

Adverse Drug Reaction Report

Global Vigilance
Fresenius Kabi
Borkenberg 14
61440 Oberursel, Deutschland

Email: pharmacovigilance@fresenius-kabi.com
T +49 6172 686 7313 / out-of-office-hours: +49 6172 686 0
F +49 6172 686 4505

[Above text in italics to be adapted to local requirements. Please ensure to fill all the sections (from A to G) of this form]

A. Patient						
Initials: _____	Date of Birth: _____	Age/Age Group: _____	Gender: <input type="checkbox"/> f <input type="checkbox"/> m	Pregnancy: _____ week	Weight: _____ kg	Height: _____ cm

B. Reporter	
Healthcare Professional? <input type="checkbox"/> yes <input type="checkbox"/> no	
If yes, please provide Healthcare Professional details: <input type="checkbox"/> Physician <input type="checkbox"/> Pharmacist <input type="checkbox"/> Others _____ Name: Address: Phone number: E-mail:	If no, please provide consumer/patient details: <input type="checkbox"/> Consumer (patient caregiver or other) <input type="checkbox"/> Patient Name: Address: Phone number: E-mail:
Consent for Fresenius Kabi to follow-up with consumer/patient for more information? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> not applicable	
Consent for Fresenius Kabi to follow-up with Healthcare Professional? <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> not applicable	
Note: please fill the Healthcare Professional contact details above accordingly.	

C. Drug(s) (Trade name or active substance / dosage form)	Batch/Lot No.*	Route of Administration	Dosage (dose and frequency)	Duration of treatment		Indication
				start	end	
1						
2						
3						
4						
5						

Suspected causality with drug No. 1 2 3 4 Please tick at least one drug

*If Batch/Lot no. of Fresenius Kabi suspect drugs is unavailable, please fill with appropriate reason(s): "asked but unknown", "unavailable & consent not received for follow-up" or "unavailable & follow-up requested".

D. Adverse Reaction(s) [please describe the reaction(s) and any treatment given]:		
Start date: _____ Stop date: _____ Duration: _____		
Seriousness Criteria of Reaction(s) <input type="checkbox"/> Death (autopsy: <input type="checkbox"/> yes <input type="checkbox"/> no) <input type="checkbox"/> life threatening <input type="checkbox"/> hospitalization or prolonged hospitalization <input type="checkbox"/> permanent injury or disability <input type="checkbox"/> important medical event	Outcome: <input type="checkbox"/> unknown <input type="checkbox"/> complete recovery <input type="checkbox"/> recovered with sequelae <input type="checkbox"/> not yet recovered <input type="checkbox"/> recovering	Treatment discontinued due to Adverse Reaction <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> no data Improvement after discontinuation <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> no data Reappearance after re-challenge <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> no data

In cases of serious Adverse Reactions, it may be helpful to **attach doctor and/or hospital discharge letter.**

[This footer is editable for the users of the form. Please remove the text in brackets, if you use the form.]

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E. Medical History and other characteristics (e.g. underlying and concomitant diseases, other drugs, allergies, smoking, alcohol, liver-/renal deterioration):

F. Relevant Investigations and Laboratory Data (with date and normal range):

G. Form completed/filled by:

Name:

Date & Signature: