Case Number: 2022145066

Initial Receipt Date:	01-JUL-2022
Initial Case User:	Tanja Franz
Initial Case Site:	CSL Behring

General Information

Report Type	Country	Initial Receipt Date	Medically Confirm	Case Status
Spontaneous	CANADA	01-JUL-2022	☐	Book In

Initial Justification

Case Requires Follow-up	Central Receipt Date	Classification
☐	01-JUL-2022	Health Care Professional

Case Processing Owner	Nullification Reason	I/FU Received By
Global		

Generate Null Flavors

Follow-up Log

#	Follow-up Received	Safety Received	Significant			Amendment	Amendment / Follow up Justification
2	03-OCT-2022	03-OCT-2022	☒ Yes ☐ No			☐ Yes ☒ No	
1	10-JUL-2022	10-JUL-2022	☒ Yes ☐ No			☐ Yes ☒ No	

Study Information

No information present

Reporter Information

1

Name		Occupation	Health Care Professional
ASKU			Yes
Institution	**Institution ID**	**Department**	**Reporter ID**
Address 1		**J only - Address 2**	
City	**State**		**Postal Code**
Country	**Phone Number**	**Alternate Phone**	**FAX Number**
CANADA			
Email Address		**Reporter's Reference #**	
Reporter Type		**Follow-up consent?**	**Intermediary**
Physician			
Report Sent to Regulatory Authority by Reporter?			☒ Primary Reporter
☐ Yes ☐ No ☐ Unk		☐ Protect Confidentiality	☐ Correspondence Contact

Reporter Notes

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Literature Information				**No information present**		
Patient Information						
			First Name	**MI**	**Last Name**	**Initials**
						TB
		☐ Protect Confidentiality		☐ Child Only Case		
Address 1						
City			**State**			**Postal Code**
Country			**Phone Number**		**Email Address**	
Date of Birth	**Age**	**Units**	**Age Group**	**Height**	**Weight**	
	61	Years	Adult			☐ Concomitant Therapy Administered
						BMI
Gender	**Pregnant**		**Date of LMP**			
Male				☐ Breastfeeding		
Occupation				**Ethnic Group**		
Race Information						
Patient Died						
No						
Pregnancy Information				**No information present**		
Event Death Details						
Death Date			**Autopsy Done?**		**Autopsy Results Available?**	
					☐ Yes	☐ No
Lab Data				**No information present**		
Other Relevant History				**No information present**		
Relevant Tests						
Current Medical Status						
Patient Notes				**No information present**		
Patient Parent Information				**No information present**		

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Parent Pregnancy Information				**No information present**			
Other Relevant History				**No information present**			
Product Information							
1	**Product Name** Accupaque			**Drug Code** 005505.01.008		☒ Suspect ☐ Concomitant ☐ Treatment / Other	
	Generic Name IOHEXOL						**Company Drug Code** Accupaque_NC
	Product Identifier Type	**Product Identifier**	**Version**	**MFDS Product Code**	**OTC Product** ☐ Yes ☒ No		**Compounded Product** ☐ Yes ☐ No
	Manufacturer MAH outside CSL Group						
	Formulation Unknown			**Concentration**	**Units**	☐ Drug Not Administered	
	Indications						
	Reported Indication			**Coded Indication**			
	Obtain Drug Country WORLD	**Authorization Type**	**Authorization Number** MKT	**Drug Authorization Country** WORLD		**Market Authorization Holder** MAH outside CSL Group	
				Interaction? ☐ Yes ☐ No ☐ Unk		**Contraindicated?** ☐ Yes ☐ No	
	Product As Reported	**Configured Product Name** Accupaque			**Potential AE associated to product?**		
	Substance Information						
	Substance Name IOHEXOL			**Strength**			
	Product Name Parts Information						
	Dosage Regimens						
1	**Start Date/Time** ASKU	**Stop Date/Time** ASKU		☐ Ongoing ☐ Outside Therapeutic Range			
	Duration of Regimen	**Dose Number**	**Dose**	**Units**		**Frequency**	
	Patient Route of Administration Not reported	**Parent Route of Administration**	**Daily Dosage**	**Units**	**Dose Description**		
	Package ID		**Lot #**		**Expiration Date**	**Regimen Dosage**	**Units**

