Canada Vigilance AER#:	000941763 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210305 CCYYMMDD
	HC Initial Received Date:	20210305 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

[redacted]

Primary source country (A.1.1): Canada	Occur country (A.1.2): Canada	Serious? (A.1.5.1)	Serious
Type of report: Spontaneous		Seriousness (A.1.5.2)	
		Caused/prolonged hospitalization?	No
		Results in death?	Yes
MAH/Sponsor Initial Received Date (A.1.6): 2021 CCYY	MAH/Sponsor Latest Received Date (A.1.7): 2021 CCYY	Disabling/Incapacitating?	No
		Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13): No	Reason for nullification (A.1.13.1)

Medically confirmed or from health professional? (A.1.14): Yes

Source (A.1.4): Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5): Male	Patient height (B.1.4)	Patient weight (B.1.3)
Date of birth (B.1.2.1)	Age group (B.1.2.3)		Onset Age (B.1.2.2): 84 Years
Gestation Period (B.1.2.2.1)		LMP date (B.1.6)	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3): Unknown

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502135 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
200 Milligram		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	25.0	COVID-19 virus test positive
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
2020[redacted] CCYYMMDD	2020[redacted] CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
8 Days	4 Days	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DEXAMETHASONE	
Active Substance names (B.4.k.2.2)		
dexamethasone phosphate		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AZITHROMYCIN	
Active Substance names (B.4.k.2.2)		
azithromycin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CEFTRIAXONE FOR INJECTION USP	
Active Substance names (B.4.k.2.2)		
ceftriaxone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	MELATONIN	
Active Substance names (B.4.k.2.2)		
melatonin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ZOPICLONE	
Active Substance names (B.4.k.2.2)		
zopiclone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

2 SUICIDE ATTEMPTS IN THE SPACE OF 5 DAYS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Suicide attempt		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
25.0	Suicide attempt		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2020[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
8 Days	4 Days		

Reaction/event as reported by primary source (B.2.i.0) Current reaction

2 SUICIDE ATTEMPTS IN THE SPACE OF 5 DAYS, AND WAS ULTIMATELY SUCCESSFUL ON THE SECOND ATTEMPT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Accomplished suicide		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
25.0	Completed suicide		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	2020[redacted]		
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
13 Days	9 Days		

Summary (B.5)

Case narrative (B.5.1)

Narrative: Concommitant health products: Dexamethasone 6mg from [redacted]
Azithromycin 500mg IV daily [redacted]
Ceftriaxone 2g IV daily [redacted]
Melatonin 9mg qHS [redacted]
Zopiclone 3.75mg qHS PRN [redacted]
Indications: COVID+ on oxygen

Handler Comment : Lot number, expiry dates of all drugs are not known.

E2B R2 Log
Original File Name: [redacted]
Received Date: 2021/03/05
Safety Report Version: 0
Safety Report ID: [redacted]

Serious: Yes
Death: No
Life Threatening: No
Hospitalization: No
Disability: No
Congenital Anomaly: No
Seriousness Other: No

Documentation Date: 2021/02/03
WW ID: [redacted]
Medically Confirmed: Yes

HC Org. ID: [redacted]
Reporter Org.: [redacted]
Reporter Dept.: [redacted]
Reporter Province: [redacted]
Reporter Country: Canada
Sender Organization: [redacted]
Sender Given Name: [redacted]
Sender Family Name: [redacted]
Sender Province: [redacted]
Sender Phone: [redacted]
Sender Phone Ext: [redacted]
Sender Email: [redacted]

Patient Age: 84
Patient Age Unit: Years
Patient Sex: Male
Patient Med. History: HTN, COVID+
Primary Reaction: Patient with no previous hx of depression, reportedly a very happy person according to family made 2 suicide attempts in the space of 5 days, and was ultimately successful on the second attempt. Patient was COVID+, admitted to hospital on [redacted]. Had a 6 day stay in ICU before stepping down to Medicine on [redacted]. Received Dexamethasone x 10 days ([redacted]) which was up until the first suicide attempt. Remdesivir was given [redacted] 2020. Suicide attempts were [redacted] & [redacted]. There was no evidence of delirium or psychiatric SEs related to his COVID diagnosis or related to the use of steroids other than poor sleep. Both suicide attempts appeared to be impulsive. There were no obvious SEs from Remdesivir infusions over his 5 day course.

I am submitting this due to the lack of knowledge and evidence behind SEs of remdesivir. I'm not sure if there is a link, but felt that there was potential and have been unable to find another contributor to cause 2 suicide attempts in a patient with no previous depression history. A brief lit search did not find anything substantial for psychiatric SEs, although there were reports of delirium and one case of neuropsychological SEs in Ebola trials.
Reaction Start Date: 2020[redacted]

Product Role: Suspect
Dosage Text: 200mg
Substance Name: Remdesivir
Report Medium: sFTP Report Format: E2B R2 XML

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	Hypertension	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	COVID-19 virus test positive	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c): [redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Other health professional

Literature reference(s) (A.2.2):

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a):

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l):

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a):

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l):

Canada Vigilance AER#:	000948411 (0)	Page#1
Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210430 CCYYMMDD
	HC Initial Received Date:	20210430 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20210430152843_11965()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021 CCYY	2021 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female	162 Centimeter	72 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			50 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	AN8363CA	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502143 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
100 Milligram,1 every 1 (Days)		
Dosage text (B.4.k.6)		
frequencytext:daily		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	25.0	COVID-19
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20210428 CCYYMMDD	20210430 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
2 Days		
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	EPINEPHRINE	
Active Substance names (B.4.k.2.2)		
epinephrine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RANITIDINE	
Active Substance names (B.4.k.2.2)		
ranitidine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	BENADRYL	
Active Substance names (B.4.k.2.2)		
diphenhydramine hydrochloride		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

SEVERE SWELLING OF HER EYES

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Eye swelling		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
25.0	Eye swelling		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**
	20210430 CCYYMMDD	20210430 CCYYMMDD	
Reaction first time (B.2.i.7.1)	**Reaction last time (B.2.i.7.2)**	**Outcome (B.2.i.8)**	
2 Days			

Reaction/event as reported by primary source (B.2.i.0) Current reaction

ANGIOEDEMA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Angioedema
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Angioedema

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CLOSING OF HER THROAT

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Throat constriction
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Throat tightness

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

WHEEZING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Wheezing
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Wheezing

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DIFFUSE ITCHING

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Itching all over
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Pruritus

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

null

Dhpr log details:
Safety Report ID: CA-DHPR_H-20210430152843_11965
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20210430
Documentation Date: 20210430
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.: [redacted]
Address: [redacted]
City: [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization: [redacted]
HC ID:
Reporter Type: Pharmacist

Patient ID: [redacted]
Age: 50 Year(s)
Sex: Female
Height: 162 cm
Weight: 72 kg
Med History: no other comorbidities.
Allergies: no known allergies to medication or food prior to reaction

Serious Death:
Date of Death:
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other: Yes
Serious Other Explain: severe swelling of her eyes, angioedema, closing of her throat, wheezing, and diffuse itching. Epinephrine, ranitidine, and Benadryl were given and patient improved significantly

Reaction 1
Outcome: Recovered
Reaction Start Date: 20210430
Reaction End Date: 20210430
Reaction Description: severe swelling of her eyes, angioedema, closing of her throat, wheezing, and diffuse itching. Epinephrine, ranitidine, and Benadryl were given and patient improved significantly

Suspect Product 1
DIN #/NPN #: 02502143
UPHN #:
Brand Name: Veklury
Common Name: remdesivir
Strength: 100 mg milligram(s)
Strength other:
Dosage form:
Manufacturer: Gilead
Lot #: AN8363CA
Expiry date: 20230930
Product start date: 20210428
Product end date: 20210430
Dosage: 100 mg milligram(s)
Dosage other:
Frequency: daily
Route of administration: Intravenous (not otherwise specified)
Route of administration - Other:
Indication: covid-19 infection
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Drug withdrawn
Dechallenge: Unknown
Rechallenge: Unknown

Concomitants: Epinephrine, ranitidine, and Benadryl were given for reaction
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Canada Vigilance AER#:	000948411 (0)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c)
[redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

ATIA - 19(1)

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2 | Serious adverse drug reaction reporting form for hospitals

* = required, if known (if information is in the control of or reasonably accessible by the hospital for mandatory reporting)
** = required (hospital is exempt from mandatory reporting if this information is unavailable)
Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

A. General information

1. Type of report* ☒ Initial ☐ Follow-up
2. Health Canada reference no. (for follow-up reports only)
3. Organization file no. [redacted]
4. Date report submitted: 2021-09-10
5. Documentation date*: 2021-08-21
6. a. Organization contact first name* [redacted]
b. Last name* [redacted]
7.a. Phone no.* [redacted] ext. [redacted]
b. Email [redacted]
c. Fax
8. Organization name* [redacted]
9. Source of report (profession): Pharmacist
10. Health Canada institutional ID (If ID provided, no need to provide address)
11. Address [redacted]
12. City [redacted]
13. Province / Territory [redacted]
14. Postal code

15. Reason for seriousness* (explain (f) in section F)

☐ (a) Death (yyyy-mm-dd) _____ ☐ (b) Life-threatening ☐ (c) Disability ☐ (d) Congenital malformation
☐ (e) Caused/prolonged in-patient hospitalization ☒ (f) Required medical intervention to avoid any of (a) to (e)

B. Patient information

1. Patient ID (e.g. initials, record no.)	2. Sex**	3. Age**	4. Height	5. Weight
[redacted]	Female	78 Year(s)	cm or ft in	kg or lbs oz

6. Known medical conditions and relevant lifestyle factors* (e.g. hepatic and/or renal impairment, diabetes mellitus, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.)

none

7. Known allergies* (e.g. food, drugs, environmental, etc.; provide details)

none

C. Serious adverse drug reaction(s)

1. Did the patient recover?* (please choose one of the following)
☒ Recovered ☐ Recovering ☐ Not recovered
☐ Died ☐ Unknown ☐ Recovered with sequelae

2. Reaction start date*: 2021-08-26

3. Reaction end date*: 2021-08-27

4. Description of the serious adverse drug reaction(s)**
Significant asymptomatic bradycardia and hypotension overnight HR between 30-50 bpm

D. Suspect product one

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known. This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*: 02502143

2. Identifying code for urgent public health need drugs**:

3. Brand name** (per product label): veklury

4. Common/proper name** (active ingredient): remdesivir

5. Strength (per unit): 5 mg milligram(s) per ml

6. Dose: 100 mg milligram(s)

7. Frequency: daily

8. Dosage form (e.g. tablet, powder, liquid):

9. Route of administration: Intravenous (not otherwise specified)

10. Product start date*: 2021-08-26

11. Product end date*: 2021-08-27

12. Indication: COVID positive pneumonia hospitalized

13. Lot no.:

14. Expiry date:

15. a. Manufacturer name

b. Did you also report to the manufacturer?*
☐ Yes ☒ No

c. Date reported

d. Reference no.* (if known)

16. What action was taken?
Drug withdrawn

17. Did the reaction stop if dose was reduced or removed?
☐ Yes ☒ No ☐ Unknown ☐ N/A

18. Did the reaction return with reintroduction of the product?
☐ Yes ☐ No ☐ Unknown ☒ N/A

D. Suspect product two

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*	2. Identifying code for urgent public health need drugs**
3. Brand name** (per product label)	4. Common/proper name** (active ingredient)
5. Strength (per unit)	6. Dose

7. Frequency

8. Dosage form (e.g. tablet, powder, liquid)

9. Route of administration	10. Product start date*	11. Product end date*

12. Indication

13. Lot no.	14. Expiry date

15. a. Manufacturer name

b. Did you also report to the manufacturer?*
☐ Yes ☐ No

c. Date reported

d. Reference no.* (if known)

16. What action was taken?

17. Did the reaction stop if dose was reduced or removed?
☐ Yes ☐ No ☐ Unknown ☐ N/A

18. Did the reaction return with reintroduction of the product?
☐ Yes ☐ No ☐ Unknown ☐ N/A

E. Concomitant therapeutic product(s)

1. Known therapeutic product(s) taken or used at the same time the reaction occurred* (e.g. prescription and non-prescription drugs, medical devices, natural health products, etc. include details of use if available).

No previous home medications. On August 26th was started on dexamethasone 6 mg daily, Vitamin D 2000 units daily, Atrovent 20 mcg inh q1h prn, PEG 17.2-34.4 grams po daily PRN, rabeprazole 20 mg daily, remdesivir 100 mg IV daily, salbutamol 100 mcg 1 puff q1h prn, senokot 8.6 mg 2 tablets po daily prn, tinzaparin 14,000 units sq daily x 1 dose for PE protocol then reduced to 4500 units SQ bid when PE ruled out, tocilizumab 600 mg IV once.

F. Additional information

1. Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to the assessment of the serious adverse drug reaction(s).

Instructions on completing the serious adverse drug reaction (ADR) reporting form for hospitals

A. General information

A1. **Initial or follow-up***: Indicate whether the report is the first one submitted for this specific adverse drug reaction (i.e. initial) or a follow-up to a previously submitted report.

A2. **Health Canada reference number**: If the report is identified as a follow-up in A1, provide the reference number of the serious ADR report generated by Health Canada and provided to the submitter further to initial report submission.

A3. **Organization file number**: Indicate the hospital's identification number for the case. For follow-up reports, the file number should be the same as the number assigned to the initial report.

A4. **Date submitted**: Indicate the date the report was sent to Health Canada.

A5. **Documentation date***: Indicate the date when the hospital first documented this serious ADR.

A6. **Organization contact first & last name***: Enter the first and last name of a contact for the hospital.

A7. **Phone number, email or fax***: Enter the telephone number, email address or facsimile number to contact in the case of follow-up.

A8. **Organization name***: Enter the full name of the reporting hospital.

A9. **Source of report**: Indicate the profession of the hospital employee who first flagged this as a potential serious ADR.

A10. **Health Canada institutional ID**: Indicate the submitter's unique hospital identifier as assigned by Health Canada. To obtain this identifier, please contact hc.canada.vigilance.sc@canada.ca. Address details do not need to be completed if this unique number is provided.

A11. **Hospital address**: Enter the civic address for the hospital.

A12. **City**: Indicate the city in which the hospital is located.

A13. **Province/Territory**: Select the province or territory in which the hospital is located.

A14. **Postal code**: Provide the postal code of the hospital.

A15. **Reason for seriousness***: Select a criterion that makes the report a serious adverse reaction. More than one can be selected. Enter the date of death if known.

B. Patient information

B1. **Patient ID**: Provide a patient identifier in order to readily locate the case for follow-up purposes. This can be the patient's initials or the record number. Please do not provide the full name of the patient.

B2. **Sex***: Enter the patient's biological sex. Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male.

B3. **Age***: Provide the patient's age at the time of the reaction.

B4. **Height**: Enter the patient's height.

B5. **Weight**: Enter the patient's weight.

B6. **Known medical conditions and lifestyle factors***: If available, provide information on the patient's history and other known conditions.

B7. **Known allergies***: Provide the allergies the patient is known to have experienced, whether to food, drugs, environmental components, etc.

C. Serious adverse drug reaction(s)

C1. **Recovery status***: Indicate the outcome of the serious ADR.

C2. **Reaction start date***: Provide the date of onset of the serious ADR. Partial dates are acceptable

C3. **Reaction end date***: Provide the end date of the serious ADR if applicable. Do not provide this for reports involving death. Partial dates are acceptable.

C4. **Description of the serious adverse drug reaction(s)****: List the serious adverse drug reaction(s) that the patient experienced. Please try to avoid use of acronyms in this section.

D. Suspect product(s)

Up to two suspected products may be reported on one form. Attach additional forms if there are more than two suspected products for the reported serious ADR.

Reporting of product-specific identifiers is important for traceability of an adverse reaction to a specific suspect product. The drug identification number (DIN) is a unique identifier for all drug products sold in Canada. If the DIN is unknown, biologic drugs including biosimilars can be uniquely identified by providing their brand name. Generic drugs can be uniquely identified by providing both the generic name and the manufacturer name. Please also include the lot number, if known.

D1. **Drug identification number (DIN)***: Provide the drug identification number of the product the patient took, if available. For drugs accessed under an urgent public health need, provide the identifying code or number for the country in which the product is marketed. If the DIN is provided, it is not necessary to provide manufacturer, product name, active ingredient(s), strength, or dosage form.

D2. **Identifying code for urgent public health need drugs****: If the drug was imported as part of the access to drugs in exceptional circumstances, provide the code or number of the drug, if any, assigned in the country in which the drug was authorized for sale.

D3. & D4. Brand name, common/proper name**: Provide the brand name as per the product label if the DIN is not known. If the brand name cannot be provided, or is not specific (e.g. an active ingredient as brand name), please provide the proper name (active ingredients) and the manufacturer name.

D5. **Strength**: Provide the amount of active ingredient per single dosage form of the drug. For example, if the patient took two tablets of a medication, please provide the strength of only one tablet. Strength is defined as the amount of an active ingredient that the product contains.

D6. **Dose**: Indicate the amount of the product taken by the patient per the dosing regimen. Dose is normally expressed as a quantity.

D7. **Frequency**: Indicate how often the dose was taken by the patient. Shorthand text, such as b.i.d., is acceptable in this field.

D8. **Dosage form**: Indicate the dosage form of the product (e.g. tablet, powder, liquid)

D9. **Route of administration**: Provide the means by which the drug entered the patient's body. The top five most common routes of administration are at the top of the dropdown list.

D10. **Product start date***: Indicate the date on which the patient started using the product. If the exact date is not known, partial dates are acceptable.

D11. **Product end date***: Indicate the date the patient stopped using the product, if applicable. Please only enter data in this field if it is known that the patient stopped taking the product. Partial dates are acceptable.

D12. **Indication**: Enter the therapeutic reason for use.

D13. **Lot no.**: If known, indicate the lot number(s) of the suspect product.

D14. **Expiry date**: If known, indicate the expiry date.

D15. **Manufacturer details***: Indicate the manufacturer name of the suspect product and if the adverse reaction details were also provided to the manufacturer. If so, please also provide the date on which the case was reported to the manufacturer and the reference number if known.

D16. **Action taken**: Indicate what action was taken with the product.

D17. **Reaction stopped if dose was reduced or removed**: Indicate if the adverse reaction stopped after the suspect product was discontinued or the dose was reduced.

D18. **Reaction returned with reintroduction**: Indicate if the adverse reaction reappeared after the suspect product was reintroduced.

E. Concomitant therapeutic product(s)

E1. **Concomitant therapeutic products***: List all known health products, other than the suspect product, the patient was taking at the same time (i.e. concomitantly) the reaction occurred. Information related to therapy details of these products is not required but encouraged. Do not include health products used to treat the reaction.

F. Additional information

F1. This section can be used to provide a narrative summary of the serious adverse drug reaction, additional information on the underlying diagnosis that is pertinent to the reaction, or information that did not fit in the structured fields that could help to determine why the reaction occurred. For serious cases involving death, this section can also be utilized to provide details on the official cause of death and autopsy results.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices.html

Health Canada / Santé Canada

Protected "B" when completed

Serious adverse drug reaction reporting form for hospitals

Canada Vigilance - Adverse reaction reporting program

For best results, download and open this form in a PDF reader.

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance adverse reaction reporting program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

Purpose of collection: Health Canada requires this information to assess adverse reaction reports, monitor the safety of health products and enforce relevant legislation where applicable. Personal information may be used to analyze general trends, report to senior management and evaluate related programs and services. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools and/or responses to inquiries. A subset of de-identified Canada Vigilance adverse reaction reporting program data is made publicly available from the Canada Vigilance adverse reaction online database.

Other uses or disclosures: Personal information may be shared within Health Canada and with the Public Health Agency of Canada, the Canadian Medication Incident Reporting and Prevention System Program (managed in partnership with the Canadian Institute for Health Information, the Institute for Safe Medication Practices Canada, and the Canadian Patient Safety Institute), and international regulatory and health product monitoring authorities, for monitoring adverse reactions. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described in Info Source, available online at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a26. Refer to the personal information bank HC PPU 417.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's privacy coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Submission methods

Electronic reporting
If you are interested in submitting reports electronically (e.g. secure file transfer protocol - sFTP) to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca

Fax
Download, complete and print the Serious adverse drug reaction reporting form for hospitals.
Send by fax at: 1-866-678-6789

Mail it to the Canada Vigilance National Office
Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Address Locator 1908C
Ottawa, Ontario
K1A 0K9

If you have any questions related to mandatory reporting for hospitals, you may contact the Canada Vigilance Program by:
Email: hc.canada.vigilance.sc@canada.ca
Toll-free telephone: 1-866-234-2345

Canada

[redacted]

F A X / TÉLÉCOPIE

Date: 2021-11-08 14 | Time/*Heure* : | Pages : 1 of / de 13

To/*Destinataire* : Health Canada

From/*Expéditeur* : [redacted]

Fax/*Télécopieur* : 1-866-678-6789

Phone/*Tél.*: 1-866-234-2345

Fax/*Télécopieur* :

Phone/*Tél.*:

[redacted]

Comments/Commentaires:

Adverse Drug Reaction Report Submission

Please find the attached Adverse Drug Reaction Report from [redacted] Regarding IReport# [redacted]

Kindest Regards,

[redacted]

[redacted]

[redacted]

Canada Vigilance AER#:	000976680 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20211122 CCYYMMDD
	HC Initial Received Date:	20211122 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20211122134405_163885()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2021 CCYY	2021 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			49 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	
GP medical record no. (B.1.1.1a)	**Specialist record no. (B.1.1.1b)**	**Hospital record no. (B.1.1.1c)**	**Investigation no. (B.1.1.1d)**

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)	
MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)	
MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	DEXAMETHASONE	
Active Substance names (B.4.k.2.2)		
dexamethasone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12) 20210827 CCYYMMDD	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	ACTEMRA	
Active Substance names (B.4.k.2.2)		
tocilizumab		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
20210827 CCYYMMDD		
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502143 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12) 20210827 CCYYMMDD	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

PANCREATITIS

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Pancreatitis		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**		
25.0	Pancreatitis		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date (B.2.i.4)**	**End Date (B.2.i.5)**	**Duration (B.2.i.6)**

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

null

Dhpr log details:
Safety Report ID: CA-DHPR_H-20211122134405_163885
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20211122
Documentation Date: 20211122
First Name: [redacted]
Last Name: [redacted]
Telephone:
Ext.:
Address:
City:
Province/Territory:
Postal Code:
Email address: [redacted]
Organization: [redacted]
HC ID:
Reporter Type: Risk Management Coordinator

Patient ID:
Age: 49 Year(s)
Sex: Male
Height:
Weight:
Med History:
Allergies:

Serious Death:
Date of Death:
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization: Yes
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Recovered
Reaction Start Date:
Reaction End Date:
Reaction Description: Patient admitted for COVID. Started on Dexamethasone and then prescribed Tocilizumab and then prescribed Remdesevir. Patient indicative of pancreatitis.

Suspect Product 1
DIN #/NPN #:
UPHN #:
Brand Name: Dexamethasone, and Tocilizumab, and Remdesevir
Common Name:
Strength:
Strength other:
Dosage form:
Manufacturer:
Lot #:
Expiry date:
Product start date: 20210827
Product end date:
Dosage:
Dosage other:
Frequency:
Route of administration:
Route of administration - Other:
Indication:
Reported to Mfr:
Date reported to Mfr:
Mfr Reference number:
Drug action taken:
Dechallenge:
Rechallenge:

Concomitants:
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	COVID-19	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

SIDE EFFECT REPORTING FORM

Reporting suspected side effects (also known as adverse reactions) to marketed health products in Canada may contribute to the identification of previously unrecognized rare or serious side effects, which may lead to changes in the product's safety information.

FAX completed form to 1-866-678-6789
For more information call 1-866-234-2345

PROTECTED "B" WHEN COMPLETED"

Instructions on how to complete and submit this form and information about confidentiality can be found on Page 2.
Complete all mandatory fields, marked by a *, and provide as much detail as possible for the remaining fields.

A) About the person who had the side effect

Reference # (if applicable):

1. Age*	2. Sex*	3. Height	4. Weight
55 Years / Months	☐ Male ☒ Female	cm / ft in	74 kg / lbs oz

5. Medical history and other related information (allergies, pregnancy, smoking/alcohol use, liver disease, etc.)

Patient with no known allergies and no cardiac history, has a history of follicular stage III Lymphoma, completed 6 cycles of chemotherapy with Bendamustine and Rituximab in May 2021 and is now on maintenance therapy every 3 months. She is also on Zoster prophylaxis with Acyclovir.

B) Reporter information

1. Name*	2. Telephone*	3. Province/Territory
[redacted]	[redacted]	[redacted]

4. Address	5. E-mail
[redacted]	[redacted]

6. Preferred language: ☒ English ☐ French

7. Organization (if applicable): [redacted]

8. Select one that best describes you
☐ Consumer or other non-health professional ☐ Physician ☒ Pharmacist
☐ Other health professional (specify)

9. Has this also been reported to the manufacturer?
☐ Yes ☒ No

C) Side Effect

1. Seriousness of the side effect
☐ Death (yyyy-mm-dd)
☒ Life-threatening
☐ Admitted to hospital
☐ Lengthened hospital stay
☐ Disability
☐ Birth defect
☐ Needed medical attention

2. Recovered after the side effect*
☒ Yes ☐ No ☐ Unknown
☐ Recovering (explain)

3. Side effect start date* (yyyy-mm-dd)	4. Side effect end date (yyyy-mm-dd)
2022-01-13	2022-01-14

5. Describe the side effect (timeliness, treatment, etc.)*

Patient tested positive for COVID and started on Dexamethasone and Remdesivir on January 10th. She then developed a long QT up to 600 ms range,bigeminy with frequent PVCs and bradycardia. She had two episodes of torsades de pointes in [redacted] first episode on January 13th and second the following day,she also became unconscious, Code Blue was called, she received 5 minutes of CPR with no shocks or injection of Epinephrine and she self reverted back to normal sinus rhythm and regained consciousness afterwards.She was brought to [redacted] She had similar episodes while in ICU at [redacted] that were short-lived. QT interval improved with removal of Remdesivir.

D) Suspected health product

1. Product name*	2. Strength	3. Manufacturer
Remdesivir	100mg	Gilead Sciences

4. Lot #	5. DIN #/NPN #
	2502143

6. Country of purchase
☒ Canada
☐ United States
☐ Other (specify):

7. Where it was purchased/obtained
☐ Pharmacy
☐ Grocery store
☐ Internet
☐ Other (specify):

8. Product start date (yyyy-mm-dd)*	9. Product end date (yyyy-mm-dd)
2022-01-10	2022-01-14

At the time of the side effect, specify:

10. Dosage* (strength and quantity)	11. Frequency (e.g. twice daily)	12. How the product was taken* (e.g. by mouth)
100mg	once daily	IV

13. What was the product prescribed/taken for?*
COVID-19

14. Did use of the product stop after the side effect appeared?	15. If the product was stopped did the side effect stop?
☒ Yes ☐ No	☐ Yes ☒ No ☐ Does not apply

16. Was the product restarted after the side effect stopped?	17. If the product was restarted, did the side effect return?
☐ Yes ☒ No ☐ Does not apply	☐ Yes ☐ No ☐ Does not apply

18. Likelihood that the product caused the side effect
☐ Certain
☒ Probably/Likely
☐ Possible
☐ Not available/Unable to assess
☐ Unlikely
☐ Unrelated

19. Other health products taken at the time of the side effect, excluding treatment (length of use, timelines, etc.)

20. Related test/laboratory results

** As per the Treasury Board of Canada Secretariat Government Security Policy.

Pub : 150142 | Date: April 2020

Health Canada Santé Canada

Canada

Canada Vigilance AER#:	000989483 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220224 CCYYMMDD
	HC Initial Received Date:	20220224 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20220224145340_18095()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2022 CCYY	2022 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			85 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502135 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

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Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

BRADYCARDIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	Bradycardia		
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT)** (B.2.i.2.b)		
25.0	Bradycardia		
Term hightlighted by the reporter? (B.2.i.3)	**Start Date** (B.2.i.4)	**End Date** (B.2.i.5)	**Duration** (B.2.i.6)
	20220121		
Reaction first time (B.2.i.7.1)	**Reaction last time** (B.2.i.7.2)	**Outcome** (B.2.i.8)	

Summary (B.5)

Case narrative (B.5.1)

null

Dhpr log details:
Safety Report ID: CA-DHPR_H-20220224145340_18095
Type of Report: Initial
HC Ref. No:
Reporter File No.: [redacted]
Transmission Date: 20220224
Documentation Date: 20220124
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.: [redacted]
Address:
City: [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization: [redacted]
HC ID:
Reporter Type:

Patient ID: [redacted]
Age: 85 Year(s)
Sex: Male
Height:
Weight:
Med History:
Allergies:

Serious Death:
Date of Death:
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization: Yes
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome:
Reaction Start Date: 20220121
Reaction End Date:
Reaction Description: Bradycardia

Suspect Product 1
DIN #/NPN #:
UPHN #:
Brand Name: Veklury
Common Name: Remdesivir
Strength:
Strength other:
Dosage form:
Manufacturer:
Lot #:
Expiry date:
Product start date:
Product end date:
Dosage:
Dosage other:
Frequency:
Route of administration:
Route of administration - Other:
Indication:
Reported to Mfr:
Date reported to Mfr:
Mfr Reference number:
Drug action taken:
Dechallenge:
Rechallenge:

Concomitants:
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

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Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c)
[redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Other health professional

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

Field	
A.1 - Type of report*	Initial
A.2 - Health Canada (HC) Reference No. (for follow-up reports only)	
A.3 - Organization File No.	[redacted]
A.4 - Date report submitted	2022-02-28
A.5 - Documentation date*	2022-02-14
A.6a - Organization contact first name*	[redacted]
A.6b -Last name*	
A.7.a - Phone no.*	
A.7.a- ext.	N/A
A.7.b - Email	[redacted]
A.7.c - Fax	N/A
A.8 - Organization name*	[redacted]
A.9- Source of report (profession)	Pharmacist
A.10 - Heath Canada institutional ID (If ID provided, no need to provide address)	[redacted]
A.11 - Address	N/A
A.12 - City	N/A
A.13 - Province/Territory	[redacted]
A.14 - Postal code	N/A
A.15.a - Reason for seriousness: Death*	No
A.15.a - Date of death*	
A.15.b - Reason for seriousness: Life-threatening*	No
A.15.c - Reason for seriousness: Disability*	No
A.15.d - Reason for seriousness: Congenital malformation*	No
A.15.e - Reason for seriousness: Caused/prolonged in-patient hospitalization*	No
A.15.f - Reason for seriousness: Required medical intervention to avoid any of (a) to (e)*	Yes
B.1 - Patient ID (e.g. initials, record no.)	
B.2 - Sex**	Male
B.3.a - Age**	75
B.3.b - Age unit**	Year(s)
B.4. Height (cm)	
B.5. Weight (kg)	

B.6 - Known medical conditions and relevant lifestyle factors*	COVID positive
B.7 - Known allergies*	
C.1 - Did the patient recover?*	Recovered
C.2 - Reaction start date*	2022-02-12
C.3 - Reaction end date*	2022-02-14
C.4 - Description of the serious adverse drug reaction(s)**	Patient started on Remdesivir Feb 11, 2022. Patient started experiencing bradycardia on Feb 12, 2022. Heart rate of 35 reported on Feb 12, 2022. No previous history of bradycardia and no other medications likely causing the bradycardia. Patient received further monitoring and follow up including blood work, ECG and a holter monitor for 48 hours.
D.1 - Drug identification number (DIN)*	
D.2 - Identifying code for urgent public health need drugs (if applicable)**	
D.3 - Brand name (per product label)**	
D.4 - Common/proper name (active ingredient)	remdesivir
D.5 - Strength	
D.5 - Strength unit	
D.5 - Other strength unit	
D.6 - Dose	
D.6 - Dose unit	
D.6 - Other dose unit	
D7 - Frequency	
D.8 - Dosage form	
D.9 - Route of administration	
D.9 - Other route of administration	
D.10 - Product start date*	
D.11 - Product end date*	
D.12 - Indication	
D.13 - Lot no.	
D.14 - Expiry date	
D.15.a - Manufacturer name*	
D.15.b - Did you also report to the manufacturer?	
D.15.c - Date reported	
D.15.d - Reference no. (if known)	
D.16 - What action was t aken?	
D.17 - Did the reaction stop if dose was reduced or removed?	Yes

D.18 - Did the reaction return with reintroduction of the product?	
E - Known therapeutic products taken or used at the same time the reaction occurred*	Ceftriaxone 2000mg IV daily Cetirizine 20mg po daily Cyanocobalamin 1000mcg po daily Folic acid 1mg po daily Hydroxyzine 25mg po daily at bedtime Multivitamins - 1 tablet po daily Pantoprazole Magnesium 40mg po daily Lax-a-day 17g po daily at bedtime Tamsulosin 0.4mg po daily Thiamine 300mg po daily Tinzaparin 4500 units sc daily Acetaminophen 650mg po q6h prn Omega 3 - 1 capsule po daily Ondansetron 4mg po qid prn sennosides 17.2mg po daily at bedtime prn
F.1 - Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction(s).	

2 | Serious adverse drug reaction reporting form for hospitals

* = required, if known (if information is in the control of or reasonably accessible by the hospital for mandatory reporting)

** = required (hospital is exempt from mandatory reporting if this information is unavailable)

Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

A. General information

1. Type of report*	2. Health Canada reference no. (for follow-up reports only)
☒ Initial ☐ Follow-up	

3. Organization file no.	4. Date report submitted	5. Documentation date*
	2022-04-04	[redacted]

6. a. Organization contact first name* [redacted] b. Last name* [redacted]	7.a. Phone no.* [redacted] ext. b. Email c. Fax

8. Organization name* [redacted]

9. Source of report (profession)	10. Health Canada institutional ID (If ID provided, no need to provide address)
Pharmacist	

11. Address	12. City	13. Province / Territory	14. Postal code
	[redacted]	[redacted]	

15. Reason for seriousness* (explain (f) in section F)

☒ (a) Death (yyyy-mm-dd) [redacted] ☐ (b) Life-threatening ☐ (c) Disability ☐ (d) Congenital malformation

☐ (e) Caused/prolonged in-patient hospitalization ☐ (f) Required medical intervention to avoid any of (a) to (e)

B. Patient information

1. Patient ID (e.g. initials, record no.)	2. Sex**	3. Age**	4. Height	5. Weight
[redacted]	Female	51 Year(s)	cm or ft in	108 kg or lbs oz

6. Known medical conditions and relevant lifestyle factors* (e.g. hepatic and/or renal impairment, diabetes mellitus, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.).

Type 2 Diabetes, GERD, Hypertension, Anemia, Obesity, Chronic back and leg pain,Blue toe syndrome/foot cellulitis/infectious myositis of her anterior compartment of right lower leg, amputation of D1 and D5 ([redacted]) secondary to aortic thrombus with embolic phenomena

Covid positive [redacted]

Smokes 6 cigarettes per day. No alcohol, no IV drug use. Opioid use for chronic pain.

[redacted] - Serum creatinine was 85, egfr 69ml/min and ALT 52

7. Known allergies* (e.g. food, drugs, environmental, etc.; provide details).

NKA

C. Serious adverse drug reaction(s)

1. Did the patient recover?*
(please choose one of the following)

☐ Recovered ☐ Recovering ☐ Not recovered
☒ Died ☐ Unknown ☐ Recovered with sequelae

2. Reaction start date* [redacted]

3. Reaction end date* [redacted]

4. Description of the serious adverse drug reaction(s)**

[redacted] @ 1523 - SCr 310, egfr 14ml/min, K+ 5.6, Ca 1.89, Phos 2.74, AST 223, ALT 106, CRP 69.1, A1C 10%,VBG 7.19,HCO3 19.
@ 1030 - SCR 498, egfr 8ml/min, K+ 6.6, VBG ph 6.89, HCO3 5, then @ 1245 - SCr 476, egfr 9ml/min, K+ 7.9,
New onset AKI, LFT inc, sudden onset somnolence, significant respiratory efforts, O2 sats 76%, resp arrest, cardiac arrest

D. Suspect product one

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*
02502143

2. Identifying code for urgent public health need drugs**

3. Brand name** (per product label)
Velkury

4. Common/proper name** (active ingredient)
Remdesivir

5. Strength (per unit)
100 mg milligram(s)

6. Dose
200 mg milligram(s) loading

7. Frequency
daily x 5 days

8. Dosage form (e.g. tablet, powder, liquid) powder

9. Route of administration Intravenous drip

10. Product start date* [redacted]

11. Product end date* [redacted]

12. Indication
COVID

13. Lot no.

14. Expiry date

15. a. Manufacturer name
Gilead Sciences Canada Inc.

b. Did you also report to the manufacturer?*
☐ Yes ☒ No

c. Date reported

d. Reference no.* (if known)

16. What action was taken?

17. Did the reaction stop if dose was reduced or removed?
☐ Yes ☒ No ☐ Unknown ☐ N/A

18. Did the reaction return with reintroduction of the product?
☐ Yes ☐ No ☐ Unknown ☒ N/A

D. Suspect product two

If the DIN is not provided, please provide the brand name or the proper name, as well as the manufacturer name if known
This information is important for traceability of an adverse reaction to a specific suspect product.

1. Drug identification number (DIN)*
00445282

2. Identifying code for urgent public health need drugs**

3. Brand name** (per product label)
Sulfatrim DS

4. Common/proper name** (active ingredient)
Trimethoprim/Sulfamethoxazole DS

5. Strength (per unit)
160mg Trimethoprim
800mg Sulfamethoxazole

6. Dose
1 DF dosage form 1 tablet

7. Frequency
BID

8. Dosage form (e.g. tablet, powder, liquid) tablet

9. Route of administration Oral

10. Product start date* [redacted]

11. Product end date* [redacted]

12. Indication
Foot infection

13. Lot no.

14. Expiry date

15. a. Manufacturer name

b. Did you also report to the manufacturer?*
☐ Yes ☐ No

c. Date reported

d. Reference no.* (if known)

16. What action was taken?

17. Did the reaction stop if dose was reduced or removed?
☐ Yes ☐ No ☐ Unknown ☐ N/A

18. Did the reaction return with reintroduction of the product?
☐ Yes ☐ No ☐ Unknown ☐ N/A

E. Concomitant therapeutic product(s)

1. Known therapeutic product(s) taken or used at the same time the reaction occurred* (e.g. prescription and non-prescription drugs, medical devices, natural health products, etc. Include details of use if available).

Amitriptyline 25mg po qhs, EC ASA 81mg po daily, Atorvastatin 40mg po qhs, Dexamethasone 6mg po daily, empagliflozin 12.5mg po daily (first dose [redacted]), Enoxaparin 110mg sc bid, Fluoxetine 20mg po daily, Humalog sliding scale, Morphine ER 15mg [redacted] @ 1008, Morphine ER 45mg [redacted] @1152, Morphine ER 10mg [redacted] @1142, Narcan 0.4mg [redacted] @1648, Narcan [redacted] @1250, Metformin 250mg po bid, Nicotine patch 7mg daily, pantoprazole 40mg po daily,pramipexole 0.25mg po daily, pregabalin 300mg po daily, quinapril 5mg po daily, Septra DS 1 tab po bid (started [redacted] @1000)

F. Additional information

1. Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to the assessment of the serious adverse drug reaction(s).

Autopsy is pending.

Instructions on completing the serious adverse drug reaction (ADR) reporting form for hospitals

A. General information

A1. **Initial or follow-up***: Indicate whether the report is the first one submitted for this specific adverse drug reaction (i.e. initial) or a follow-up to a previously submitted report.

A2. **Health Canada reference number**: If the report is identified as a follow-up in A1, provide the reference number of the serious ADR report generated by Health Canada and provided to the submitter further to initial report submission.

A3. **Organization file number**: Indicate the hospital's identification number for the case. For follow-up reports, the file number should be the same as the number assigned to the initial report.

A4. **Date submitted**: Indicate the date the report was sent to Health Canada.

A5. **Documentation date***: Indicate the date when the hospital first documented this serious ADR.

A6. **Organization contact first & last name***: Enter the first and last name of a contact for the hospital.

A7. **Phone number, email or fax***: Enter the telephone number, email address or facsimile number to contact in the case of follow-up.

A8. **Organization name***: Enter the full name of the reporting hospital.

A9. **Source of report**: Indicate the profession of the hospital employee who first flagged this as a potential serious ADR.

A10. **Health Canada institutional ID**: Indicate the submitter's unique hospital identifier as assigned by Health Canada. To obtain this identifier, please contact hc.canada.vigilance.sc@canada.ca. Address details do not need to be completed if this unique number is provided.

A11. **Hospital address**: Enter the civic address for the hospital.

A12. **City**: Indicate the city in which the hospital is located.

A13. **Province/Territory**: Select the province or territory in which the hospital is located.

A14. **Postal code**: Provide the postal code of the hospital.

A15. **Reason for seriousness***: Select a criterion that makes the report a serious adverse reaction. More than one can be selected. Enter the date of death if known.

B. Patient information

B1. **Patient ID**: Provide a patient identifier in order to readily locate the case for follow-up purposes. This can be the patient's initials or the record number. Please do not provide the full name of the patient.

B2. **Sex****: Enter the patient's biological sex. Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male.

B3. **Age****: Provide the patient's age at the time of the reaction.

B4. **Height**: Enter the patient's height.

B5. **Weight**: Enter the patient's weight.

B6. **Known medical conditions and lifestyle factors***: If available, provide information on the patient's history and other known conditions.

B7. **Known allergies***: Provide the allergies the patient is known to have experienced, whether to food, drugs, environmental components, etc.

C. Serious adverse drug reaction(s)

C1. **Recovery status***: Indicate the outcome of the serious ADR.

C2. **Reaction start date***: Provide the date of onset of the serious ADR. Partial dates are acceptable

C3. **Reaction end date***: Provide the end date of the serious ADR if applicable. Do not provide this for reports involving death. Partial dates are acceptable.

C4. **Description of the serious adverse drug reaction(s)****: List the serious adverse drug reaction(s) that the patient experienced. Please try to avoid use of acronyms in this section.

D. Suspect product(s)

Up to two suspected products may be reported on one form. Attach additional forms if there are more than two suspected products for the reported serious ADR.

Reporting of product-specific identifiers is important for traceability of an adverse reaction to a specific suspect product. The drug identification number (DIN) is a unique identifier for all drug products sold in Canada. If the DIN is unknown, biologic drugs including biosimilars can be uniquely identified by providing their brand name. Generic drugs can be uniquely identified by providing both the generic name and the manufacturer name. Please also include the lot number, if known.

D1. **Drug identification number (DIN)***: Provide the drug identification number of the product the patient took, if available. For drugs accessed under an urgent public health need, provide the identifying code or number for the country in which the product is marketed. If the DIN is provided, it is not necessary to provide manufacturer, product name, active ingredient(s), strength, or dosage form.

D2. **Identifying code for urgent public health need drugs****: If the drug was imported as part of the access to drugs in exceptional circumstances, provide the code or number of the drug, if any, assigned in the country in which the drug was authorized for sale.

D3. **& D4. Brand name, common/proper name****: Provide the brand name as per the product label if the DIN is not known. If the brand name cannot be provided, or is not specific (e.g. an active ingredient as brand name), please provide the proper name (active ingredients) and the manufacturer name.

D5. **Strength**: Provide the amount of active ingredient per single dosage form of the drug. For example, if the patient took two tablets of a medication, please provide the strength of only one tablet. Strength is defined as the amount of an active ingredient that the product contains.

D6. **Dose**: Indicate the amount of the product taken by the patient per the dosing regimen. Dose is normally expressed as a quantity.

D7. **Frequency**: Indicate how often the dose was taken by the patient. Shorthand text, such as b.i.d., is acceptable in this field.

D8. **Dosage form**: Indicate the dosage form of the product (e.g. tablet, powder, liquid)

D9. **Route of administration**: Provide the means by which the drug entered the patient's body. The top five most common routes of administration are at the top of the dropdown list.

D10. **Product start date***: Indicate the date on which the patient started using the product. If the exact date is not known, partial dates are acceptable.

D11. **Product end date***: Indicate the date the patient stopped using the product, if applicable. Please only enter data in this field if it is known that the patient stopped taking the product. Partial dates are acceptable.

D12. **Indication**: Enter the therapeutic reason for use.

D13. **Lot no.**: If known, indicate the lot number(s) of the suspect product.

D14. **Expiry date**: If known, indicate the expiry date.

D15. **Manufacturer details***: Indicate the manufacturer name of the suspect product and if the adverse reaction details were also provided to the manufacturer. If so, please also provide the date on which the case was reported to the manufacturer and the reference number if known.

D16. **Action taken:** Indicate what action was taken with the product.

D17. **Reaction stopped if dose was reduced or removed:** Indicate if the adverse reaction stopped after the suspect product was discontinued or the dose was reduced.

D18. **Reaction returned with reintroduction:** Indicate if the adverse reaction reappeared after the suspect product was reintroduced.

E. Concomitant therapeutic product(s)

E1. **Concomitant therapeutic products***: List all known health products, other than the suspect product, the patient was taking at the same time (i.e. concomitantly) the reaction occurred. Information related to therapy details of these products is not required but encouraged. Do not include health products used to treat the reaction.

F. Additional information

F1. This section can be used to provide a narrative summary of the serious adverse drug reaction, additional information on the underlying diagnosis that is pertinent to the reaction, or information that did not fit in the structured fields that could help to determine why the reaction occurred. For serious cases involving death, this section can also be utilized to provide details on the official cause of death and autopsy results.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospitalreporting/drugs-devices.html

Health Canada Santé Canada

Protected "B" when completed

Serious adverse drug reaction reporting form for hospitals

Canada Vigilance - Adverse reaction reporting program

For best results, download and open this form in a PDF reader.

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance adverse reaction reporting program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

Purpose of collection: Health Canada requires this information to assess adverse reaction reports, monitor the safety of health products and enforce relevant legislation where applicable. Personal information may be used to analyze general trends, report to senior management and evaluate related programs and services. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools and/or responses to inquiries. A subset of de-identified Canada Vigilance adverse reaction reporting program data is made publicly available from the Canada Vigilance adverse reaction online database.

