

Please complete the following sections, including as much info as possible.

1. Patient details

Patient's Initials (F-M-L): _____ Male Female Age (at onset of event): _____ Date of Birth (dd/Mmm/yyyy): _____
 Weight: _____ kg lbs Height: _____ cm in Pregnant: Yes No

2. Primary Suspect Drug (If more than one, add additional page)	Indication	Dose, Units (at AE start)	Frequency	Route	Start Date dd/Mmm/yyyy	Stop Date dd/Mmm/yyyy
Batch number (LOT): _____ <input type="checkbox"/> Not available				Was a product defect suspected?		
Expiry date (dd/Mmm/yyyy): _____ <input type="checkbox"/> Not available				<input type="checkbox"/> Yes <input type="checkbox"/> No		

3. Adverse Event(s) (AEs) or Special Situation(s) <small>Special Situations include exposure during pregnancy (male or female) and exposure from breastfeeding, Lack of efficacy, Medication Errors, Overdose, Abuse, Misuse, Occupational exposure, Suspected transmission of an infectious agent</small>	Start Date dd/Mmm/yyyy	Stop Date or Duration dd/Mmm/yyyy	Serious	Outcome (see below and choose numbers)
AE no. 1			<input type="checkbox"/> Yes <input type="checkbox"/> No	
AE no. 2			<input type="checkbox"/> Yes <input type="checkbox"/> No	
AE no. 3			<input type="checkbox"/> Yes <input type="checkbox"/> No	
AE no. 4			<input type="checkbox"/> Yes <input type="checkbox"/> No	

If any SERIOUS adverse event, select seriousness criteria (more than one can be chosen)		Outcome (add applicable numbers for each AE above):	
<input type="checkbox"/> Patient died	<input type="checkbox"/> Resulted in persistent or significant disability/incapacity	Recovered/Resolved = 1	Recovered with sequel = 4
<input type="checkbox"/> Life threatening		Recovering/Resolving = 2	Fatal = 5
<input type="checkbox"/> Required inpatient hospitalization	<input type="checkbox"/> Congenital anomaly/birth defect	Not recovered/Not resolved = 3	Unknown = 6
<input type="checkbox"/> Required prolonged hospitalization	<input type="checkbox"/> Other medically important condition		

If the Patient died

Specify cause of death: _____ Date of death (dd/Mmm/yyyy): _____ Autopsy performed? Yes No
If yes, please attach report

4. Actions taken with Suspect Drug due to the Adverse Event(s) or Special Situation(s) described

a) Was the Suspect Drug discontinued? Yes, permanently Yes, temporarily No Unknown
 b) Was the dose changed? Yes, increased Yes, decreased No Unknown
If Suspect Drug was discontinued or dose changed:
 c) Did any AE improve (see table above for AE number)? Yes, AE number: _____ No Unknown
If Suspect Drug was stopped:
 d) Was the suspect drug re-introduced? Yes No Unknown
If yes:
 e) Did any AE reappear (see table above for AE number)? Yes, AE number: _____ No Unknown

5. Possible causes for the event

If the reporter of the event is a **healthcare professional (HCP)**:

a) Was the Sobi drug suspected to have caused the event? Yes No
 b) Please provide any other factors that may have contributed to the event?

6. Laboratory tests and investigations

Were any relevant laboratory tests or investigations performed? Yes No
If yes, please provide a copy of the report or provide dated details of the results in section 7. Please include units and reference values for any laboratory test.

The information and personal data provided on this form will be recorded and processed electronically by Swedish Orphan Biovitrum AB (publ). The information provided will be used for the purpose of drug safety surveillance.

Please return to: Drug Safety Swedish Orphan Biovitrum, SE-112 76 Stockholm, Sweden
 FAX: +46 8 697 32 30 Phone: +46 8 697 20 00 (switchboard) e-mail: drugsafety@sobi.com

7. Event details

Please provide any further relevant information about the Adverse Event(s) or Special Situation(s), including results of related investigations and interventions

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8. Medical History and concurrent disease(s) (e.g. other relevant medical conditions, allergies and past drug reactions)

Condition	Onset Date (dd/Mmm/yyyy)	Status
		<input type="checkbox"/> Past <input type="checkbox"/> Present
		<input type="checkbox"/> Past <input type="checkbox"/> Present
		<input type="checkbox"/> Past <input type="checkbox"/> Present
		<input type="checkbox"/> Past <input type="checkbox"/> Present
		<input type="checkbox"/> Past <input type="checkbox"/> Present

9. Concomitant Drug(s) <small>Exclude drugs for treatment of the AE(s)</small>	Indication	Dose, Unit(s)	Frequency	Route	Start Date <small>dd/Mmm/yyyy</small>	Stop Date <small>dd/Mmm/yyyy</small>

10. Reporter contact details

Reporter's Qualification	<input type="checkbox"/> Physician <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other HCP (specify): <input type="checkbox"/> Non HCP (specify):				
Reporter's name:	Reporter's hospital (if applicable):				
Address:					
Email:	Phone:	Fax:			

11. Prescriber contact details

Prescriber's name:	Prescriber's hospital (if applicable):	
Address:		
Email:	Phone:	Fax:

Case reported to Regulatory Authority by patient/reporter? Yes No Unknown

Does the reporter agree to be contacted for follow-up? Yes No

If the reporter of the information is a **patient or consumer**: Does the reporter allow Sobi to contact the responsible physician for follow-up?
 Yes No *If yes, please provide contact details:*

12. Person completing this form (if not the same as reporter or prescriber)

Name:	Title:	Organization/Company:	
E-mail:	Phone:	Fax:	Internal ref. no for this case:

13. Date of awareness – to be completed by Sobi personnel and person working on behalf of Sobi

Date you first received the information provided in this report (dd/Mmm/yyyy):

Signature:	Date (dd/Mmm/yyyy):
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