	ASKU	
RAVE Drug Start Time	**RAVE Drug End Time**	**Bulk #**
DRUGID_EXTENSION		

Product Details

First Dose	**Last Dose**	**Duration of Administration**	**Total Dosage**	**Units**
Time Between First Dose/Primary Event	**Time between Last Dose/Primary Event**		**Gestation Period at Exposure**	**Unit**

Taken Previously / Tolerated
Unknown / N/A

☐ Off label use

Quality Control

Product Notes

Event Information

1

Description as Reported
Ras

Diagnosis
☒ Diagnosis ☐ Symptoms

Original Language

Description to be Coded
Ras

Patient Has Prior History?
☐ Yes ☐ No ☐ Unk

IMDRF Code

Onset Date/Time	**Onset From Last Dose**	**Stop Date/Time**	**Duration**	**Onset Latency**
15-JUN-2022 00:00		ASKU		

Intensity

Medical Confirmation by HCP
☐ Suspected transmission of infectious agent

Treatment Received?	**Country in which Event Occurred**	**Outcome of Event**	**Term Highlighted by Reporter**

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☐ Yes	☐ No	☐ Unk	CANADA	Not recovered / Not resolved	☐ Yes	☐ No	☐ Unk

☐ Progression of Disease

Seriousness Criteria

☐ Death ☐ Congenital Anomaly ☐ Disability ☒ Medically Significant

☐ Hospitalized ☐ Life-threatening

Nature of Event

Details

AEID_Extension	**RAVE ENDPOINT**	**RAVE ENDPOINT - Negative Adjudication**
NCI CTCAE Toxicity Grade	**Reported Seriousness**	**AESI**

Event Relationships — No information present

Event Assessment

Event (Description as Reported) /	Data Sheet / License	Causality as Reported Source / Method / Result	Causality as Determined Source / Method / Result	Other Causality Source / Method / Result	As Determined Listedness
Overdose (Ras) Seriousness: MS D/S: Diagnosis Accupaque	CORE (Rev # 1 : 19-SEP-2022) / WW (Mkt: MKT)	Primary Source Reporter / Global Introspection / Related	Pharmaceutical Company / Global Introspection / Related		Unknown
Accupaque	CORE (Rev # 1 : 19-SEP-2022) / WW (Inv: INV)	Primary Source Reporter / Global Introspection / Related	Pharmaceutical Company / Global Introspection / Related		Unknown

Product - Event Details

Event (Description as Reported) / ()

Overdose

(Ras)

Accupaque

Most Important Diagnosis? ☐ Yes ☐ No

Event more specific/severe than PT? ☐ Yes ☐ No

Onset from First Dose

Onset from Last Dose

Total Dose to Event/Units

Dechallenge Results ☐ Yes ☐ No ☐ Unk ☐ N/A

Rechallenge Results ☐ Yes ☐ No ☐ Unk ☐ N/A

Action Taken

Other

Case Analysis

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Narrative

This spontaneous case from Canada, initially received on 01-Jul-2022, was reported by a health professional and concerns a(n) 61-year-old male patient.

Administration of company suspect drug(s):
On an unknown date, the patient received Hizentra for Indication not reported. Administration Dates, dosage Regimen and route of Administration not reported. Lot number: Not reported, will be requested upon follow up.

No additional suspect drugs.

Adverse reactions/events and outcomes:
On 15-Jun-2022, the patient experienced Liver cirrhosis (Medically Significant, Hospitalization, outcome: Not recovered / Not resolved).

Reporter's assessment: The Reporter assessed the Event as serious and did not provide a causality assessment.

Follow-up (10-Jul-2022) received from physician via Health Canada. Seriousness criterion hopsitalization added.

Abbreviated Narrative

Case Comment

The Event is assessed as serious, unlisted and causality is unassessable.

Reporter or Company Internal Comment

Evaluation in light of similar events in the past

Case Serious

☒ Yes ☐ No

Company Agent Causal

☒ Yes ☐ No ☐ Unk

Listedness Determination

Unlisted

Case Outcome

Not recovered / Not resolved

Company Diagnosis/Syndrome

MedWatch Info

B. Adverse event or product problem			C. Suspect medication(s)
1. ☒ Adverse Event	and / or	☐ Product Problem	9. NDC # :

F. For use by user facility/importer-devices

1. Check one ☐ User Facility ☐ Importer ☒ Suppress Block F Printing

G. All manufacturers

3. Report Source (check all that apply)

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☒ Foreign	☐ Literature	☒ Health Professional	☐ Company Representative	☐ Study	☐ Consumer
☐ User Facility	☐ Distributor	☐ Other:			
5. STN #	☐ Pre-1938	☐ OTC product			

BfArM Info

Beurteilung des kausalzusammenhanges (Causality)				**Manual Cause Text**			
*Alcohol Abuse	☐ Yes	☐ No	☐ Unk	*Metabolic Disease	☐ Yes	☐ No	☐ Unk
*Allergic History	☐ Yes	☐ No	☐ Unk	*Nicotine Use	☐ Yes	☐ No	☐ Unk
*Contraceptives	☐ Yes	☐ No	☐ Unk	*Pacemaker	☐ Yes	☐ No	☐ Unk
*Drug Abuse	☐ Yes	☐ No	☐ Unk	*Physiotherapy	☐ Yes	☐ No	☐ Unk
*Immunodeficiency	☐ Yes	☐ No	☐ Unk	*Radiotherapy	☐ Yes	☐ No	☐ Unk
*Implants	☐ Yes	☐ No	☐ Unk	*Special Diet	☐ Yes	☐ No	☐ Unk
*Other	☐ Yes	☐ No	☐ Unk				

AFSSaPS Info — **No information present**

Imputability Assessment Information — **No information present**

Contact Log — **No information present**

Routing Comments

#	Date / User	Comment
3	03-OCT-2022 12:54 Nitin Saxena	Case Unlocked. Testing
2	03-OCT-2022 12:39 Nitin Saxena	Case Locked with significant follow up on 10-JUL-2022. Test Case
1	03-OCT-2022 12:32 Nitin Saxena	Automated initial case routing set responsible group to "CSLB Book In".

Action Items — **No information present**

Case Lock / Close

Lock Date	Closure Date	Locked or Closed By

Notes

Notes and Attachments

#	Date / Incl. Reg. Sub	Classification / Keywords	Description / Literature Reference
1	01-JUL-2022 ☐	Source Doc Initial SAE form	Initial SAE form
2	10-JUL-2022	Source Doc follow up 1	FUP SAE form

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	☐	SAE form

References

#	ID	Type	Notes
1	0005387749	Canada Vigilance	
2	2022144479	Source Case	Original Case : 2022144475
3	2022144480	Source Case	Original Case : 2022144480
4	2022144681	Source Case	Original Case : 2022144480
5	CA-BEHTEST-2022145066	E2B Company Number	

Regulatory Reports

#	Seq	Destination / Report Type	License Type / License #	Responsibility (User User Group)	Date Scheduled / Date Generated	Date Due / Date Submitted
1	Initial	CSLB_REG_EMA_PM E2B	Marketed MKT	Nitin Saxena	03-OCT-2022 03-OCT-2022 12:46	25-JUL-2022 03-OCT-2022 12:47

Scheduling / Submission Notes

Manual: Accupaque(Accupaque) Unknown (WORLD (Marketed Drug) MKT)

Submission Required	Determined On	Determined By
☒ Yes ☐ No		

Reason for Non-Submission

Local Comment

Report Transmission Information

Report Form	Fax Number / Recipient Name	Date Created	# of Pages	Sender
Agency Name	**Recipient Company**	**Date Sent**	**Attempts**	**Status**

#	Seq	Destination / Report Type	License Type / License #	Responsibility (User User Group)	Date Scheduled / Date Generated	Date Due / Date Submitted
2	F/U# 1	CSLB_REG_EMA_PM E2B	Marketed MKT	Nitin Saxena	03-OCT-2022	18-OCT-2022

Scheduling / Submission Notes

Manual: Accupaque(Accupaque) Unknown (WORLD (Marketed Drug) MKT)

Submission Required	Determined On	Determined By
☒ Yes ☐ No		

Reason for Non-Submission

Local Comment

Report Transmission Information

Report Form	Fax Number / Recipient Name	Date Created	# of Pages	Sender

Case Number: 2022145066

	Agency Name	Recipient Company	Date Sent	Attempts	Status
Justifications		No information present			