octapharma

Suspect Adverse Drug Reaction Reporting Form
For further assistance please contact 1800 780 169
Please email completed form to: aumedinfo@octapharma.com

Local Case No (internal use only):

REPORTER INFORMATION		
Date:	Name of Reporter:	
Reporter's Position: ☐ Physician ☐ Nurse ☐ Pharmacist ☐ Other (specify):		
Institution:		
Telephone No. (including area code):	Email:	

PATIENT INFORMATION & HISTORY		
Patient Initials:	Date of Birth (dd/mm/yy):	Gender: ☐ M ☐ F; ☐ Pregnant: wks
Weight (kg):	Age (years):	Blood Group/Rh factor:
Relevant Family History of Disease: ☐ Yes (specify below) ☐ None ☐ Unknown		
Concomitant Illnesses and Disease: ☐ Yes (specify below) ☐ None ☐ Unknown		
Was the patient taking any concomitant medications? ☐ Yes ☐ No ☐ Unknown If yes, please specify (include product, dose, route of administration, indication for use, frequency):		

ADVERSE DRUG REACTION (ADR) INFORMATION	
Description of ADR:	
Date of onset of ADR (dd/mm/yy):	Duration of ADR (min/hrs/days):
Time of onset of ADR after administration of suspected drug (e.g. 30 minutes):	
Diagnosis of ADR (including methods used and laboratory results, units, normal ranges):	
Action taken with suspect product?	If the infusion was stopped, did ADR abate?
Did reaction(s) reappear after reintroduction? If yes, please specify date and time of reintroduction:	
Was treatment of ADR required? If yes, please specify product, dose, route of administration, therapy dates:	
ADR outcome:	
Seriousness Assessment: ☐ Non-serious ☐ Serious (please classify according to at least one of the criteria below)	
☐ Life threatening ☐ Resulting in congenital anomaly or birth defect	☐ Resulting in persistent or significant disability/incapacity ☐ Suspected transmission of an infectious agent
☐ Patient hospitalised; date from to ☐ Hospitalisation prolonged; date from to ☐ Fatal; date of death: Autopsy performed: Cause of death: ☐ Other, please specify:	

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SUSPECT PRODUCT INFORMATION	
Product (including concentration):	Route of Administration:
Batch No.(s):	
Daily Dose(s):	Infusion Rate:
Therapy Dates (from/to):	Therapy Duration:
Indication for Use:	
Has the patient previously received treatment with the suspect product?	
Has the patient previously experienced ADRs with the suspect product?	
Has the patient previously experienced ADRs with similar products?	
Causality of suspect product to the ADR:	
Other Comments:	

Octapharma is collecting this information to enable us to process and manage the adverse event which you have reported and to communicate with you and others about this matter. As you are providing us information about a patient, we ask that you please inform them that: you have provided this information to Octapharma; we will only use or disclose it for the purposes outlined above; we may disclose this information to service providers which assist in providing our products and services, including distribution and IT services, and to Octapharma's subsidiary located in Austria; and that the Octapharma Privacy Policy (www.octapharma.com.au) contains more details including how to access or correct personal information, and how to make a complaint in relation to Octapharma's handling of such information.