Other uses or disclosures: Personal information may be shared within Health Canada and with the Public Health Agency of Canada, the Canadian Medication Incident Reporting and Prevention System Program (managed in partnership with the Canadian Institute for Health Information, the Institute for Safe Medication Practices Canada, and the Canadian Patient Safety Institute), and international regulatory and health product monitoring authorities, for monitoring adverse reactions. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described in Info Source, available online at https://www.canada.ca/en/health-canada/corporate/about-health-canada/activities-responsibilities/access-information-privacy/info-source-federal-government-employee-information.html#a26. Refer to the personal information bank HC PPU 417.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's privacy coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Submission methods

Electronic reporting
If you are interested in submitting reports electronically (e.g. secure file transfer protocol - sFTP) to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca

Fax
Download, complete and print the Serious adverse drug reaction reporting form for hospitals.
Send by fax at: 1-866-678-6789

Mail it to the Canada Vigilance National Office
Canada Vigilance Program
Health Products Surveillance and Epidemiology Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Address Locator 1908C
Ottawa, Ontario
K1A 0K9

If you have any questions related to mandatory reporting for hospitals, you may contact the Canada Vigilance Program by:
Email: hc.canada.vigilance.sc@canada.ca
Toll-free telephone: 1-866-234-2345

Canada

From: Canada Vigilance (HC/SC)
Sent: 2022-04-04 3:27 PM
To: HPFB MHPSEIB EFAX / BIIEPSC DGPSA (HC/SC)
Cc: Chen, Rebecca x (HC/SC)
Subject: [redacted] FW: ADR Report
Attachments: [redacted] ADR report.pdf

Hello EFAX,

Please see attached for DE.

@Rebecca: This has been assigned to you to notify the reporter of the appropriate methods of submission.
\\Ncr-a-irbv1s\irbv1\HC\HPFB\MHPD\MHPSEIB-PROS\COMMUNICATIONS GC2\ENQUIRIES\Correspondence\Mandatory Reporting for Hospitals\2022\[redacted]

Thanks,
CV

From: [redacted]
Sent: 2022-04-04 3:09 PM
To: hc.canada.vigilance.sc@canada.ca
Subject: ADR Report

See attached

[redacted]

[redacted]

[redacted]

Please consider the environment before printing this email.

Canada Vigilance AER#:	000997134 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220419 CCYYMMDD
	HC Initial Received Date:	20220419 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20220419143400_16847()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	Yes
2022 CCYY	2022 CCYY	Life threatening?	Yes
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
	N/A

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital -

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			79 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502143 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
200 Milligram		
Dosage text (B.4.k.6)		
Frequency Text: Once		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
	Intravenous (not otherwise specified)	
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
	25.0	COVID-19
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20220415 CCYYMMDD	20220416 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
4 Days	2 Days	
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	

Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ELIQUIS	
Active Substance names (B.4.k.2.2)		
apixaban		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DEXAMETHASONE	
Active Substance names (B.4.k.2.2)		
dexamethasone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** DILTIAZEM CD	
Active Substance names (B.4.k.2.2) diltiazem hydrochloride		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DULOXETINE HYDROCHLORIDE	
Active Substance names (B.4.k.2.2)		
duloxetine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	LORAZEPAM	
Active Substance names (B.4.k.2.2)		
lorazepam		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VENTOLIN	
Active Substance names (B.4.k.2.2)		
salbutamol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

CVA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
25.0	CVA		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
25.0	Cerebrovascular accident		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	20220418 CCYYMMDD	20220419 CCYYMMDD	1 Days

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
4 Days	2 Days	

Summary (B.5)

Case narrative (B.5.1)

Received 3 days total remdesivir: 200mg IV on April 14 then 100mg IV daily April 15-16 (per PINETREE trial).
Discharged from ICU after dose April 16.

Dhpr log details:
Safety Report ID: CA-DHPR_H-20220419143400_16847
Type of Report: Initial
HC Ref. No:
Reporter File No.:
Transmission Date: 20220419
Documentation Date: 20220419
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.:
Address: [redacted]
City: [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization: [redacted]
HC ID:
Reporter Type: Pharmacist

Patient ID: [redacted]
Age: 79 Year(s)
Sex: Female
Height:
Weight:
Med History: Atrial fibrillation (treated with Eliquis).
Allergies: NKA

Serious Death:
Date of Death:
Serious Life-Threatening: Yes
Serious Disability: Yes
Serious Hospitalization: Yes
Serious Congenital Anomaly:
Serious Other:
Serious Other Explain:

Reaction 1
Outcome: Recovering
Reaction Start Date: 20220418
Reaction End Date: 20220419
Reaction Description: Admitted to hospital with CVA.

Suspect Product 1
DIN #/NPN #: 02502143
UPHN #: N/A
Brand Name: Veklury
Common Name: remdesivir
Strength:
Strength other:
Dosage form:
Manufacturer: Gilead Sciences
Lot #:
Expiry date:
Product start date: 20220414
Product end date: 20220416
Dosage: 200 mg milligram(s)
Dosage other:
Frequency: Once
Route of administration: Intravenous (not otherwise specified)
Route of administration - Other:
Indication: COVID
Reported to Mfr: No
Date reported to Mfr:
Mfr Reference number: N/A
Drug action taken: Not applicable
Dechallenge: Unknown
Rechallenge: Unknown

Concomitants: Apixaban 5mg po BID, dexamethasone 6mg PO/IV daily (COVID therapy), diltiazem CD 180mg po daily, duloxetine 60mg po daily, lorazepam 1mg po q4-6h PRN, Ventolin 100mcg 1 puff q4h PRN.
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	Atrial fibrillation	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)

Comments (B.1.7.1g)

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Atrial fibrillation (treated with Eliquis).
Allergies:NKA

Past drug therapy (B.1.8)

Drug name (B.1.8a)

Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)

Comments (B.1.10.7.1g)

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)

Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Canada Vigilance AER#:	000997134 (0)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c)

[redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

ATIA - 19(1)

fax: 1-866-678-6789

FORMULAIRE DE DÉCLARATION DES EFFETS SECONDAIRES

La déclaration des effets secondaires (aussi appelés « effets indésirables ») de produits de santé commercialisés au Canada peut contribuer à l'identification d'effets secondaires graves ou rares, ce qui peut entraîner la modification de l'information sur l'innocuité du produit.

Les instructions sur la façon de compléter et de soumettre le présent formulaire ainsi que l'information concernant la confidentialité se trouvent à la page 2. Compléter tous les items obligatoires, indiqués par un *, et fournir autant d'information que possible pour les autres items.

Veuillez envoyer le formulaire rempli par télécopieur au 1-866-678-6789. Pour de plus amples renseignements, composez le 1-866-234-2345.

PROTÉGÉ « B » LORSQUE REMPLI*

A) Renseignements sur la personne ayant subi l'effet secondaire

N° de référence (le cas échéant) :

1. Âge*	2. Sexe*	3. Taille	4. Poids
93 ans 6 mois	☐ Homme ☒ Femme	150 cm ____ pi ____ po	____ kg 131 lbs ____ oz

5. Antécédents médicaux et autres renseignements pertinents (allergies, grossesse, consommation de tabac/d'alcool, dysfonctionnement hépatique, etc.)

FA
HTA
insuffisance cardiaque
Allergie: pénicilline

B) Renseignements sur le déclarant

1. Nom*	2. Téléphone*	3. Province/Territoire
[redacted]		

4. Adresse	5. Courriel
[redacted]	

6. Langue préférée	7. Organisation (le cas échéant)
☒ français ☐ anglais	[redacted]

8. Choisir ce qui vous décrit le mieux

☐ Consommateur ou autre non-professionnel de la santé ☐ Médecin ☒ Pharmacien

☐ Autre professionnel de la santé (spécifier) : _____

9. Cela a-t-il été déclaré au fabricant?

☐ Oui ☒ Non

C) Effet secondaire

1. Niveau de sévérité de l'effet secondaire

☐ Décès (fournir la date) _____
☐ Met la vie en danger
☒ Hospitalisation
☐ Prolongation d'une hospitalisation
☐ Incapacité
☐ Malformation congénitale
☐ Besoin d'une intervention médicale

2. Rétablissement suite à l'effet secondaire*

☒ Oui ☐ Non ☐ Inconnu

☐ En cours de rétablissement (expliquer) : _____

3. Date du début de l'effet secondaire* (aaaa-mm-jj)	4. Date de la fin de l'effet secondaire (aaaa-mm-jj)
2022-04-26	2022-04-27

5. Décrire l'effet secondaire (ligne de temps, traitement, etc.)*

Réaction d'hypersensibilité :
frissons en fin de perfusion
puis nausée, vomissement
tachycardie 120 bpm, pt transférée à l'urgence

D) Produit de santé soupçonné

1. Nom du produit*	2. Concentration	3. Fabricant
Veklury (Remdesivir)	200mg	Gilead

4. N° du lot	5. N° du DIN / N° du NPN
N/A.	02502143

6. Pays d'achat	7. Où le produit a-t-il été acheté/obtenu?
☒ Canada ☐ États-Unis ☐ Autre (spécifier) : _____	☐ Pharmacie ☐ Épicerie ☐ Internet ☒ Autre (spécifier) : Hôpital

8. Date du début du traitement (aaaa-mm-jj)*	9. Date de la fin du traitement (aaaa-mm-jj)
2022-04-26	2022-04-26

Aux environs de l'apparition de l'effet secondaire, spécifier :

10. Posologie (concentration, quantité)	11. Fréquence (p. ex. 2 fois par jour)	12. Voie d'administration du produit (p. ex. voie orale)
200mg	1 dose	IV

13. Pourquoi le produit a-t-il été pris/prescrit?*

covid-19

14. Est-ce que l'utilisation du produit a cessé suite à l'apparition de l'effet secondaire?	15. Si l'utilisation du produit a cessé, l'effet secondaire s'est-il arrêté?
☒ Oui ☐ Non	☒ Oui ☐ Non ☐ Ne s'applique pas

16. Est-ce que l'utilisation du produit a recommencé suite à l'arrêt de l'effet secondaire?	17. Si l'utilisation a été recommencée, l'effet secondaire s'est-il reproduit?
☐ Oui ☒ Non ☐ Ne s'applique pas	☐ Oui ☐ Non ☒ Ne s'applique pas

18. Probabilité que le produit ait causé l'effet secondaire

☒ Certain
☐ Probablement/vraisemblablement
☐ Possiblement
☐ Pas disponible / incapable de vérifier
☐ Improbable
☐ Sans rapport

19. Autres produits de santé consommés aux environs de l'apparition de l'effet secondaire, excluant le traitement (temps d'utilisation, ligne de temps, etc.)

N/A

20. Tests/données de laboratoire pertinents

DFGe 52 ml/min.

* Selon la Politique du gouvernement du Canada émise par le Secrétariat du Conseil du Trésor du Canada.

Pub. : 150143 | Date : avril 2020

Health Canada Santé Canada

Canada Vigilance National Office
Health Products Surveillance and Epidemiology Bureau
Health Products and Food Branch
Tunney's Pasture AL: 1908C
Ottawa, (Ontario) K1A 0K9
Tel (toll-free): 1-866-234-2345
Fax (toll-free): 1-866-678-6789
canadavigilance@hc-sc.gc.ca

2022-06-01

[redacted]

Re: Adverse Reaction Number 001000056

Dear [redacted],

Thank you for submitting an adverse reaction report to the Canada Vigilance Program on 2022-05-04, regarding the following health product(s):

VEKLURY SINGLE-DOSE VIAL

The information that you included in your report has been recorded in the Canada Vigilance Program database and assigned the Adverse Reaction Number 001000056. Please reference this number should you wish to report additional information on this event. Please note that Health Canada will contact you about your report only if additional information is required for its surveillance activities.

The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products that have been submitted by manufacturers and by hospitals, or by health professionals and consumers either directly to Health Canada or via the manufacturers and/or hospitals.

The information from adverse reaction reports as well as information from other sources of data is used to determine whether the benefits of a given health product continue to outweigh its risks and to take appropriate action to minimize any new risks. Such actions may include the update of the label of a health product in its authorized Canadian monograph, risk communication(s) to inform Canadians about possible new adverse reactions and/or a recall of the product.

For information on health products authorized for sale in Canada, you may wish to consult the following:

- Drug Product Database:
https://health-products.canada.ca/dpd-bdpp/index-eng.jsp

- Licensed Natural Health Products Database:
https://health-products.canada.ca/lnhpd-bdpsnh/index-eng.jsp

- Canada Vigilance Adverse Reaction Online Database:
https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html

- Health Canada's advisories, recalls and other communication on health products:
https://www.canada.ca/en/health-canada/services/drugs-health-products/advisories-warnings-recalls.html

We would like to thank you once again for your report, as your contribution and commitment to health product safety monitoring are appreciated.

Sincerely,

Canada Vigilance Program
Marketed Health Products Directorate
Health Canada

Canada

Health Canada Santé Canada

Bureau national de Canada Vigilance
Bureau de la surveillance des produits de santé et de l'épidémiologie
Direction des produits de santé commercialisés
Pré Tunney, I.A. : 1908C
Ottawa (Ontario) K1A 0K9
Tél. (sans frais) : 1-866-234-2345
Téléc. (sans frais) : 1-866-678-6789
canadavigilance@hc-sc.gc.ca

2022-06-01

[redacted]

Objet : Déclaration d'effet indésirable 001000056

Cher / Chère [redacted],

Nous vous remercions d'avoir communiqué des renseignements sur des effets indésirables à Santé Canada, le 2022-05-04, concernant le(s) produit(s) de santé suivant(s) :

VEKLURY SINGLE-DOSE VIAL

L'information que vous avez fournie dans votre déclaration a été enregistrée dans la base de données du Programme Canada Vigilance sous le numéro d'effet indésirable 001000056. Veuillez indiquer ce numéro si vous voulez fournir des renseignements supplémentaires au sujet de cet incident. Veuillez noter que Santé Canada ne vous contactera à propos de votre rapport que si des informations complémentaires sont requises pour ses activités de surveillance.

Le Programme Canada Vigilance est le programme de surveillance après la mise en marché de Santé Canada qui recueille et évalue les déclarations d'effets indésirables présumés associés aux produits de santé qui ont été soumises directement à Santé Canada par les professionnels de la santé et les consommateurs ou par l'entremise des détenteurs d'une autorisation de mise en marché ou des hôpitaux.

Les renseignements tirés des déclarations d'effets indésirables et d'autres sources de données servent à déterminer si les avantages d'un produit de santé donné continuent de l'emporter sur ses risques et à prendre les mesures appropriées pour minimiser les nouveaux risques. Ces mesures peuvent comprendre la mise à jour de l'étiquette d'un produit de santé dans sa monographie canadienne autorisée, la communication des risques pour informer les Canadiens au sujet des nouveaux effets indésirables possibles et/ou le retrait du produit.

Pour obtenir des renseignements sur les produits de santé dont la vente est autorisée au Canada, vous pouvez consulter les pages Web suivantes :

- Base de données sur les produits pharmaceutiques :
https://produits-sante.canada.ca/dpd-bdpp/index-fra.jsp

- Base de données sur les produits de santé naturels homologues :
https://produits-sante.canada.ca/lnhpd-bdpsnh/index-fra.jsp

- Base de données en ligne des effets indésirables de Canada Vigilance :
https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medeffet-canada/base-donnees-effets-indesirables.html

- Avis, mises en garde et retraits – Médicaments et produits de santé :
https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/avis-mise-garde-retrait.html

Nous vous remercions à nouveau pour votre déclaration. Votre contribution et votre participation à la surveillance de l'innocuité des produits de santé sont appréciées.

Cordialement,

Programme Canada Vigilance
Direction des produits de santé commercialisés
Santé Canada

Canada

Field	
A.1 - Type of report*	Initial
A.2 - Health Canada (HC) Reference No. (for follow-up reports only)	
A.3 - Organization File No.	[redacted]
A.4 - Date report submitted	2022-05-16
A.5 - Documentation date*	2022-04-29
A.6a - Organization contact first name*	[redacted]
A.6b -Last name*	
A.7.a - Phone no.*	
A.7.a- ext.	N/A
A.7.b - Email	[redacted]
A.7.c - Fax	N/A
A.8 - Organization name*	[redacted]
A.9- Source of report (profession)	Other health professional
A.10 - Heath Canada institutional ID (If ID provided, no need to provide address)	[redacted]
A.11 - Address	N/A
A.12 - City	N/A
A.13 - Province/Territory	[redacted]
A.14 - Postal code	N/A
A.15.a - Reason for seriousness: Death*	No
A.15.a - Date of death*	
A.15.b - Reason for seriousness: Life-threatening*	Yes
A.15.c - Reason for seriousness: Disability*	No
A.15.d - Reason for seriousness: Congenital malformation*	No
A.15.e - Reason for seriousness: Caused/prolonged in-patient hospitalization*	Yes
A.15.f - Reason for seriousness: Required medical intervention to avoid any of (a) to (e)*	
B.1 - Patient ID (e.g. initials, record no.)	
B.2 - Sex**	Female
B.3.a - Age**	91
B.3.b - Age unit**	Year(s)
B.4. Height (cm)	
B.5. Weight (kg)	

B.6 - Known medical conditions and relevant lifestyle factors*	covid-19
B.7 - Known allergies*	
C.1 - Did the patient recover?*	Recovered
C.2 - Reaction start date*	2022-04-29
C.3 - Reaction end date*	2022-04-29
C.4 - Description of the serious adverse drug reaction(s)**	MIH team in with this Pt to give her day 1/3 Remdesivir infusion in community setting. Pt given 200mg in 250mL NS beginning at 1345 and on reassessment following infusion completion, approx 1430 hrs, Pt noted to be hypotensive at 89/43, when she was previously ~122/70. While on phone with [redacted] physician to discuss, Pt then began becoming hypoxic, bottoming out at ~78% on 2 LPM nasal cannula, tested on multiple fingers/both hands/good waveform. On assessment of IV site, red blotchy rashes noted to be present, not there when infusion was initiated. Pt normally GCS 13, but speaks with caregivers and during entirety of event does not report any adverse feelings such as itchiness, SOB, dizziness, nausea, chest pain, etc. Pt treated as anaphylactic medication reaction, and given: O2 via NRB @ 15LPM NS bolus 500mL epi 1:1,000 0.3mg IM benadryl 50mg IV dexamethasone 10mg IV Pt returned to normotensive and o2 >90% after this Tx and then transported to [redacted] hosp via EMS for further assess.
D.1 - Drug identification number (DIN)*	
D.2 - Identifying code for urgent public health need drugs (if applicable)**	
D.3 - Brand name (per product label)**	
D.4 - Common/proper name (active ingredient)	remdesivir
D.5 - Strength	
D.5 - Strength unit	
D.5 - Other strength unit	
D.6 - Dose	
D.6 - Dose unit	200
D.6 - Other dose unit	milligrams
D7 - Frequency	
D.8 - Dosage form	

D.9 - Route of administration	
D.9 - Other route of administration	
D.10 - Product start date*	2022-04-29
D.11 - Product end date*	2022-04-29
D.12 - Indication	
D.13 - Lot no.	
D.14 - Expiry date	
D.15.a - Manufacturer name*	
D.15.b - Did you also report to the manufacturer?	
D.15.c - Date reported	
D.15.d - Reference no. (if known)	
D.16 - What action was t aken?	
D.17 - Did the reaction stop if dose was reduced or removed?	
D.18 - Did the reaction return with reintroduction of the product?	
E - Known therapeutic products taken or used at the same time the reaction occurred*	[illegible] folic acid amlodipine eliquis flecainide centrum perindopril pentaza
F.1 - Use this section to include details that did not fit in the previous sections' structured boxes, or related test/lab results, autopsy information, treatment details, or any other details you feel would contribute to assessment of the serious adverse drug reaction(s).	

[redacted]

Notification concernant un effet indésirable soupçonnée dû à des produits de santé commercialisés au Canada

001002947

A-Données relatives au patient

Identifiant pour [redacted] : [redacted]
Identifiant pour Santé Canada : [redacted]
Age au moment de la réaction : 1 an 11 mois
Sexe du patient : Masculin
Taille du patient (en cm) : 80
Poids du patient (en kg) : 11

B-Effet indésirable

Suites de l'effet indésirable

Décès : Non
Date du décès (aaaa-mm-jj) :
Met la vie en danger : Non
Hospitalisation : Non
Hospitalisation prolongée : Oui
Incapacité : Non
Malformations congénitales : Non
Besoin d'intervention pour prévenir lésion/invalidité permanente : Non
Autre : Non
Décrivez :

Date de l'effet indésirable (aaaa-mm-jj) : 2022-05-06

Date de la présente notification (aaaa-mm-jj) : 2022-05-19

Description de l'effet : Il s'agit d'un patient d'âgé de presque 2 ans connu pour syndrome polymalformatif avec cardiopathie complexe. Il est admis le 4 mai 2022 pour diagnostic d'adénoïdite avec cellulite des pilliers antérieurs et du palais mou. Il y a mise en évidence de COVID-19 positif donc un traitement avec dexaméthasone pour 10 jours et remdésivir pour 5 jours est débuté. Le 8 mai, il y a apparition de bradycardie cardiaque jusqu'à 38-40 battements par minute au sommeil sans instabilité hémodynamique. Le patient est admis aux soins intensifs le 9 mai pour surveillance de bradycardie foyer auriculaire (14e hospitalisations aux soins intensifs depuis la naissance). Le remdésivir et la dexaméthasone sont cessés dans ce contexte. Il y a par la suite amélioration progressive des bradycardies de cause médicamenteuse. Le patient retourne à l'étage le 11 mai puis obtient son congé d'hospitalisation le 15 mai.

Type de réaction	Date de début (aaaa-mm-jj)	Date de fin (aaaa-mm-jj)	Commentaires
Bradycardie	2022-05-08	2022-05-11	

Données (tests, analyses de laboratoire) pertinentes

Paramètre	Valeur	Unité	Date (aaaa-mm-jj)	Commentaire

Histoire médicale pertinente, y compris les facteurs pré-existants

Type d'événement	Date de début (aaaa-mm-jj)	Date de fin (aaaa-mm-jj)	Description
Syndrome polymalformatif			incluant cardiopathie de type canal atrio-ventriculaire débalancé et hypoplasie du ventricule gauche

C-Produit(s) de santé commercialisé(s)

Produit(s) de santé suspect(s)

Nom commercial	Nom générique	Teneur	Fabricant	Dose	Fréquence	Voie	Date de début	Date de fin	Indication	Déchallenge	Rechallenge	Lot	Expiration	Commentaire	Délai (heures)
	remdésivir	100 mg/fiole	Gilead		60 mg puis 30 mg	pour une dose puis une fois par jour	2022-05-05	2022-05-09	COVID-19	Positif	Ne s'applique pas	an8364ba		DIN 02502143	
	dexaméthasone	1 mg/mL			7 mg puis 1,7 mg	pour une dose puis une fois	2022-05-04	2022-05-09	COVID-19	Positif	Ne s'applique pas				

[redacted]

par jour

Produit de santé concomitant

Nom générique	Dose administrée ?	Fréquence	Voie d'administration	Date de début (aaaa-mm-jj)	Date de fin (aaaa-mm-jj)	Commentaire	Délai (heures)
amoxicilline + acide clavulanique	360 mg	TID	PO	2022-05-04	2022-05-10		
énoxaparine	5 mg	aux 24 heures	SC	2022-05-05	2022-05-09		
acide acétylsalicylique	40 mg	DIE	PO				
sildénafil	15 mg	QID	PO				
pénicilline V potassique	150 mg	BID	PO				
fluconazole	80 mg	DIE	PO				
esoméprazole	10 mg	BID	PO				
cholécalciférol	1000 ui	DIE	PO				

Traitement de l'effet indésirable

Traitement	Type	Dose	Fréquence	Voie d'administration	Date de début (aaaa-mm-jj)	Date de fin (aaaa-mm-jj)	Commentaire	Délai (heures)
remdésivir	Arrêt				2022-05-09			
dexaméthasone	Arrêt				2022-05-09			

D-Déclarant

Identification du déclarant, nom et profession : [redacted] Spécialiste en activités cliniques - Pharmacovigilance)

[redacted]

Également déclaré au fabricant : Non

[redacted]

[redacted]

Canada Vigilance AER#:	001003507 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220525 CCYYMMDD
	HC Initial Received Date:	20220525 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

[redacted]

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2022 CCYY	2022 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
	Female		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
1946[redacted] CCYYMMDD			75 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502143 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

DYSPEPSIA

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Dyspepsia
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Dyspepsia

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
	20220502		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

Narrative:
Concommitant health products: Unknown
Indications: Exact start date unknown

E2B R2 Log
Source: Hospital
Original File Name: [redacted]
Received Date: 2022/05/25
Safety Report Version: 0
Safety Report ID: [redacted]
Serious: Yes
Death: No
Life Threatening: No
Hospitalization: Yes
Disability: No
Congenital Anomaly: No
Seriousness Other: No
Documentation Date: 2022/05/02
WW ID: [redacted]
Medically Confirmed: Yes
HC Org. ID: [redacted]
Reporter Org.: [redacted]
Reporter Dept.: [redacted]
Reporter Province: [redacted]
Reporter Country: Canada
Reporter Qualification: Pharmacist
Sender Organization: [redacted]
Sender Given Name: [redacted]
Sender Family Name: [redacted]
Sender Province: [redacted]
Sender Phone: [redacted]
Sender Phone Ext: [redacted]
Sender Email: [redacted]
Patient DOB: 1946/[redacted]
Patient Age: 75
Patient Age Unit: Years
Patient Sex: Female
Patient Med. History: none
Primary Reaction: Dyspepsia probably from remdesivir
Reaction Start Date: 2022/05/02
Product Role: Suspect
Route of Admin: Intravenous (not otherwise specified)
Substance Name: Remdesivir
Report Medium: sFTP
Report Format: E2B R2 XML

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Canada Vigilance AER#:	001003507 (0)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	[redacted]

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

Canada Vigilance AER#:	001011502 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20220726 CCYYMMDD
	HC Initial Received Date:	20220726 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-DHPR_H-20220726143303_503885()

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada	Canada	Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	No
Spontaneous		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
2022 CCYY	2022 CCYY	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
		Other medically important condition?	Yes

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
	Company number (A.1.10.2)

Other case identifiers in previous transmission? (A.1.11)

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)

Duplicate (D) / Link (L) Report number(s) (A.1.12)

()

Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Yes

Source (A.1.4)

Hospital - [redacted]

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
[redacted]	Female	154 Centimeter	107 Kilogram
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
			67 Years

Gestation Period (B.1.2.2.1)	LMP date (B.1.6)

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Suspect	VEKLURY SINGLE-DOSE VIAL	
Active Substance names (B.4.k.2.2)		
remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
	AR09768A	
Holder and authorization/application no. of drug (B.4.k.4)		
Authorization/Application no.: 02502143 Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
200 Milligram		
Dosage text (B.4.k.6)		
Frequency Text: 1 dose		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
20220719 CCYYMMDD	20220719 CCYYMMDD	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	SALBUTAMOL	
Active Substance names (B.4.k.2.2)		
salbutamol		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CYCLOBENZAPRINE	
Active Substance names (B.4.k.2.2)		
cyclobenzaprine hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Oral	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	HEPARIN (PORCINE)	
Active Substance names (B.4.k.2.2)		
heparin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** CLONIDINE	
Active Substance names (B.4.k.2.2) clonidine hydrochloride		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AMLODIPINE	
Active Substance names (B.4.k.2.2)		
amlodipine		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ACETAMINOPHEN	
Active Substance names (B.4.k.2.2)		
acetaminophen		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PREGABALIN	
Active Substance names (B.4.k.2.2)		
pregabalin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	TRAZODONE	
Active Substance names (B.4.k.2.2)		
trazodone hydrochloride		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	AMITRIPTYLINE	
Active Substance names (B.4.k.2.2) amitriptyline hydrochloride		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B.4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	CALCIUM	
Active Substance names (B.4.k.2.2)		
calcium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1) Concomitant	**Medicinal product name (B.4.k.2.1)** MAGNESIUM	
Active Substance names (B.4.k.2.2) magnesium		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4) Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)**	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)**	**Indication (B.4.k.11b)**
Start date of drug (B.4.k.12)	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16)	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	**Reaction assessed (B.4.k.18.1b)**	
Source of assessment (B.4.k.18.2)	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)**

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	PANTOPRAZOLE	
Active Substance names (B.4.k.2.2)		
pantoprazole		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	DEXAMETHASONE	
Active Substance names (B.4.k.2.2)		
dexamethasone		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
	Unknown	
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	ONGLYZA FILM-COATED	
Active Substance names (B.4.k.2.2)		
saxagliptin		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	VITAMIN D	
Active Substance names (B.4.k.2.2)		
vitamin d		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Drug characterization (B.4.k.1)	Medicinal product name (B.4.k.2.1)	
Concomitant	RISEDRONATE SODIUM	
Active Substance names (B.4.k.2.2)		
risedronate sodium		
Country drug obtained (B.4.k.2.3)	Batch/lot no. (B.4.k.3)	
Holder and authorization/application no. of drug (B.4.k.4)		
Country of authorization/application: Canada		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6)		
Pharmaceutical form (B.4.k.7)	Route of administration (B.4.k.8)	Parent route of admin (B.4.k.9)
Gestation period (B.4.k.10)	MedDRA version (B.4.k.11a)	Indication (B.4.k.11b)
Start date of drug (B.4.k.12)	Drug end date (B.4.k.14)	
Start period (B.4.k.13.1)	Last period (B.4.k.13.2)	Duration of drug Admin (B. 4.k.15)
Action(s) taken with drug (B.4.k.16)	Did reaction recur on readministration? (B.4.k.17.1)	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	Which reaction(s)/event(s) recurred? (B.4.k.17.2b)	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a)	Reaction assessed (B.4.k.18.1b)	
Source of assessment (B.4.k.18.2)	Method of assessment (B.4.k.18.3)	Result (B.4.k.18.4)

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0)

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)		
MedDRA version for reaction/event term PT (B.2.i.2.a)	Reaction/event MedDRA term (PT) (B.2.i.2.b)		
Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)

Summary (B.5)

Case narrative (B.5.1)

19 juillet 19h30: FC 47 batt/min, 23h30: FC 52 batt/min
20 juillet: 08h00 35 batt/min
21 juillet: 02h15 pause de 3,1 secondes
~~~~~~~~~~~~~~~~~~
Dhpr log details:
Safety Report ID: CA-DHPR_H-20220726143303_503885
Type of Report: Initiale
HC Ref. No:
Reporter File No.: [redacted]
Transmission Date: 20220726
Documentation Date: 20220719
First Name: [redacted]
Last Name: [redacted]
Telephone: [redacted]
Ext.: [redacted]
Address: [redacted]
City: [redacted]
Province/Territory: [redacted]
Postal Code: [redacted]
Email address: [redacted]
Organization: [redacted]
HC ID:
Reporter Type: Pharmacien

Patient ID: [redacted]
Age: 67 Année(s)
Sex: Femme
Height: 154 cm
Weight: 107 kg
Med History: Diabète type 2, obésité, MPOC, RGO, DLP, HTA, néo sein (2021), covid positive le 19 juillet 2022
Allergies:

Serious Death:
Date of Death:
Serious Life-Threatening:
Serious Disability:
Serious Hospitalization:
Serious Congenital Anomaly:
Serious Other: Oui
Serious Other Explain: déjà admis CH mais transfert USI avec application pace externe

Reaction 1
Outcome: Rétabli
Reaction Start Date: 20220719
Reaction End Date: 20220721
Reaction Description: Bradycardie sévère nécessitant transfert vers USI (déjà admise ch), pour application du protocole de pace externe.

Suspect Product 1
DIN #/NPN #: 02502143
UPHN #:
Brand Name: Remdésivir
Common Name: Remdésivir
Strength: 100 mg milligramme(s)
Strength other:
Dosage form:
Manufacturer: Gilead
Lot #: AR09768A
Expiry date:
Product start date: 20220719
Product end date: 20220719
Dosage: 200 mg milligramme(s)
Dosage other:
Frequency: 1 dose
Route of administration:
Route of administration - Other:
Indication: Covid positif et symptomatique
Reported to Mfr: Non
Date reported to Mfr:
Mfr Reference number:
Drug action taken: Ne s'applique pas
Dechallenge: Oui
Rechallenge: Inconnu

Concomitants: Salbutamol, cyclobenzaprine, héparine IV, clonidine, Amlodipine, Acétaminophène, Prégabaline, Trazodone, Amitriptyline, Calcium, Magnésium, Pantoprazole, Dexaméthasone, Saxagliptine, vitamine D, Risédronate.
Test/Lab results narrative:

Reporter's comments (B.5.2)

MedDRA version for sender's diagnosis (B.5.3a)
~~~~~~~~~~~~~~~~~~

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	Normal low range (B.3.1.1)	Normal high range (B.3.1.2)	More info (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
Start date (B.1.7.1c)	Continuing (B.1.7.1d)	End date (B.1.7.1f)
Comments (B.1.7.1g)		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	End date (B.1.8e)
Indication MedDRA version (B.1.8f.1)	Indication (B.1.8f.2)
Reaction MedDRA version (B.1.8g.1)	Reaction (B.1.8g.2)

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	Height (cm) (B.1.10.5)	Sex (B.1.10.6)	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	Continuing (B.1.10.7.1d)	End date (B.1.10.7.1f)
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	Drug end date (B.1.10.8e)
MedDRA version for Indication (B.1.10.8f.1)	Indication (B.1.10.8f.2)
MedDRA version for reaction (B.1.10.8g.1)	Reactions (B.1.10.8g.2)

Canada Vigilance AER#:	001011502 (0)	

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c)
[redacted]

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
[redacted]	Canada	Pharmacist

Literature reference(s) (A.2.2)

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)

Canada Vigilance AER#:	E2B_04571093 (0)	Page#1

Canada Vigilance Adverse Reaction Report	HC Latest Received Date:	20210819 CCYYMMDD
	HC Initial Received Date:	20210819 CCYYMMDD

Safety Report (A.1)

Safety report I.D. (Ver.) (A.1.0.1)

CA-TEVA-2021-CA-1942301(0)

Primary source country (A.1.1)	Occur country (A.1.2)	Serious? (A.1.5.1)	Serious
Canada		Seriousness (A.1.5.2)	
Type of report		Caused/prolonged hospitalization?	Yes
Published		Results in death?	No
MAH/Sponsor Initial Received Date (A.1.6)	MAH/Sponsor Latest Received Date (A.1.7)	Disabling/Incapacitating?	No
20210809 CCYYMMDD	20210809 CCYYMMDD	Life threatening?	No
Additional documents? (A.1.8.1)		Congenital anomaly/birth defect?	No
No		Other medically important condition?	No

List of documents held by sender (A.1.8.2)

Fulfill expedited criteria? (A.1.9)	Regulatory authority's number (A.1.10.1)
Yes	Company number (A.1.10.2)
	CA-TEVA-2021-CA-1942301

Other case identifiers in previous transmission? (A.1.11)

Yes

Duplicate Source(s) (A.1.11.1)	Duplicate Case identifiers (A.1.11.2)
Springer Nature TEVA	[redacted] CA-TEVA-2021-CA-1942301

Duplicate (D) / Link (L) Report number(s) (A.1.12)

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Report nullification? (A.1.13)	Reason for nullification (A.1.13.1)
No	

Medically confirmed or from health professional? (A.1.14)

Source (A.1.4)

MAH - TEVA CANADA LIMITED

Patient (B.1)

Patient Initial (B.1.1)	Sex (B.1.5)	Patient height (B.1.4)	Patient weight (B.1.3)
unknown	Male		
Date of birth (B.1.2.1)	**Age group (B.1.2.3)**		**Onset Age (B.1.2.2)**
	Elderly		70 Years
Gestation Period (B.1.2.2.1)		**LMP date (B.1.6)**	

GP medical record no. (B.1.1.1a)	Specialist record no. (B.1.1.1b)	Hospital record no. (B.1.1.1c)	Investigation no. (B.1.1.1d)

Canada Vigilance AER#:	E2B_04571093 (0)	Page#2

Patient death (B.1.9)

Date of death (B.1.9.1)	Was autopsy done? (B.1.9.3)

Patient death cause (B.1.9.2)

MedDRA version for cause (B.1.9.2.a)	Reported cause(s) (B.1.9.2.b)

Patient autopsy (B.1.9.4)

MedDRA version for autopsy-determined cause(s) of death (B.1.9.4a)	Autopsy-determined cause(s) of death (B.1.9.4b)

Drug (B.4)

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **METHYLPREDNISOLONE**	
Active Substance names (B.4.k.2.2) methylprednisolone		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Received two courses		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Other	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** SARS-CoV-2 infection
Start date of drug (B.4.k.12) 2021 CCYY	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Unknown	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19) Additional info: Additional info: ROUTE: {Pulse}; Off label use		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Lack of drug effect	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)** Possible
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Off label use in unapproved indication	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)** Possible

Drug characterization (B.4.k.1) **Suspect**	**Medicinal product name (B.4.k.2.1)** **REMDESIVIR**	
Active Substance names (B.4.k.2.2) remdesivir		
Country drug obtained (B.4.k.2.3)	**Batch/lot no. (B.4.k.3)**	
Holder and authorization/application no. of drug (B.4.k.4)		
Structured dosage info (B.4.k.5)		
Dosage text (B.4.k.6) Received two courses of 5 days each		
Pharmaceutical form (B.4.k.7)	**Route of administration (B.4.k.8)** Intravenous (not otherwise specified)	**Parent route of admin (B.4.k.9)**
Gestation period (B.4.k.10)	**MedDRA version (B.4.k.11a)** 25.0	**Indication (B.4.k.11b)** SARS-CoV-2 infection
Start date of drug (B.4.k.12) 2021 CCYY	**Drug end date (B.4.k.14)**	
Start period (B.4.k.13.1)	**Last period (B.4.k.13.2)**	**Duration of drug Admin (B. 4.k.15)**
Action(s) taken with drug (B.4.k.16) Not Applicable	**Did reaction recur on readministration? (B.4.k.17.1)**	
Additional info (B.4.k.19)		
Drug Recurrence (B.4.k.17)		
MedDRA version (B.4.k.17.2a)	**Which reaction(s)/event(s) recurred? (B.4.k.17.2b)**	
Drug Reaction relatedness (B.4.k.18)		
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Lack of drug effect	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)** Possible
MedDRA version (B.4.k.18.1a) 25.0	**Reaction assessed (B.4.k.18.1b)** Off label use in unapproved indication	
Source of assessment (B.4.k.18.2) Reporter	**Method of assessment (B.4.k.18.3)**	**Result (B.4.k.18.4)** Not Related

Reaction (B.2)

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE EXHIBITED A LACK OF EFFICACY DURING TREATMENT WITH REMDESIVIR AND OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Lack of drug effect
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Drug ineffective

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Reaction/event as reported by primary source (B.2.i.0) Current reaction

HE EXHIBITED A LACK OF EFFICACY DURING OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION

MedDRA version for reaction/event term LLT (B.2.i.1.a)	Reaction/event MedDRA term(LLT) (B.2.i.1.b)
25.0	Off label use in unapproved indication
MedDRA version for reaction/event term PT (B.2.i.2.a)	**Reaction/event MedDRA term (PT) (B.2.i.2.b)**
25.0	Off label use

Term hightlighted by the reporter? (B.2.i.3)	Start Date (B.2.i.4)	End Date (B.2.i.5)	Duration (B.2.i.6)
No	2021		

Reaction first time (B.2.i.7.1)	Reaction last time (B.2.i.7.2)	Outcome (B.2.i.8)
		Unknown

Summary (B.5)

Case narrative (B.5.1)

09-Aug-2021, Spontaneous, Literature Serious report Report duplicates - Springer Nature: [redacted])
A Other health professional reported the case of a 70-Years-old Male patient who received Methylprednisolone (Product cannot be excluded as a Teva product), Remdesivir (not Teva's product).
The patient took Methylprednisolone for SARS-COV-2 INFECTION (Other, from --2021, Received two courses), Remdesivir for SARS-COV-2 INFECTION (Intravenous (not otherwise specified), from --2021, Received two courses of 5 days each).
While on the suspect medication(s), the patient experienced HE EXHIBITED A LACK OF EFFICACY DURING OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION(Not Serious , since --2021); HE EXHIBITED A LACK OF EFFICACY DURING TREATMENT WITH REMDESIVIR AND OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION(Serious , since --2021) .

A 70-year-old man exhibited lack of efficacy during treatment with remdesivir for SARS-CoV-2 infection. He further exhibited lack of efficacy during off-label treatment with methylprednisolone for SARS-CoV-2 infection [not all routes stated; dosages not stated]. [redacted]

Author comment: [redacted]

At the time of the report the outcome of the AEs was: HE EXHIBITED A LACK OF EFFICACY DURING TREATMENT WITH REMDESIVIR AND OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION:Unknown, HE EXHIBITED A LACK OF EFFICACY DURING OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION:Unknown.
Action taken with suspect drugs: Methylprednisolone due to HE EXHIBITED A LACK OF EFFICACY DURING OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION - Not Applicable; Methylprednisolone due to HE EXHIBITED A LACK OF EFFICACY DURING TREATMENT WITH REMDESIVIR AND OFF-LABEL TREATMENT WITH METHYLPREDNISOLONE FOR SARS-COV-2 INFECTION - Unknown; Remdesivir - Not Applicable.

The patient had medical history of PULMONARY FIBROSIS(Not Continuing), LUNG TRANSPLANT(since --2021, until --2021, Not Continuing), SARS-COV-2 INFECTION(since --2021, Continuing).

The patient's concomitant medication were unspecified.
The patient's past medication were unspecified.

Lab tests were not reported.

This case was considered serious based on the following criteria: (Hospitalization Required)

Literature Reference: [redacted]

Reporter's comments (B.5.2)

[redacted]

MedDRA version for sender's diagnosis (B.5.3a)

Sender's diagnosis (B.5.3b)

Sender's comments (B.5.4)

Test (B.3)

Test date (B.3.1b)	Test name (B.3.1c)	Test result (B.3.1d)	
Unit (B.3.1e)	**Normal low range** (B.3.1.1)	**Normal high range** (B.3.1.2)	**More info** (B.3.1.3)

Results of tests and procedures (B.3.2)

Patient Medical History (B.1.7)

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	Pulmonary fibrosis	
Start date (B.1.7.1c)	**Continuing** (B.1.7.1d)	**End date** (B.1.7.1f)
	No	

Comments (B.1.7.1g)

PULMONARY FIBROSIS

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	Lung transplant	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2021 CCYY	No	2021 CCYY
Comments (B.1.7.1g)		
LUNG TRANSPLANT		

MedDRA version (B.1.7.1a.1)	Episode name (B.1.7.1a.2)	
25.0	SARS-CoV-2 infection	
Start date (B.1.7.1c)	**Continuing (B.1.7.1d)**	**End date (B.1.7.1f)**
2021 CCYY	Yes	
Comments (B.1.7.1g)		
SARS-COV-2 INFECTION		

Relevant medical history/ Concurrent conditions text (B.1.7.2)

Past drug therapy (B.1.8)

Drug name (B.1.8a)	
Start date (B.1.8c)	**End date (B.1.8e)**
Indication MedDRA version (B.1.8f.1)	**Indication (B.1.8f.2)**
Reaction MedDRA version (B.1.8g.1)	**Reaction (B.1.8g.2)**

Parent (B.1.10)

Parent Initials (B.1.10.1)	DOB of Parent (B.1.10.2.1)	Age (B.1.10.2.2)	LMP date (B.1.10.3)
Weight (Kg) (B.1.10.4)	**Height (cm) (B.1.10.5)**	**Sex (B.1.10.6)**	

Parent medical history (B.1.10.7)

MedDRA version (B.1.10.7.1a.1)	Medical history (B.1.10.7.1a.2)	
Start date (B.1.10.7.1c)	**Continuing (B.1.10.7.1d)**	**End date (B.1.10.7.1f)**
Comments (B.1.10.7.1g)		

Relevant medical history / Concurrent conditions text (B.1.10.7.2)

Parent Drug Therapy (B.1.10.8)

Drug name (B.1.10.8a)	
Drug start date (B.1.10.8c)	**Drug end date (B.1.10.8e)**
MedDRA version for Indication (B.1.10.8f.1)	**Indication (B.1.10.8f.2)**
MedDRA version for reaction (B.1.10.8g.1)	**Reactions (B.1.10.8g.2)**

Primary Source (A.2)

Reporter title (A.2.1.1a)	Reporter given name (A.2.1.1b)	Reporter middle name (A.2.1.1c)	Reporter family name (A.2.1.1d)
	[redacted]		[redacted]

Reporter organization (A.2.1.2a)	Reporter department (A.2.1.2b)
[redacted]	

Reporter street (A.2.1.2c)

Reporter city (A.2.1.2d)	Reporter state (A.2.1.2e)
[redacted]	[redacted]

Reporter postcode (A.2.1.2f)	Reporter country (A.2.1.3)	Qualification (A.2.1.4)
	Canada	Other health professional

Literature reference(s) (A.2.2)

[redacted]

Study name (A.2.3.1)	Project No

Sponsor Study no. (A.2.3.2)	Observed study type (A.2.3.3)

Sender (A.3.1)

Type (A.3.1.1)	Organization (A.3.1.2)

Department (A.3.1.3a)	Title (A.3.1.3b)

Given name (A.3.1.3c)	Middle name (A.3.1.3d)	Family name (A.3.1.3e)

Street (A.3.1.4a)

City (A.3.1.4b)	State (A.3.1.4c)

Postcode (A.3.1.4d)	Country code (A.3.1.4e)

Tel No. (A.3.1.4f)	Fax no. (A.3.1.4i)

Email Address (A.3.1.4l)

Receiver (A.3.2)

Type (A.3.2.1)	Organization (A.3.2.2a)

Department (A.3.2.2b)	Title (A.3.2.2c)

Given name (A.3.2.2d)	Middle name (A.3.2.2e)	Family name (A.3.2.2f)

Street (A.3.2.3a)

City (A.3.2.3b)	State (A.3.2.3c)

Postcode (A.3.2.3d)	Country (A.3.2.3e)

Tel no. (A.3.2.3f)	Fax no. (A.3.2.3i)

Email address (A.3.2.3l)