV) route over 35 minutes for each dose at unspecified frequency for Coronavirus infection (COVID-19) (OFF LABEL USE). On an unspecified date, the patient initiated treatment with co-suspect hydroxychloroquine at unspecified dose, route and frequency for lupus. Soliris lot/batch number and expiration date were not reported but will be requested once consent is confirmed. The most recent dose of Soliris administered prior to the onset of the events was not reported.

On 23 Mar 2020, within 4 hours after the first dose of eculizumab her chest x ray improved, and her Murray score improved from 13 to 10. She had a daily improvement in Murray score except on 27 March 2020 when her endotracheal tube moved out of place while she was prone and had to be readjusted in which case her Murray score rose slightly but still remained lower than her pre-trial baseline. Another 900 mg IV eculizumab dose was given 4 days after the first dose and, again, her chest x-ray improved. Her hydroxychloroquine was stopped on 28 March 2020 due to possible contribution to a normocytic anemia (NORMOCYTIC ANAEMIA). Norepinephrine was discontinued on 29 March 2020 as her blood pressor stabilized. The patient was able to be adequately oxygenated in the supine position and her rotabed was discontinued on 31 March 2020. On 02 April 2020 her third dose of eculizumab 900mg IV was given and her Murray score improved from 8/16 on 01 April 2020 to 6/16 recorded 7 hours after the third dose of eculizumab was given on 02 April 2020. On 03 April 2020 the medical critical care team started to wean the patients sedation (propofol, fentanyl, and midazolam). The patient passed a 30 spontaneous breathing trial and followed appendicular commands on 04 April 2020. Mechanical ventilation was continued to allow the sedation to fully wear off in preparation for extubation. The patient's Murray score had decreased to 3/16, she was able to oxygenate in the supine position, remained afebrile, and did

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not require presser medications. She was successfully extubated on 05 April 2020. She was neurologically intact and even face-timed on the phone with family a few hours subsequent to extubation.

No other clinical details reported. Treatment for the event of normocytic anemia was not reported. Action taken to Soliris in response to the events was not reported whereas hydroxychloroquine was withdrawn due to normocytic anemia. The outcome of the events was not reported.

The author provided the causality assessment of the event of normocytic anemia as not related to Soliris therapy but did not provide causality assessment of the event of off label use in relation to Soliris therapy. The author reported that hydroxychloroquine was stopped due to possible contribution to a normocytic anemia. No other possible etiological factors were reported.

Conclusion: Distal complement inhibition preventing formation of the membrane attack complex and was associated catastrophic end organ damage is a promising and relatively safe approach in covid-19 related cute respiratory distress syndrome. This was demonstrated in this 44-year-old patient with concomitant lupus who was intubated and did not improve despite being on hydroxychloroquine chronically or with the addition of azithromycin. After the administration of eculizumab the objective data shows a clear and sustained clinical improvement and preservation of life. The patient was successfully extubated.

Additional information will be requested, once consent is confirmed.

Publication attached.

Upon internal quality review by Alexion on 03-May-2020 the following changes were made to the database: Significant correction of the event from Coronavirus infection to Covid-19 and the indication of Soliris from Coronavirus infection to Covid-19 treatment.

Additional information will be requested once consent is provided

Follow-up information was received from an Alexion affiliate on 08-MAY-2020.
No new significant information was reported.

No furthe information has been requested since necessary follow-up attempts have been completed.

Follow-up information was received from an Alexion affiliate on 04-Jun-2020.

No new significant information was reported.

No additional information has been requested as no further information is required.

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Follow-up information was received from an Alexion affiliate on 04-Jun-2020.

On an unspecified date, the patient was discharged.

No additional information has been requested as no further information is required.

Company comment: 12-Jun-2020: This case is a Serious, medically confirmed, literature report of COVID-19 (H, MS), Off label use (H) and Normocytic anaemia (H). The events are not listed in the CCDS. The company considers the events as Not related to Soliris since the Off label use (H) was considered as an alternative for the COVID-19 (H, MS) that may be a cofounding factor for the Normocytic anaemia (H).

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Chest X-ray	Mar-2020		UNKNOWN
Chest discomfort	Mar-2020		UNKNOWN
Cough	Mar-2020		UNKNOWN
Critical illness	Mar-2020		UNKNOWN
Dyspnoea	Mar-2020		UNKNOWN
Lung disorder	Mar-2020		UNKNOWN
Mechanical ventilation	Mar-2020		UNKNOWN
Myalgia	Mar-2020		UNKNOWN
Pneumonia	Mar-2020		UNKNOWN
Pulmonary oedema	Mar-2020		UNKNOWN
Pyrexia	Mar-2020		UNKNOWN
Rales	Mar-2020		UNKNOWN
Sedative therapy	Mar-2020		UNKNOWN

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Seizure	Mar-2020		UNKNOWN
Systemic lupus erythematosus	Mar-2020		UNKNOWN
Chest X-ray	16-Mar-2020		UNKNOWN
Rhonchi	16-Mar-2020		UNKNOWN
Computerised tomogram	18-Mar-2020		UNKNOWN
Dizziness	18-Mar-2020		UNKNOWN
Dyspnoea	18-Mar-2020		UNKNOWN
Endotracheal intubation	18-Mar-2020		UNKNOWN
Hospitalisation	18-Mar-2020		UNKNOWN
Intensive care	18-Mar-2020		UNKNOWN
Chest X-ray	27-Mar-2020		UNKNOWN
Extubation	05-Apr-2020	05-Apr-2020	NO
Acute respiratory distress syndrome			
Antinuclear antibody positive			
COVID-19 treatment			
Exposure to SARS-CoV-2			
Hypoxia			
Oxygen saturation decreased			
Pyrexia			
Systemic lupus erythematosus			

Medical History Product(s)	Start Date	End Date	Indications	Events
MENINGOCOCCAL VACCINES	Mar-2020	Mar-2020	Immunisation	No adverse event
DOXYCYCLINE			Pneumonia	No adverse event

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MENINGOCOCCAL VACCINES	Mar-2020	Mar-2020	Immunisation	No adverse event
FUROSEMIDE			Pulmonary oedema	No adverse event
PIPERACILLIN AND TAZOBACTAM	18-Mar-2020	Mar-2020	Product used for unknown indication	No adverse event
PREDNISONE			Product used for unknown indication	No adverse event
MYCOPHENOLATE MOFETIL			Systemic lupus erythematosus	No adverse event

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Oxygen saturation	95	%	Not reported		N
Respiratory rate	43	/min	Not reported		N
Oxygen saturation	88	%	Not reported		N
PO2	71	%	Not reported		N
Body temperature	38.8	C	Not reported		N
Body temperature	39	C	Not reported		N

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event
1	AZITHROMYCIN		Unknown	UNK	Product used for unknown indication			
2	CEFTRIAXONE	2 MG/Q12H	Unknown	2 mg, q12h	Product used for unknown indication			
3	FENTANYL		Unknown	UNK	Sedative therapy			
4	MIDAZOLAM		Unknown	UNK	Sedative therapy			
5	NOREPINEPHRINE		Unknown	UNK	Product used for unknown indication	Mar-2020	29-Mar-2020	
6	PROPOFOL		Unknown	UNK	Sedative therapy			
7	ROCEPHIN		Unknown	UNK	Prophylaxis			

FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 17685979

Reporter Source:

Study Report?: No

Sender Organization: ALEXION

503B Compounding Outsourcing Facility?:

Literature Text: Pitts TC. A Preliminary Update to The Soliris To Stop Immune Mediated Death in Covid-19 (SOLID-C19) Compassionate Use Study. Hudson Medical. 2020;UNK:1-8

Printer: CDPEDQ5
User: STEPPERH
Date - Time: 16-Jul-2020 12:05 PM
Total Number of Cases (Non-Esub): 15
Total Number of Pages: 91
Print Job Number: 22557

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:
17605416 17605425 17611030 17614765 17649456 17654933 17665521 17669916 17675095 17689015 17704031 17705322 17710887 17722744 17727439

Failed Case Id's for Images:

Total Failed Cases: 0

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 3/22. 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		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) 8 of 9

	Concomitant	Yes
	Does this report involve cosmetic, dietary supplement or food/medical food?	
	Primary?	
	Type	Drug/Biologic
	Product Name	pantoprazole
	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) 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 moniroting. 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 (b) (6) 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)	

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		

Reset Form

CaseID: 17614765

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500 (10/18)

The FDA Safety Information and Adverse Event Reporting Program

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

Form Approved OMB No 0910 0291 Expires 9 30 2021
See PRA statement on reverse

FDA USE ONLY

Triage unit sequence #

FDA Rec Date

Note: For date prompts of "dd mmm yyyy" please use 2 digit day 3 letter month abbreviation and 4 digit year; for example 01 Jul 2018

A. PATIENT INFORMATION

1 **Patient Identifier**
(b) (6)

n Confidence

2 **Age**
65 ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)

or Date of Birth *(e g 08 Feb 1925)*

3 **Gender**
☐ Female ☑ Male ☐ ntersex ☐ Transgender ☐ Prefer not to disclose

4 **Weight**
105.3 ☐ lb ☐ kg

5 **Ethnicity** *(check one)*
☐ Hispanic/Latino ☐ Not Hispanic/Latino

6 **Race** *(check all that apply)*
☐ Asian ☐ American ndian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific slander

B. ADVERSE EVENT, PRODUCT PROBLEM

1 **Type of Report** *(check all that apply)*
☑ Adverse Even ☐ Produc Problem *(e g defects/malfunctions)*
☐ Produc Use/ Medica ion Error ☐ Problem wi h Differen Manufac urer of Same Medicine

2 **Outcome Attributed to Adverse Event** *(check all that apply)*
☑ Death *Date of death (dd mmm yyyy):*
☑ Life threatening ☐ Disability or Permanent Damage
☐ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or mportant Medical Events
☐ Required ntervention to Prevent Permanent mpairment/Damage

3 **Date of Event** *(dd mmm yyyy)*
17 - Mar - 2020

4 **Date of this Report** *(dd mmm yyyy)*
31 - Mar - 2020

5 **Describe Event, Problem or Product Use/Medication Error**

FDA/CDER/OSE Follow-up for FAERS Case ID#:

17591609: follow-up report from pharmacist

(Continue on page 2)

6 **Relevant Tests/Laboratory Data** **Date** *(dd-mmm-yyyy)*

(Continue on page 2)

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

Hypertension, ESRD on hemodialysis, CAD, s/p percutaneous transluminal coronary angioplasty, hypercholesteremia, sleep apnea,

(Continue on page 2)

C. PRODUCT AVAILABILITY

1 **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd mmm yyyy)*

2 **Do you have a picture of the product?** *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1 **Name, Strength, Manufacturer/Compounder** *(from product label)*
Does this report involve cosmetic dietary supplement or food/medical food? **#1** ☐ Yes **#2** ☐ Yes

#1 Name and Strength	#1 NDC # or Unique D
#1 Manufacturer/Compounder	#1 Lot #
#2 Name and Strength	#2 NDC # or Unique D
#2 Manufacturer/Compounder	#2 Lot #

2	Dose or Amount	Frequency	Route
#1	400 - 200 mg	BID	PO
#2			

3 **Treatment Dates/Therapy Dates** *(give length of treatment (to/from) or your best estimate)*
#1 Start 15 - Mar - 2020
#1 Stop 17 - Mar - 2020
s therapy still on going? ☐ Yes ☑ No

#2 Start
#2 Stop
s therapy still on going? ☐ Yes ☐ No

4 **Diagnosis for Use** *(Indication)*
#1 COVID-19
#2

5 **Product Type** *(check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

6 **Expiration Date** *(dd mmm yyyy)*
#1
#2

7 **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn t apply
#2 ☐ Yes ☐ No ☐ Doesn t apply

8 **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn t apply
#2 ☐ Yes ☐ No ☐ Doesn t apply

E. SUSPECT MEDICAL DEVICE

1 **Brand Name**

2a **Common Device Name** 2b **Procode**

3 **Manufacturer Name, City and State**

4 **Model #** **Lot #** 5 **Operator of Device**
☐ Health Professional ☐ Patient/Consumer ☐ Other

Catalog # **Expiration Date** *(dd-mmm-yyyy)*

Serial # **Unique Identifier** *(UDI) #*

6a **If Implanted, Give Date** *(dd mmm yyyy)* 6b **If Explanted, Give Date** *(dd mmm yyyy)*

7a **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

7b **If Yes to Item 7a, Enter Name and Address of Reprocessor**

8 **Was this device serviced by a third party servicer?** ☐ Yes ☐ No

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1 **Product names and therapy dates** *(Exclude treatment of event)*

(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1 **Name and Address**

Last Name Swank First Name Kim

Address 10903 New Hampshire Ave

City Silver Spring State/Province/Region MD

Z P/Postal Code 20993 Country US

Phone # 301-796-2887 Email kimberley.swank@fda.hhs.gov

2 **Health Professional?** ☑ Yes ☐ No

3 **Occupation** Pharmacist

4 **Also Reported to:** ☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/ mporter

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

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event
* Please see instructions

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500 (10/18) *(continued)*

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

B.5. **Describe Event or Problem** *(continued)*

see overflow on page 3

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data** *(continued)*

Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*	Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*
WBC 12.1	(b) (6)	ALT 19	(b) (6)
BUN 33	(b) (6)	AST 53	(b) (6)
creatinine 3.88	(b) (6)	Alk phos 212	(b) (6)
potassium 3.1	(b) (6)	Total bilirubin 1.1	(b) (6)

Additional comments

Back to Item B.6

B.7. **Other Relevant History** *(continued)*

Back to Item B.7

F.1. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

Home meds: apixaban, aspirin, donepezil, ketoconazole 2% shampoo, nitroglycerin SL tablets prn, sertraline, sevelamer.
Meds during hospital stay: - Haldol (1 mg IV at 0741 and 2 mg IV at 2152 on (b) (6)), calcium carbonate, cefepime, chlorhexidine solution, cistaracurium, docusate sodium oral liquid, enoxaparin, fentanyl, heparin, hydroxychloroquine (start (b) (6) and d/c (b) (6)), versed, propofol continuous infusion, pantoprazole, sennosides, sertraline, darunavir/cobistat (start (b) (6)).

Back to Item F.1

CaseID: 17614765

65 y/o with ESRD on hemodialysis, recent diagnosis of large PE, presented to hospital (b) (6) with fever and SOB from dialysis center. Patient was not particularly conversational in setting of dementia but did answer questions. Patient stated he has not been breathing well for a few days. He hasn't noted fevers at home. Notes that daughter in law had "pneumonia" recently but denies other sick contacts. CT chest (b) (6) Patchy bilateral areas of ground-glass opacity with no specific pattern. Suspected viral pneumonia. Patient was started on vancomycin and cefepime because patient at risk for HCAP. Patient had worsening respiratory status and was intubated on (b) (6) Patient started on Plaquenil on (b) (6) 400 mg at 1847, on (b) (6) 400 mg at 0844 and 200 mg at 1716, then 200 mg on (b) (6) at 0913. QTc on (b) (6) was 482 and increased to 570 on (b) (6) Plaquenil was stopped due to prolongation of QTc. Patient was started on darunavir/cobicistat on (b) (6) Patient was eventually placed on remdesivir (date unknown) and completed 10 days. Patient eventually tested positive for COVID-19. Patient had elevated CRP, LDH, and ferritin levels throughout hospital stay and remained elevated likely related to "continued cytokine storm". Patient was receiving HD but was somewhat limited by hypotension, but overall not felt to be significantly volume overloaded. He was off sedation and was not waking up for days. Patient was restarted on home aricept for dementia. Patient self-extubated when severe coughing resulted in blown cuff on (b) (6) Patient did poorly with sats down to 60s and RR to 40s, re-intubated by anesthesia. Patient had slight increase in O2 requirements from on (b) (6) to (b) (6) Suddenly, in am on (b) (6) patient became hypotensive 40/20s after one dose of fentanyl given for tachypnea. Briefly on pressors to stabilize pressure. Family called to discuss patient care and it was decided to make the patient comfortable. Patient was put on comfort measures and expired on (b) (6)

CTU #: FDA-CDER-CTU-2020-36131 | Department: CDER | RCT #: RCT-798011 | CTU Triage Date: 01-Apr-2020 | AER #: 17614765 |
Total Pages: 4

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: http://www.fda.gov/medwatch/report/consumer/instruct.htm

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- Food (including beverages and ingredients added to foods)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves an adverse event with a vaccine, go to http://vaers.hhs.gov to report or call 1-800-822-7967.

Confidentiality:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail above.

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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	08-Apr-2020	CTU Received Date	08-Apr-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	
Date of Birth	(b) (6)
Gender	Female
Weight	90.72 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	01-Apr-2020
Date of this Report	08-Apr-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: No documented adverse event or error occurred. The patient tested positive for COVID-19 and was treated with hydroxychloroquine sulfate. The patient expired.

Relevant Test/Laboratory Data 1 of 1

Test Name	SAR-COV-2	Test Date	(b) (6)
Test Result	Positive	Test Unit	UNKNOWN
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

WBC WNL, Lactic Acid WNL, CRP 20

Other Relevant History, Including Preexisting Medical Conditions

Cough, SOB, Chills, Obesity, ? Diarrhea, Bibasilar PNA (CAP), Anemia (probably chronic), Evidence of organ failure, Supplemental O2, CXR: Bibasilar lower opacity infiltrates

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)	Yes

D. PRODUCT(S) 1 of 11

Suspect	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?	Yes		
Type	Drug/Biologic		
Product Name	Hydroxychloroquine Sulfate Tablets		
Strength	200 mg milligram(s)	If Other	
Manufacturer/Compounder	Teva (Actavis, Watson)		
NDC# or Unique ID	0591-3041-01		
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	400 mg milligram(s)	If Other	
Frequency	Twice a day	If Other	
Route	Oral	If Other	
Dosage Form			
Start	31-Mar-2020		
Stop	31-Mar-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number	1376323M		
Expiration Date	31-Jul-2021		

Diagnosis for Use (indication) 1 of 1

COVID-19

D. PRODUCT(S) 2 of 11

Concomitant	Yes
Does this report involve cosmetic, dietary supplement or food/medical food?	
Primary?	
Type	Drug/Biologic
Product Name	Oseltamivir Phosphate
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	31-Mar-2020		
	Stop	01-Apr-2020		
	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 11

	Concomitant	Yes		
	Does this report involve cosmetic, dietary supplement or food/medical food?			
	Primary?			
	Type	Drug/Biologic		
	Product Name	Pantoprazole Sodium		
	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	31-Mar-2020		
	Stop	01-Apr-2020		
	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 11

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	Sodium Chloride 0.9% 1000 ml			
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	31-Mar-2020			
Stop	01-Apr-2020			
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 11

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

	Type	Drug/Biologic		
	Product Name	Azithromycin 500 mg		
	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	31-Mar-2020		
	Stop	01-Apr-2020		
	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 11

	Concomitant	Yes		
	Does this report involve cosmetic, dietary supplement or food/medical food?			
	Primary?			
	Type	Drug/Biologic		
	Product Name	Zosyn 3.375 g		
	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	31-Mar-2020			
	Stop	31-Mar-2020			
	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 11

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Sodium Bicarbonate			
	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	01-Apr-2020			
	Stop	01-Apr-2020			

	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 11

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Atropine			
	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	01-Apr-2020			
	Stop	01-Apr-2020			
	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 11

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	Epinephrine			
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	01-Apr-2020			
Stop	01-Apr-2020			
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 10 of 11

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	31-Mar-2020		
Stop	01-Apr-2020		
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 11 of 11

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	31-Mar-2020			
	Stop	01-Apr-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

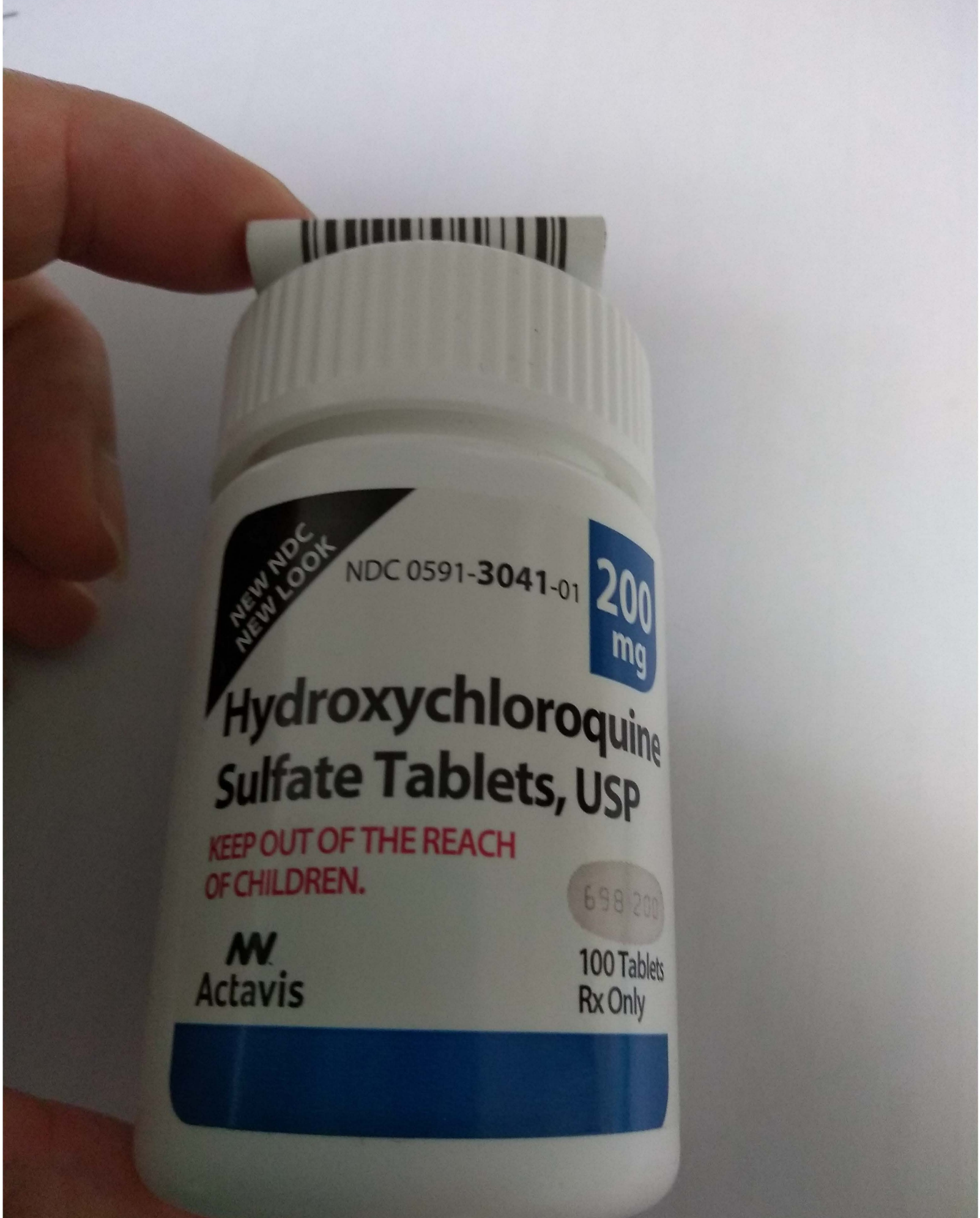
	Brand Name	
	Common Device Name	
	Procode	
	Manufacturer Name	
	City	
	State	
	Model #	
	Lot #	
	Catalog #	
	Expiration Date	
	Serial #	
	Unique Identifier (UDI)#	
	Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
	Other	
	If Implanted, Give Date	
	If Explanted, Give Date	
	Is this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


NEW NDC
NEW LOOK
NDC 0591-3041-01
200
mg
Hydroxychloroquine
Sulfate Tablets, USP
KEEP OUT OF THE REACH
OF CHILDREN.
698 200
Actavis
100 Tablets
Rx Only

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	09-Apr-2020	CTU Received Date	09-Apr-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	64 Year(s)
	Date of Birth	
	Gender	Male
	Weight	68.04 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	(b) (6)
Date of Event	08-Apr-2020
Date of this Report	09-Apr-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Report submission due to patient receiving hydroxychloroquine during hospitalization. Pt required intubation after ETT leak, ER MD informed, Pulmonologist attempted reintubation but was unsuccessful. HR drop to 40, Code blue paged, ACLS protocol initiated, Code blue terminated. Pt expired.

Relevant Test/Laboratory Data 1 of 3

Test Name	ECG	Test Date	(b) (6)
Test Result	Abnormal	Test Unit	UNKNOWN
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 2 of 3

Test Name	SARS-COV-2, NAA*	Test Date	(b) (6)
Test Result	NOT DETECTED	Test Unit	UNKNOWN
Low Test Range		High Test Range	
More Information Available?			

Relevant Test/Laboratory Data 3 of 3

Test Name	RSV AG	Test Date	
Test Result	NEGATIVE	Test Unit	UNKNOWN
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

ECG RESULTS: Vent rate 138 bpm PR interval 96 ms QRS duration 96 ms QT/QTc: 358/542 ms P-R-T axes * 4 48 Sinus tachycardia with short PR incomplete right bundle branch block ST & T wave abnormality, consider inferior ischemia Abnormal ECG

Other Relevant History, Including Preexisting Medical Conditions

SOB, CHF, Troponin I mildly elevated (0.76), D-dimer above reference range, AST/SGOT level abnormal, T2DM uncontrolled, hypoxemia, pneumonia, PE, lactic acidemia, fever, Suspected COVID-19 viral syndrome Hx of atherosclerotic heart disease post stent placement in the past, hx of DM and hyperlipidemia, on glyburide and simvastatin 3-week hx of poor appetite, somnolent the past several days, increasing dyspnea on minimal exertion for 3 days, could not walk from bed to bathroom, became very sob CXR shows upper lobe infiltrate, suggestive of severe pna, possibility of PE in LLL pulmonary, EKG no acute changes

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)	Yes

D. PRODUCT(S) 1 of 19

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	Teva		
NDC# or Unique ID	0591-3041-01		
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	400 mg milligram(s)	If Other	
Frequency	Twice a day	If Other	
Route	Oral	If Other	
Dosage Form			
Start	04-Apr-2020		
Stop	05-Apr-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number	1376323M		
Expiration Date	31-Jul-2021		

Diagnosis for Use (indication) 1 of 1

Suspected COVID-19

D. PRODUCT(S) 2 of 19

Suspect	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	Hydroxychloroquine		
Strength	200 mg milligram(s)	If Other	
Manufacturer/Compounder	Teva		

NDC# or Unique ID	0591304101
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	Twice a day	If Other	
Route	Oral	If Other	
Dosage Form			
Start	05-Apr-2020		
Stop	06-Apr-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number	1376323M		
Expiration Date	31-Jul-2021		

Diagnosis for Use (indication) 1 of 1

Suspected COVID-19

D. PRODUCT(S) 3 of 19

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	04-Apr-2020			
	Stop	07-Apr-2020			
	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 19

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Albuterol			
	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	04-Apr-2020			
	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 19

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	Lasix			
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	04-Apr-2020			
Stop	04-Apr-2020			
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 19

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

	Type	Drug/Biologic		
	Product Name	Zosyn		
	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	04-Apr-2020		
	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 19

	Concomitant	Yes		
	Does this report involve cosmetic, dietary supplement or food/medical food?			
	Primary?			
	Type	Drug/Biologic		
	Product Name	Humulin R		
	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	04-Apr-2020			
	Stop	04-Apr-2020			
	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 19

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Vancomycin			
	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	04-Apr-2020			
	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 19

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Lovenox			
	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	04-Apr-2020			
	Stop				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 10 of 19

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	Tamiflu			
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	04-Apr-2020			
Stop				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 11 of 19

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	Rocephin			
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	04-Apr-2020		
Stop	07-Apr-2020		
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 12 of 19

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) 13 of 19

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Zofran			
	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) 14 of 19

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	NS			
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	05-Apr-2020			
Stop				
Therapy Duration		If Other		
Is therapy still on-going?				
Lot Number				
Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 15 of 19

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

	Type	Drug/Biologic		
	Product Name	D50W		
	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	05-Apr-2020		
	Stop			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 16 of 19

	Concomitant	Yes		
	Does this report involve cosmetic, dietary supplement or food/medical food?			
	Primary?			
	Type	Drug/Biologic		
	Product Name	Pravachol		
	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	05-Apr-2020			
	Stop				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 17 of 19

	Concomitant	Yes			
	Does this report involve cosmetic, dietary supplement or food/medical food?				
	Primary?				
	Type	Drug/Biologic			
	Product Name	Ativan			
	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	05-Apr-2020			
	Stop	05-Apr-2020			

	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 18 of 19

	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	07-Apr-2020			
	Stop				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 19 of 19

Concomitant	Yes			
Does this report involve cosmetic, dietary supplement or food/medical food?				
Primary?				
Type	Drug/Biologic			
Product Name	Propofol			
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	08-Apr-2020			
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?	

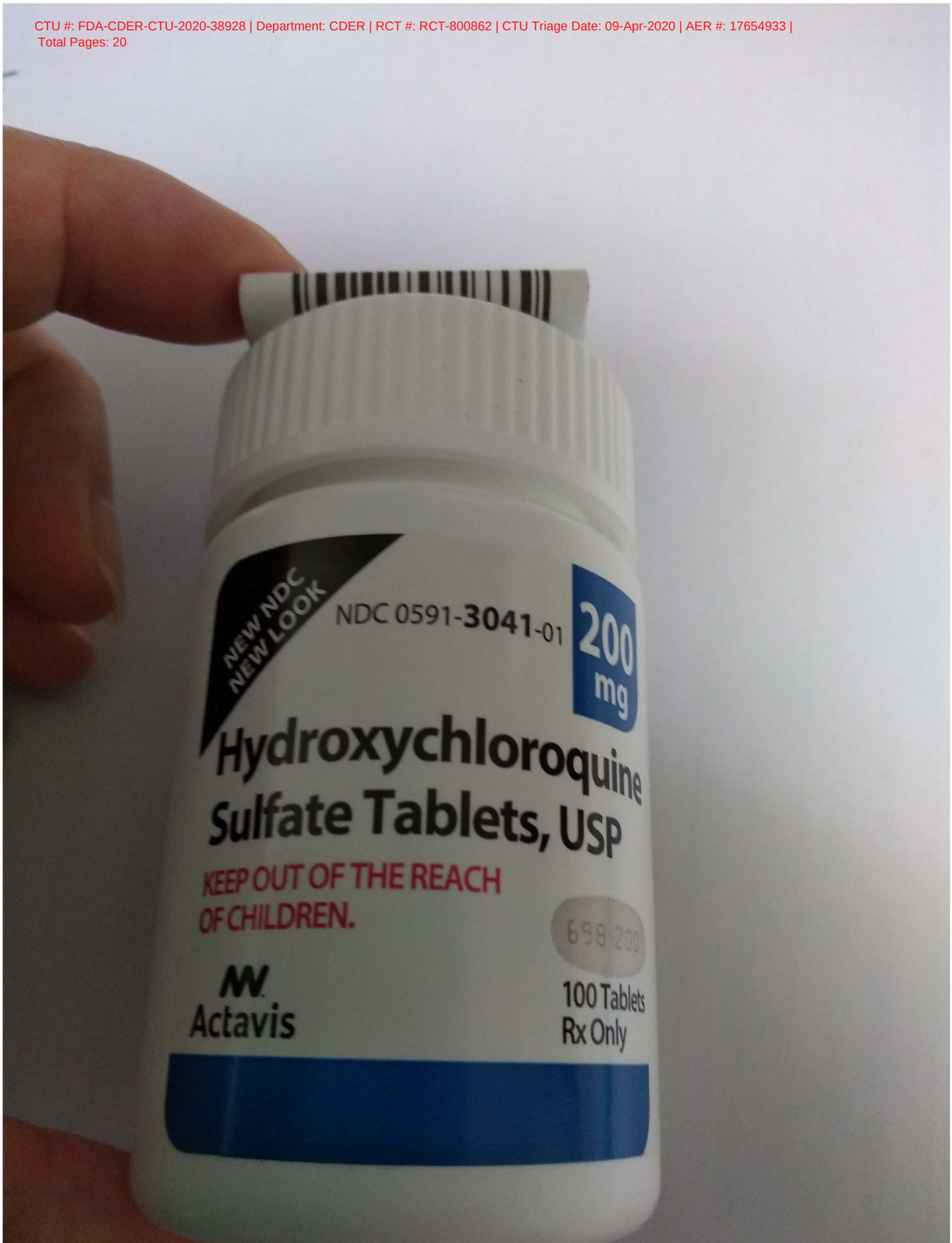
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

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


NEW NDC
NEW LOOK
NDC 0591-3041-01
200
mg
Hydroxychloroquine
Sulfate Tablets, USP
KEEP OUT OF THE REACH
OF CHILDREN.
698 200
Actavis
100 Tablets
Rx Only

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

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

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021
See PRA statement on reverse.

FDA USE ONLY
Triage unit
sequence #
FDA Rec. Date

FORM FDA 3500 (2/20)
The FDA Safety Information and Adverse Event Reporting Program

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6)
In Confidence

2. Age: 79 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth *(e.g., 09 Feb 1925)*:

3. Gender *(check one)*: ☐ Female ☑ Male ☐ Intersex ☐ Transgender ☐ Prefer not to disclose

4. Weight: 175.0 ☑ lb ☐ kg

5. Ethnicity *(check one)*: ☑ Hispanic/Latino ☐ Not Hispanic/Latino

6. 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. Type of Report *(check all that apply)*
☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use/ Medication Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event *(check all that apply)*
☑ Death *Date of death (dd-mmm-yyyy)*: (b) (6)
☐ Life-threatening ☐ Disability or Permanent Damage
☑ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage

3. Date of Event *(dd-mmm-yyyy)*: 11/APR/2020

4. Date of this Report *(dd-mmm-yyyy)*: 13/APR/2020

5. Describe Event, Problem or Product Use/Medication Error

COVID-19 positive patient on Hydroxychloroquine expired

(Continue on page 2)

6. Relevant Tests/Laboratory Data

Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*
Covid -19	(b) (6)

(Continue on page 2)

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

Diabetes type II, Hypertension

(Continue on page 2)

C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? *(Do not send product to FDA)*
☑ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

2. Do you have a picture of the product? *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1. Name, Strength, Manufacturer/Compounder *(from product label)*.
Does this report involve cosmetic, dietary supplement or food/medical food? #1 ☑ Yes #2 ☑ Yes

#1 – Name and Strength Hydroxychloroquine 200mg PO	#1 – NDC # or Unique ID 00591-3041-01
#1 – Manufacturer/Compounder Actavis	#1 – Lot # 1376323M
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

	Dose or Amount	Frequency	Route
#1	200mg	BID	Oral
#2			

3. Treatment Dates/Therapy Dates *(give best estimate of length of treatment (start/stop) or duration.)*
#1 Start 04/APR/2020
#1 Stop 10/APR/2020
Is therapy still on-going? ☐ Yes ☐ No
#2 Start
#2 Stop
Is therapy still on-going? ☐ Yes ☐ No

4. Diagnosis for Use *(indication)*
#1 Covid-19 Positive
#2

5. Product Type *(check all that apply)*

	#1	#2
	☐ OTC	☐ OTC
	☐ Compounded	☐ Compounded
	☑ Generic	☐ Generic
	☐ Biosimilar	☐ Biosimilar

6. Expiration Date *(dd-mmm-yyyy)*
#1 JUL/2021
#2

7. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☑ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2a. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model # | Lot # | 5. Operator of Device: ☐ Health Professional ☐ Patient/Consumer ☐ Other

Catalog # | Expiration Date *(dd-mmm-yyyy)*

Serial # | Unique Identifier *(UDI) #*

6a. If Implanted, Give Date *(dd-mmm-yyyy)* | 6b. If Explanted, Give Date *(dd-mmm-yyyy)*

7a. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

7b. If Yes to Item 7a, Enter Name and Address of Reprocessor

8. Was this device serviced by a third party servicer? ☐ Yes ☐ No ☐ Unknown

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. Product names and therapy dates *(Exclude treatment of event)*

(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
(b) (6)

ZIP/Postal Code: (b) (6) Country: USA
Phone #: (b) (6) Email: (b) (6)

2. Health Professional? ☑ Yes ☐ No

3. Occupation: Director of Pharmacy

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: ☑

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration
MEDWATCH

FORM FDA 3500 (2/20) *(continued)*
The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

B.5. Describe Event or Problem *(continued)*

Back to Item B.5

B.6. Relevant Tests/Laboratory Data *(continued)*

Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*	Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*

Additional comments

Back to Item B.6

B.7. Other Relevant History *(continued)*

Back to Item B.7

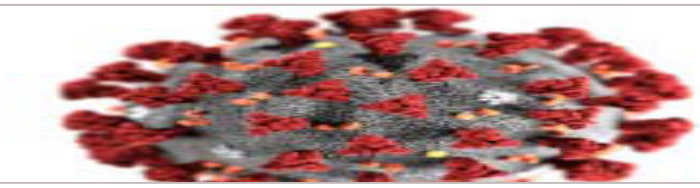
F.1. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event) (continued)*

Back to Item F.1

CTU #: FDA-CDER-CTU-2020-40547 | Department: CDER | RCT #: RCT-802409 | CTU Triage Date: 15-Apr-2020 | AER #: 17669916 |
Total Pages: 3

Case ID # 5339

Covid-19



Case ID # 5339 texts star

Disease	Covid-19
Challenge	There is no standard/approved therapy for this disease Unusual disease presentation Other - Drug toxicity on recommended therapy
Drug(s)	Hydroxychloroquine Azithromycin
Outcome	Patient died

Patient Characteristics	**Age:** 51-60 years **Sex:** Male **Country Contracted:** United States **Country Treated:** United States **Treatment Began:** 2020
Co-Morbidities and Concomitant Treatments	**Co-Morbidities:** Nil prior to admission **Co-Infections:** Acute renal failure, Hepatic transaminitis

CTU #: FDA-CDER-CTU-2020-40547 | Department: CDER | RCT #: RCT-802409 | CTU Triage Date: 15-Apr-2020 | AER #: 17669916 |
Total Pages: 3

Disease Covid-19 Challenge
There is no standard/approved therapy for this disease
Unusual disease presentation
Other - Drug toxicity on recommended therapy
Drug(s)
Hydroxychloroquine
Azithromycin
Outcome Patient died
Patient Characteristics
Age: 51-60 years
Sex: Male
Country Contracted: United States
Country Treated: United States
Treatment Began: 2020

Co-Morbidities and Concomitant Treatments
Co-Morbidities: Nil prior to admission
Co-Infections: Acute renal failure, Hepatic transaminitis

Presentation
Site(s) of disease: Pneumonia
Clinical syndrome: torsades de pointes
Treatment Setting: ICU/Critical Care

Unusual
Anything else make this case unusual:
No premonitory or concurrent QT/QTc prolongation documented

Diagnosis
Etiology:
Coronavirus - covid-19

Previous Treatment: The patient was not previously treated for this infection

---

Treatment Details
Hydroxychloroquine
400 mg x24h then 200mg BID NG X 1 Day(s)
Start: Mar 27 2020 - End: Mar 28 2020
How new way:
To treat a disease other than the one for which the drug is approved

Azithromycin
500mg x1 then 250mg QD NG X 2 Day(s)
Start: Mar 27 2020 - End: Mar 29 2020
How new way:
To treat a disease other than the one for which the drug is approved

Adverse Events:
Torsades de pointes, cardiac arrest

Surgery: No
Outcome assessed: At the time the treatment was completed
Relapse: No
Other: Covid 19 preliminary clinical reports suggest significant acute therapeutic efficacy for the combination of AZ and HC(1) above that of HC alone(2). The putative mechanism might be prevention of secondary bacterial infection in cytokine-insulted alveoli however it may be due to macrolide CYA-3A4 inhibition with elevation of hydroxychloroquine levels, perhaps unpredictably. Case Report: 52 M with no prior medical condition presenting (b) (6) with fever and dyspnea negative for influenza A and B and RSV but positive for COVID 19. Patient in moderate respiratory distress with bilateral crackles. Lab values: WBC 20.7k/μL with neutrophilic predominance (92%) and lymphopenia (2.8%). Lab values: PaO2 44 on FiO2 100%. Serum K (5.0mg/dL, normal 3.5–5.1 mg/dL) and Mg (1.9 mg/dL, normal 1.6–2.3 mg/dL). Serum Ca was low (7.7 mg/dL, normal 8.4-10.4 mg/dL) and phosphate high (9.0 mg/dL, normal < 4.5 mg/dL) in keeping with acute renal failure with Cr rising from 2.4 to 6.5mg/dl (normal < 1 1 mg/dL) within 24h of admission. AST (166 U/L, normal <59 U/L) and LDH (3546 U/L, normal <618 U/L) and PT/ INR 14.6s/1.3 (normal <12.9s/<1.16) but normal ALT. Imaging: CXR revealed bilateral peripheral focal consolidation and right pleural effusion. Baseline EKG sinus rhythm QT/QTc 298/403 msec figure 1a). Treatment & Outcome: Patient was admitted to ICU telemetry, intubated and started on hydroxychloroquine 400 mg BID day one then 200mg BID and azithromycin 500 mg day one then 250mg daily. Day 2 EKG revealed repeated torsades de pointes though QT/QTc remained normal (250/427 msec fig 1b). Six hours later patient experienced cardiac arrest. Resuscitation efforts were unsuccessful, despite defibrillation. Discussion: Both HC and AZ are capable of prolonging QT(3,4) and macrolide (AZ) is a well-known CYA-3A4 inhibitor which may decrease HC metabolism raising the potential for cardiotoxic accumulation and arrhythmia. Doses of HC as high as 1200mg are being suggested(1). In view of the beneficial results with HC alone(2) perhaps the initial loading dose of AZ might be omitted particularly in patients with multiorgan failure. Prophylactic mexiletine might also be considered based on the prior efficacy of quinidine mexiletine combinations(5). Notably, there was no premonitory QT prolongation documented prior to or concurrent with torsades.

textsms

Comments
12:14 PM, Apr 03 2020
(b) (6)

CTU #: FDA-CDER-CTU-2020-40547 | Department: CDER | RCT #: RCT-802409 | CTU Triage Date: 15-Apr-2020 | AER #: 17669916 | Total Pages: 3

Thanks for sharing the case. Agree with the Cyp3A4 inhibition caused due to Azithromycin predisposing to arrythmias due to HCQ. Did the patient have myocarditis contributing to the arrythmia too? I feel for the first sign or suspicion of myocarditis or documented hypocalcemia (causes QTc prolongation) or AKI, Azithromycin should be stopped and renal adjusted doses given for HCQ.
12:27 PM, Apr 03 2020
(b) (6)
No objective evidence of myocyte degradation (negative troponin) despite acute renal failure (Cr 6.4) and BNP not elevated. Only aware of one case report of COVID myocarditis from China. Hypocalcemia in this case was modest at best. No LVEF assessment obtained. No hypotension or pressors administered.
01:04 PM, Apr 03 2020
(b) (6)
Thanks. Though I must add,Yang et al in Lancet report 17% patients had acute cardiac injury and 23% developed heart failure in a sample of 191 patients.(https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30566-3/fulltext#tbl2). While other studies report lower numbers. But this cohort with elevated Trops have a higher associated mortality. Please keep posting. All such data is going to help make clinical decisions on the ground.
01:21 PM, Apr 03 2020
(b) (6)
Elevated troponin without attendant LVEF reduction is more likely type 2 (global watershed) infarction than myocarditis/myopathy. High output failure due to vascular (particularly pulmonary) cytokine mediated over-dilation with high (RV impairing) PEEP and sinus tachycardia more likely mechanism for secondary myocyte injury.
03:04 PM, Apr 03 2020
(b) (6)
While I agree with the possibility that elevated troponin without attendant LVEF reduction could be a type 2 infarction but given presence of abundant distribution of ACE2 – the binding site for the SARS-CoV-2 – in cardiomyocytes, it has been postulated that myocarditis might explain rise of hs-cTn. While Trops can take upto 6 to 12 hours to rise, a bed side Echo can confirm wall motion abnormalities or a reduced LVEF much faster. Much of the published literature on this topic only mentions hypothesis or assumptions. But nevertheless, this patient sub-group has the worst prognosis. Agree with the secondary myocyte injury mechanism. Thanks again for initiating the discussion.
04:09 PM, Apr 03 2020
(b) (6)
So important to note this side effect of Toursades de pointes with hydroxychloroquine and azithromycin. It is tragic that so many are using it with no data, and without contributing to scientific knowledge as this case did. Thank you for sharing so many details.
05:20 AM, Apr 04 2020
(b) (6)
Thanks for posting this case. Although the discussion of cardiac pathology is probably of interest to some, the main message is that if you have COVID19 and you delay treatment until your PO2 is 44, you're dead. Beyond that, it is a mistake to give high-dose HCQ and Zithromax loading doses because the latter will induce toxic levels of the former. HCQ doses should be limited to 200mg BID and Zithromax should be 250 BID. Going higher on either of these meds is asking for trouble. How do I know? I have lots of experience using these drugs to treat tick-borne diseases.
12:03 AM, Apr 06 2020
(b) (6)
I also echo concern about using therapies in a vacuum; we all benefit, clinicians and patients, to learn from successes and failures. As clinicians, we should make every attempt to enroll treatment of COVID patients in a clinical trial.

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	15-Apr-2020	CTU Received Date	15-Apr-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)	Unspecified
	Age	
	Date of Birth	(b) (6)
	Gender	Female
	Weight	56.25 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	(b) (6)

Date of Event	10-Apr-2020
Date of this Report	15-Apr-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: This report was mandated through the fact sheet EUA for use of hydroxychloroquine. We feel that the patient was doing better the very next morning after receiving just one dose of 200 mg. She died (b) (6) likely from a pulmonary embolism. She unexpectedly had drop in BP to 60/40 and became unresponsive just hours after she felt better and was smiling and conversing normally. This lady had nearly died three times in the past 18 months for various lung problems including COPD, CHF, pneumonia with sepsis and amiodarone toxicity and I feel that the medication hydroxychloroquine had nothing to do with her passing away.

Relevant Test/Laboratory Data 1 of 1

Test Name	COVID-19 TEST	Test Date	(b) (6)
Test Result	negative	Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Patient was dying and fragile. Order was given for hydroxychloroquine since I was highly suspicious that patient had Covid-19 and a negative test result would not have changed my mind to give my patient the best chance possible to survive her illness (false negative rate known to be 30-40% at the time of my decision. The EUA was given by our pharmacist who spoke with the patient.

Other Relevant History, Including Preexisting Medical Conditions

Severely fragile patient with COPD, CHF, PAD, Amiodarone lung toxicity, AF, DM type II with recent above knee amputation and recurrent pneumonia.

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	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?	Doesn't Apply
Event Reappeared after Reintroduction ?	Doesn't Apply

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency	Twice a day	If Other	
Route	Oral	If Other	
Dosage Form			
Start	09-Apr-2020		
Stop	10-Apr-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

suspect covid-19

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		

Reset Form

CaseID: 17689015

CTO #: FDA-CDER-CTO-2020-42604 | Department: CDER | RCT #: RCT-604318 | CTO Triage Date: 21-Apr-2020 | AER #: 17689015

Total Pages: 3

U.S. Department of Health and Human Services
Food and Drug Adminis ration

MEDWATCH

FORM FDA 3500 (10/18)

The FDA Safety Information and Adverse Event Reporting Program

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

Form Approved OMB No 0910 0291 Expires 9 30 2021
See PRA statement on reverse

FDA USE ONLY
Triage unit sequence #
FDA Rec Date

Note: For date prompts of "dd mmm yyyy" please use 2 digit day 3 letter month abbreviation and 4 digit year; for example 01 Jul 2018

A. PATIENT INFORMATION

1 **Patient Identifier**
n Confidence

2 **Age** 65 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth *(e g 08 Feb 1925)*

3 **Gender** ☑ Female ☐ Male ☐ ntersex ☐ Transgender ☐ Prefer not to disclose

4 **Weight** ☐ lb ☐ kg

5 **Ethnicity** *(check one)* ☐ Hispanic/Latino ☐ Not Hispanic/Latino

6 **Race** *(check all that apply)* ☐ Asian ☐ American ndian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific slander

B. ADVERSE EVENT, PRODUCT PROBLEM

1 **Type of Report** *(check all that apply)*
☑ Adverse Even ☐ Produc Problem *(e g defects/malfunctions)*
☐ Produc Use/ Medica ion Error ☐ Problem wi h Differen Manufac urer of Same Medicine

2 **Outcome Attributed to Adverse Event** *(check all that apply)*
☑ Death *Date of death (dd mmm yyyy):*
☐ Life threatening ☐ Disability or Permanent Damage
☐ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or mportant Medical Events
☐ Required ntervention to Prevent Permanent mpairment/Damage

3 **Date of Event** *(dd mmm yyyy)* 01-Apr-2020

4 **Date of this Report** *(dd mmm yyyy)* 20-Apr-2020

5 **Describe Event, Problem or Product Use/Medication Error**

FDA/CDER/OSE Follow-up for FAERS Case ID#:

Case # 17649456

(Continue on page 2)

6 **Relevant Tests/Laboratory Data**

	Date *(dd-mmm-yyyy)*
Increased LDH: 407 U/L	(b) (6)
All other labs WNL	

(Continue on page 2)

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

(Continue on page 2)

C. PRODUCT AVAILABILITY

1 **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd mmm yyyy)*

2 **Do you have a picture of the product?** *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1 **Name, Strength, Manufacturer/Compounder** *(from product label)*
Does this report involve cosmetic dietary supplement or food/medical food? #1 ☐ Yes #2 ☐ Yes

#1 Name and Strength: Hydroxychloroquine
#1 NDC # or Unique D:
#1 Manufacturer/Compounder:
#1 Lot #:

#2 Name and Strength: Azithromycin
#2 NDC # or Unique D:
#2 Manufacturer/Compounder:
#2 Lot #:

2 **Dose or Amount** / **Frequency** / **Route**

	Dose or Amount	Frequency	Route
#1		x 1 dose	oral
#2			

3 **Treatment Dates/Therapy Dates** *(give length of treatment (to/from) or your best estimate)*
#1 Start 01-Apr-2020
#1 Stop 01-Apr-2020
s therapy still on going? ☐ Yes ☐ No
#2 Start
#2 Stop
s therapy still on going? ☐ Yes ☐ No

4 **Diagnosis for Use** *(Indication)*
#1 COVID-19
#2 COVID-19

5 **Product Type** *(check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

6 **Expiration Date** *(dd mmm yyyy)*
#1
#2

7 **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn t apply
#2 ☐ Yes ☐ No ☐ Doesn t apply

8 **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn t apply
#2 ☐ Yes ☐ No ☐ Doesn t apply

E. SUSPECT MEDICAL DEVICE

1 **Brand Name**

2a **Common Device Name**

2b **Procode**

3 **Manufacturer Name, City and State**

4 **Model #** / **Lot #**

Catalog # / **Expiration Date** *(dd-mmm-yyyy)*

Serial # / **Unique Identifier** *(UDI)* #

5 **Operator of Device** ☐ Health Professional ☐ Patient/Consumer ☐ Other

6a **If Implanted, Give Date** *(dd mmm yyyy)*

6b **If Explanted, Give Date** *(dd mmm yyyy)*

7a **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

7b **If Yes to Item 7a, Enter Name and Address of Reprocessor**

8 **Was this device serviced by a third party servicer?** ☐ Yes ☐ No

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1 **Product names and therapy dates** *(Exclude treatment of event)*

(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1 **Name and Address**

Last Name Swank
First Name Kim
Address
City Silver Spring
State/Province/Region MD
Z P/Postal Code
Country
Phone # 301-796-2887
Email kimberley.swank@fda.hhs.gov

2 **Health Professional?** ☑ Yes ☐ No

3 **Occupation** pharmacist

4 **Also Reported to:** ☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/ mporter

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

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

* Please see instructions

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500 (10/18) *(continued)*

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

B 5 **Describe Event or Problem** *(continued)*

Patient admitted with COVID-19 and pneumonia and was admitted to ICU and intubated. Patient was started on hydroxychloroquine, azithromycin oseltamivir, ceftriaxone. Shortly after intubation patient coded and expired due to respiratory failure.

Back to Item B.5

B 6 **Relevant Tests/Laboratory Data** *(continued)*

Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*	Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*

Additional comments

Back to Item B.6

B 7 **Other Relevant History** *(continued)*

Back to Item B.7

F.1 **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

Back to Item F.1

CTU #: FDA-CDER-CTU-2020-42604 | Department: CDER | RCT #: RCT-804518 | CTU Triage Date: 21-Apr-2020 | AER #: 17689015 | Total Pages: 3

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: http://www.fda.gov/medwatch/report/consumer/instruct.htm

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- Food (including beverages and ingredients added to foods)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves an adverse event with a vaccine, go to http://vaers.hhs.gov to report or call 1-800-822-7967.

Confidentiality:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail above.

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500 (10/18)

The FDA Safety Information and Adverse Event Reporting Program

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

Form Approved: OMB No. 0910-0291, Expires: 9/30/2021
See PRA statement on reverse

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

A. PATIENT INFORMATION

1. **Patient Identifier**
In Confidence

2. **Age**
64 ☑ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth (e.g., 08 Feb 1925)

3. **Gender**
☐ Female ☑ Male ☐ Intersex ☐ Transgender ☐ Prefer not to disclose

4. **Weight**
☐ lb ☐ kg

5. **Ethnicity** *(check one)*
☐ Hispanic/Latino
☐ Not Hispanic/Latino

6. **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. **Type of Report** *(check all that apply)*
☑ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)*
☐ Product Use/Medication Error ☐ Problem with Different Manufacturer of Same Medicine

2. **Outcome Attributed to Adverse Event** *(check all that apply)*
☑ Death *Date of death (dd-mmm-yyyy):*
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage

3. **Date of Event** *(dd-mmm-yyyy)*
08-Apr-2020

4. **Date of this Report** *(dd-mmm-yyyy)*
21-Apr-2020

5. **Describe Event, Problem or Product Use/Medication Error**
FDA/CDER/OSE Follow-up for FAERS Case ID#:
Case 17654933: Patient tested positive for COVID-19
(Continue on page 2)

6. **Relevant Tests/Laboratory Data** Date *(dd-mmm-yyyy)*
(Continue on page 2)

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*
(Continue on page 2)

C. PRODUCT AVAILABILITY

1. **Product Available for Evaluation?** *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

2. **Do you have a picture of the product?** *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1. **Name, Strength, Manufacturer/Compounder** *(from product label)*
Does this report involve cosmetic, dietary supplement or food/medical food? #1 ☐ Yes #2 ☐ Yes

#1 Name and Strength: Hydroxychloroquine 400 mg
#1 NDC # or Unique ID:
#1 Manufacturer/Compounder:
#1 Lot #:
#2 Name and Strength: Hydroxychloroquine 200 mg
#2 NDC # or Unique ID:
#2 Manufacturer/Compounder:
#2 Lot #:

2.
	Dose or Amount	Frequency	Route
#1	400 mg	BID	PO
#2	200 mg	BID	PO

3. **Treatment Dates/Therapy Dates** *(give length of treatment (to/from) or your best estimate.)*
#1 Start 04-Apr-2020
#1 Stop 05-Apr-2020
Is therapy still on going? ☐ Yes ☐ No
#2 Start 05-Apr-2020
#2 Stop 06-Apr-2020
Is therapy still on going? ☐ Yes ☐ No

4. **Diagnosis for Use** *(Indication)*
#1
#2

5. **Product Type** *(check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

6. **Expiration Date** *(dd-mmm-yyyy)*
#1
#2

7. **Event Abated After Use Stopped or Dose Reduced?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

8. **Event Reappeared After Reintroduction?**
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**

2a. **Common Device Name** 2b. **Procode**

3. **Manufacturer Name, City and State**

4. **Model #** **Lot #**
Catalog # **Expiration Date** *(dd-mmm-yyyy)*
Serial # **Unique Identifier** *(UDI)* #

5. **Operator of Device**
☐ Health Professional ☐ Patient/Consumer ☐ Other

6a. **If Implanted, Give Date** *(dd-mmm-yyyy)*
6b. **If Explanted, Give Date** *(dd-mmm-yyyy)*

7a. **Is this a single-use device that was reprocessed and reused on a patient?** ☐ Yes ☐ No

7b. **If Yes to Item 7a, Enter Name and Address of Reprocessor**

8. **Was this device serviced by a third party servicer?** ☐ Yes ☐ No

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. **Product names and therapy dates** *(Exclude treatment of event)*
(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**
Last Name: Swank First Name: Kim
Address:
City: Silver Spring State/Province/Region: MD
ZIP/Postal Code: Country: US
Phone #: 301-796-2887 Email: kimberley.swank@fda.hhs.gov

2. **Health Professional?** ☑ Yes ☐ No

3. **Occupation**
Pharmacist

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:** ☐

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see instructions

U.S. Department of Health and Human Services
Food and Drug Administration

MEDWATCH

FORM FDA 3500 (10/18) *(continued)*

The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

B 5 **Describe Event or Problem** *(continued)*

Back to Item B.5

B 6 **Relevant Tests/Laboratory Data** *(continued)*

	Date *(dd-mmm-yyyy)*	**Relevant Tests/Laboratory Data**	**Date** *(dd-mmm-yyyy)*

Additional comments

Back to Item B.6

B 7 **Other Relevant History** *(continued)*

Back to Item B.7

F.1 **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

Back to Item F.1

CTU #: FDA-CDER-CTU-2020-43766 | Department: CDER | RCT #: RCT-805731 | CTU Triage Date: 24-Apr-2020 | AER #: 17704031 | Total Pages: 3

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: http://www.fda.gov/medwatch/report/consumer/instruct.htm

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- Food (including beverages and ingredients added to foods)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves an adverse event with a vaccine, go to http://vaers.hhs.gov to report or call 1-800-822-7967.

Confidentiality:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail above.

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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	24-Apr-2020	CTU Received Date	24-Apr-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	
	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)
	Date of Death	(b) (6)

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)

My husband, (b) (6) was prescribed Plaquenil in May, 2019 for a skin disorder. After a few days he started feeling weak, dizzy at times, had swelling of the wrists and ankles. The weakness and muscle coordination issues progressed and his eyes be came red and irritated. He started wheezing. He fell on (b) (6) and was admitted to the hospital. He was diagnosed with pulmonary hypertension and a cardiac issue having to do with the pumping of one chamber of his heart. The Pulmonologist said the pulmonary hypertension was due to the cardiac issue, the cardiologist said the cardiac issue was due to the pulmonary hypertension. The shortness of breath became worse, weakness progressed and he had 2 episodes of seeing things that were not there. Plaquenil was still being given to him 2x a day. (b) (6) (b) (6) died of Respiratory arrest and cardiac arrest.

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?	No
Do you have a picture of the product? (check yes if you are including a picture)	No

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)	Hydrochloroquin e		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☑ Generic ☐ Biosimilar		
Strength	200 mg mg milligram(s)	If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?			
Did the problem return if the person started taking or using the product again?			

Drug Therapy 1 of 1

Expiration date			
Lot number			
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	06-May-2019		

	Date the person stopped taking or using the product	05-Jun-2019
	Give best estimate of duration	
	Is therapy still on-going?	

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

treat a skin disorder - prescribed by his dermatologist

	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)	72 Year(s)
	Date of Birth	
	Weight	
	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

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

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

List all current prescription medications and medical devices being used.

Triamcinolone cream for his skin

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	24-Apr-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):	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	24-Apr-2020	CTU Received Date	25-Apr-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	19-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)
Date of Death	(b) (6)

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)

My Father In law was diagnosed with COVID19 on (b) (6) he was a healthy man 50 year old man with no prior heart issues. He was given the medication and sent home on (b) (6) after 3 days in the hospital. He attempted to go back to the hospital the evening of (b) (6) because he was still not feeling well. He was told by the paramedics that he shouldn't go back because of the 10 hour waits in (b) (6) to see a doctor. He passed away early afternoon (b) (6) in my mother in laws arms while bathing. After taking this medication for less than a week I believe this affected his heart and the paramedics explained it was a heart attack.

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)	hydroxychloroqu ine		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☐ Over-the-Counter ☑ Compounded by a Pharmacy or an Outsourcing Facility ☑ Generic ☐ Biosimilar		
Strength	200 mg mg milligram(s)	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?	Doesn't Apply		

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			
Date the person stopped taking or using the product			

Give best estimate of duration	
Is therapy still on-going?	

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

Covid 19

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)	
Date of Birth	(b) (6)
Weight	88.2 kg
Ethnicity (Choose only one)	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)

None

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

None

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.

None

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

Biotin

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	24-Apr-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):	No	

(b)
(6)

(b) (6)

5:58 PM

(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	Urgent		
Override Auto Calculation Rule	No		
FDA Received Date	28-Apr-2020	CTU Received Date	28-Apr-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	56 Year(s)
	Date of Birth	
	Gender	Female
	Weight	81 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	27-Apr-2020
Date of this Report	28-Apr-2020

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Hydroxychloroquine Sulfate treatment under Emergency Use Authorization (EUA): Covid-19 positive, on Plaquenil, Kaletra and Actemra

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

Other Relevant History, Including Preexisting Medical Conditions

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	Hydroxychloroquine		
Strength	200 mg milligram(s)	If Other	
Manufacturer/Compounder	Actavis		
NDC# or Unique ID	00591-3041-01		
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	Twice a day	If Other	
Route	Oral	If Other	
Dosage Form			
Start	20-Apr-2020		
Stop	25-Apr-2020		
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number	1376323 M-		
Expiration Date	30-Jul-2021		

Diagnosis for Use (indication) 1 of 1

Covid-19

D. PRODUCT(S) 2 of 2

Suspect	Yes		
Does this report involve cosmetic, dietary supplement or food/medical food?			
Primary?			
Type	Drug/Biologic		
Product Name	Katetra		
Strength	400/100 mg milligram(s)	If Other	
Manufacturer/Compounder	Abbvie		
NDC# or Unique ID	0074-3950-46		
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	400100 mg milligram(s)	If Other	
Frequency	Twice a day	If Other	
Route	Oral	If Other	

	Dosage Form			
	Start	25-Apr-2020		
	Stop	27-Apr-2020		
	Therapy Duration		If Other	
	Is therapy still on-going?	No		
	Lot Number	1128760		
	Expiration Date	31-Mar-2020		

Diagnosis for Use (indication) 1 of 1

	Covid-19

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		

CTU #: FDA-CDER-CTU-2020-44944 | Department: CDER | RCT #: RCT-806959 | CTU Triage Date: 29-Apr-2020 | AER #: 17727439 | Total Pages: 3

Created 4/29/2020 8:55:56 AM

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

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

FDA USE ONLY Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier: (b) (6)	2. Age at Time of Event: **68**	3. Sex: **Male**	4. Weight (kg): **98.88**

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ■ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
   ☐ Product Use Errors ☐ Problem with Different Mfgr of Same

2. Outcomes Attributed to Adverse Event (check all that apply)
   ■ Death (b) (6) ☐ Disability or Permanent Damage
   ☐ Life-Threatening ☐ Congenital Anomaly/Birth Defect
   ☐ Hospitalization - initial or prolonged ☐ Other Serious (Important Medical Events)
   ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (mm/dd/yyyy): 04/23/2020 (exact)	4. Date of this Report (mm/dd/yyyy) 04/29/2020

5. Describe Event, Problem or Product Use Error
Narrative: Hydroxychloroquine was given from 3/28/20 to 4/8/20, azithromycin from 3/28/20 to 4/2/20. Patient expired due to suspected cardiogenic shock due to renal failure, NSTEMI, ARDS and COVID-19.
Symptoms: , 1. cardiac arrest

6. Relevant Tests/Laboratory Data, Including Dates

SODIUM: 147((b) (6) @05) K BLOOD: 4.6((b) (6) @05) CHLORIDE: 109((b) (6) @05) CO2: 23((b) (6) @05) BUN BLOOD: 153((b) (6) @05) CREATININE BLOOD: 6.20((b) (6) @05)PLASMA GLUCOSE: 244((b) (6) @05) CALCIUM BLOOD: 8.5((b) (6) @05) ALBUMIN BLOOD: 3.2((b) (6) @0504) ALT(SGPT) BLOOD: 62((b) (6) @0504) PHOSPHATE: URIC ACID: CBC: WBC BLOOD: 15.19((b) (6) @0504) HEMOGLOBIN: 8.0((b) (6) @0504) HEMATOCRIT: 26.2((b) (6) @0504) PLATELETS: 465((b) (6) @0504)

7. Other Relevant history, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
68-year-old man with past medical history as above, who was admitted on (b) (6) for hypoxemic respiratory failure with positive CoViD19. Was intubated, sedated, and proned for ARDS. He was treated wit plaquinil, azithromycin, and one dose of tocilizumab. Covid inflammatory markers were trended Q48H, they trended high, and with fever spikes, there was suspicion for superimposed bacterial infection, for which IV zosyn and vanc was started. He also had AKI for which he was started on CRRT. Blood cultures were sent and they have been negative to date. During the hospital course he became hypotensive, more abx were added including micofungin, but since no source of infection was identified and cultures remained negative, micofungin was discontinued after 2 days. CRRT was continued. His ARDS improved and he was restrted on his home medications for hypertension with an addition of metoprolol. Tube feeds were started. He remained hyperglycemic, for which insulin gtt was started on (b) (6) for a brief period and was stopped on (b) (6) he was then satrted on insulin NPH. His inflammatory markers began trending down on (b) (6) Repeat COVID-19 testing on (b) (6) came back positive again. On (b) (6) patient spiked a fever, tracheal aspirate was sent that did not show any organsims, no abx were started. He was given on/off spontaneous trials on vent. Palliative was taken on board to talk with the wife regarding long term management plan. Patient clinically improved significantly

and extubated on (b) (6) On (b) (6) pt has a cardiac arrest. Upon review of tele strips, pt was in NSR, then had junctional escape with bradycardia with HR: 35 bpm, followed by 18 beats of what looks like non-sustained VT, self-terminating into asystole. Standard ACLS protocol agents administered during Code Blue.

C. PRODUCT AVAILABILITY

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

☐ Yes ■ No ☐ Returned to Mfgr on _____

D. SUSPECT PRODUCT(S)

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

#1: HYDROXYCHLOROQUINE (HYDROXYCHLOROQUINE SO4 200MG TAB)

#2: AZITHROMYCIN (AZITHROMYCIN 500MG/VIL INJ)

2. Dose or Amount	Frequency	Route
#1 200 MG	BID	PO
#2 250 MG	EVERY DAY	IV

3. Dates of Use (If unknown, give duration) from/to (or best estimate)

#1 03/28/2020 thru 04/08/2020

#2 03/28/2020 thru 04/02/2020

5. Event Abated After Use Stopped or Dose Reduced?

#1 N/A

#2 N/A

4. Diagnosis for Use (indication)

#1 , COVID-19

#2 , COVID-19

8. Event Reappeared After Reintroduction?

#1 N/A

#2 N/A

6. Lot #:	7. Expiration Date	9. NDC Number or Unique ID
#1	#1	#1
#2	#2	#2

E. SUSPECT MEDICAL DEVICE

(Section intentionally left blank)

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

(Section intentionally left blank)

G. REPORTER

1. Name and Address

(b) (6)

Phone #: (b) (6) E-mail: (b) (6)

2. Health Professional? Yes

3. Occupation: Pharmacist

4. Also Reported to:

☐ Manufacturer
☐ User Facility
☐ Distributor/importer

5. If you do not want your identity disclosed to the manufacturer, place an 'x' in this box.

■

FORM vaADERS-3500 (03/2008) *Adapted from FORM FDA 3500 (10/08) for use in auto-faxing vaADERS ADR reports to MedWatch*

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