octapharma

Local Log Number: _____

CDSU Case Number: _____

Case Safety Report Form

1. GENERAL INFORMATION

1.1 Report version/Date	1.2 Report source	1.3 Special situation:
Date initially received (dd/mm/yyyy): Date of additional information received (dd/mm/yyyy):	☐ Health care professional ☐ Consumer (e.g.: patient) ☐ Health Authority ☐ Literature ☐ Non-Interventional study Study ID: ☐ Other	☐ Pregnancy/breast feeding (if yes, please complete also Pregnancy Report Form) ☐ Misuse/abuse/overdose ☐ Off-label-use ☐ Lack of efficacy ☐ Medication error ☐ Other:
1.4 Country		
Country of occurrence:		

2. REPORTER

2.1 Primary reporter	2.1 Additional primary reporter *(if applicable)*
Name: Institution: Address: Telephone: Fax: Email: Qualification: ☐ Physician ☐ Pharmacist ☐ Nurse ☐ Health care professional (unspecified) ☐ Patient ☐ Other non-health care professional	Name: Institution: Address: Telephone: Fax: Email: Qualification: ☐ Physician ☐ Pharmacist ☐ Nurse ☐ Health care professional (unspecified) ☐ Patient ☐ Other non-health care professional

3. PATIENT INFORMATION

3.1 Patient details

Initials (first name/surname):	Date of Birth (*dd/mm/yyyy):*	Height (cm):
Gender: ☐ Male ☐ Female	Age:	Weight (kg):
Blood Group/Rh factor:	☐ Patient pregnant Week of gestation:	Ethnic group: ☐ Caucasoid ☐ Mongoloid ☐ Negroid ☐ Australoid ☐ Other:

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3.2 Patient history of illnesses and diseases (e.g. allergy, medical history, alcohol abuse, etc.)

☐**None** ☐**Unknown** ☐**Yes *(please specify below):***

3.3 Concomitant medication *(other medication the patient received prior to the adverse reaction(s) or at the time of suspect drug(s) administration).*

☐**None** ☐**Unknown** ☐**Yes *(please specify below):***

Tradename	Active ingredient	Dosage	Route	Frequency	Indication

4. SUSPECT PRODUCT(S) *(Information on treatment that led to the adverse reaction(s)).*

4.1 Overall treatment regimen

Product *(with strength/ concentration)*	**Route**	**Treatment dosage**	**Batch number(s)**	**Infusion rate**	**Start & end date**	**Duration**	**Indication**

Did the patient receive previous treatment with suspect product(s) and/or similar product(s)?	☐Yes ☐No ☐Unknown
IF YES, please complete:	
Name of the product(s):	Treatment date(s) (approx. period):

Did the patient experience adverse reaction in previous treatment? ☐Yes ☐No	Adverse reaction:	Reaction date and outcome:

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☐Unknown		

5. ADVERSE REACTION *(Adverse reaction(s) according to the primary reporter's words and/or phrases)*				
5.1 Adverse reaction/ diagnosis	**Date**	**Duration** *(With units, as minutes, hours, days, weeks, etc.)*	**Latency** *(Time since the treatment with suspect drug(s))*	**Outcome**
	Start: End:			☐Recovered ☐Recovering ☐Recovered with sequelae ☐Not recovered ☐Unknown ☐Fatal
	Start: End:			☐Recovered ☐Recovering ☐Recovered with sequelae ☐Not recovered ☐Unknown ☐Fatal
	Start: End:			☐Recovered ☐Recovering ☐Recovered with sequelae ☐Not recovered ☐Unknown ☐Fatal
	Start: End:			☐Recovered ☐Recovering ☐Recovered with sequelae ☐Not recovered ☐Unknown ☐Fatal
	Start: End:			☐Recovered ☐Recovering ☐Recovered with sequelae ☐Not recovered ☐Unknown ☐Fatal

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	Start: End:			☐Recovered ☐Recovering ☐Recovered with sequelae ☐Not recovered ☐Unknown ☐Fatal

Action taken with respect to suspect product(s)? *(State product for resp. action in case different actions were taken for different products)*	☐Drug(s) withdrawn:.....☐Dose reduced:..... ☐Dose not changed:..... ☐Dose increased :..... ☐Unknown:..... ☐Not applicable
If product was withdrawn, did reaction(s) stop/improve after stopping suspect product without patient receiving remedial therapy?	☐Yes ☐No ☐Unknown ☐NA
Did reaction(s) reappear after reintroduction?	☐Yes ☐No ☐Unknown ☐NA

5.2 Remedial therapy *(information on therapy to treat the adverse reaction(s)).*

☐**None** ☐**Unknown** ☐**Yes *(please specify below):***

5.3 Laboratory tests performed (Any tests relating to the adverse reaction(s) including results, units, and normal range)

☐None ☐Unknown ☐Yes (please specify below)

6. CASE REPORT ASSESSMENT

Seriousness assessment

☐ non-serious ☐ not provided by the primary reporter
☐ serious

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IF SERIOUS, please choose at least one of the following criteria (defined by the primary reporter):

☐Patient hospitalized Date: from to
☐Hospitalization prolonged Date: from to
☐Life threatening
☐Resulting in persistent or significant disability/incapacity
☐Resulting in congenital anomaly or birth defect
☐Medically significant
☐Fatal

IF FATAL, please complete:

Date of death:	Autopsy performed:	Cause of death:
	☐Yes ☐No ☐Unknown	

6.1 Causality assessment

Relatedness of the observed symptoms/reactions to the administration of suspected Octapharma product:

☐Probably related ☐Possibly related ☐Unlikely related ☐Not related ☐Unclassifiable/unknown

Comment:

Other possible cause(s) of the adverse reaction(s):
☐Underlying disease ☐ Concomitant medication ☐ Other suspect product (non-Octapharma)
☐Other:

7. DETAILED DESCRIPTION / NARRATIVE *(A detailed description of the chronology and outcome of the adverse reaction(s))*

8. OTHER COMMENTS

Was the competent authority informed? ☐No ☐Unknown ☐Yes

If yes, authority reference number: