Endotherapeutics

MONTAVIT (CATHEJELL LIDOCAINE 2%) PRODUCT COMPLAINT FORM

COMPLAINT STATUS		
Name of Sales Representative lodging complaint:	**Status of Supplied Stock:**	**Case Origin:**
Date of Incident / Product Fault:	☐ Sales Representative Stock ☐ Hospital Owned Stock ☐ Demonstration or Trial	☐ Email ☐ Phone ☐ Sales Rep attended case

CUSTOMER AND PRODUCT DETAILS	
Name of Hospital / Institution:	
Address (Incl. Department):	
Name of Contact / Job Title:	
Phone Number of Contact:	
Email Address of Contact:	
Product Code and Description:	
Product Batch / Lot / Serial No.	
Name of End User:	
Requested Course of Action	

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DETAILS OF THE COMPLAINT
Please provide a detailed description of the product complaint. *This description must include details of the product setup, the fault scenario, what troubleshooting may have occurred, what the outcome of the fault was and how the fault impacted the patient or procedure.*

Experience of end user:	Status of stock:	Current location of stock:
☐ First Time User	☐ Sterile	☐ Sales Representative*
☐ Limited User	☐ Non-Sterile	☐ Hospital*
☐ Trained and Proficient	☐ Other:	☐ Disposed of
☐ Extensive User	_____	☐ Returned to Head Office

**If the stock is with a sales representative or the hospital, please return the stock to Head Office.*

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REPORTER INFORMATION			
Name of Reporter:		Nationality:	
Further Information:			
Qualification of Reporter	☐ Physician ☐ Patient ☐ Pharmacist ☐ Other: _____		

PATIENT INFORMATION			
Date of Birth:		Age at time of ADR:	
Initials:		Is the Patient Pregnant? If so, Gestation Period	
Weight (kg):		Height (cm):	
Sex:	☐ Male ☐ Female		
Concomitant Diseases: Previous/Continuing (if applicable)			
Medical History (e.g. Diagnostics, allergies):		Start Date:	End Date:
		Outcome Recovered?	
		☐ Yes ☐ No ☐ Unknown	

DRUG – INFORMATION ABOUT THE SUSPECTED DRUG:				
Product Name:	Cathejell Lignocaine 2% Sterile Lubricant Gel			
Active Substance(s):	Lidocaine (Lignocaine) Hydrochloride Monohydrate 2.133% w/w			
Therapy Duration:		Therapy Dates:	From:	
			To:	
Dosage:		Administration Route:		
Indication(s) for Use:				

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ADVERSE DRUG REACTION (ADR)			
Description of the Suspected ADR(s), Name Every ADR:		Time Interval Between Beginning of Drug Administration and ADR Start:	
		ADR Duration (hours/days):	
		Start Date:	End Date:
		Outcome Recovered?	
		☐ Yes ☐ No ☐ Unknown	
ADR(s) Category: (Tick all Appropriate)	☐ Life-Threating Situation ☐ Requires or Prolonged Inpatient Hospitalisation ☐ Congenital Anomaly / Birth Defect ☐ Results in Persistent or Significant Disability/Incapacity ☐ Results in Death ☐ Other Significant Medical Event (e.g. Intensive treatment at home for allergic bronchospasm) ☐ NONE of the mentioned (Non-Serious ADR)		
ADR(s) Treatment, Test:			
Treatment of the ADR:			
Tests Relevant to the investigation of the Patient:			
Action Taken with The Suspected Drug: (Tick all Appropriate)			
Was Treatment with the Suspected Drug Discounted?	☐ Yes	☐ No	☐ Unknown ☐ N/A
If Discontinued, Did Event Abate Stopping Drug?	☐ Yes	☐ No	☐ Unknown ☐ N/A
If Drug was Reintroduced, Did Event Reappear After Reintroduction?	☐ Yes	☐ No	☐ Unknown ☐ N/A

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If Treatment with the Suspect Drug was Continued, was the Dosage Changed?	☐ Yes ☐ No ☐ Unknown ☐ N/A
If Yes, Specify the Changed Dosage:	
Was the Suspected Drug Taken by the Patient Previously Without any Complaints?	☐ Yes ☐ No ☐ Unknown ☐ N/A
Has the Reporter informed the Authorities?	☐ Yes ☐ No ☐ Unknown ☐ N/A
Causality Assessment of the Reporter:	
Causal Relationship Between the Suspected Drug and the ADR(s):	☐ Certain ☐ Unlikely ☐ Probable ☐ Not Available ☐ Possible ☐ Not Assessable
Concomitant Drug	
Concomitant Drug(s): (Name, Dosage, Duration) Excludes Those to Treat ADR(s):	
Causal Relationship Between the Suspected Drug and the ADR(s):	☐ Certain ☐ Unlikely ☐ Probable ☐ Not Available ☐ Possible ☐ Not Assessable
Comments: (if applicable)	

Once all fields are populated, please return an electronic copy of this form along with any relevant photographs, additional information or correspondence to Pharmacovigilance@endotherapeutics.com.au

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