Adverse Drug Reaction Report

Fresenius Kabi South Africa (Pty) Ltd
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[Please ensure to fill all the sections (from A to G) of this form]

A. Patient

Initials:	Date of Birth:	Age/Age Group:	Gender:	Pregnancy:	Weight:	Height:
_____	_____	_____	☐ f ☐ m	_____week	_____kg	_____cm

B. Reporter

Healthcare Professional? ☐ yes ☐ no

If yes, please provide Healthcare Professional details:	If no, please provide consumer/patient details:
☐ Physician ☐ Pharmacist ☐ Others _____	☐ Consumer (patient caregiver or other) ☐ Patient
Name:	Name:
Address:	Address:
Phone number:	Phone number:
E-mail:	E-mail:

Consent for Fresenius Kabi to follow-up with consumer/patient for more information? ☐ yes ☐ no ☐ not applicable

Consent for Fresenius Kabi to follow-up with Healthcare Professional? ☐ yes ☐ no ☐ 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 start	Duration of treatment end	Indication
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)	**Outcome:**	**Treatment discontinued due to Adverse Reaction**
☐ Death (autopsy: ☐ yes ☐ no)	☐ unknown	☐ yes ☐ no ☐ no data
☐ life threatening	☐ complete recovery	**Improvement after discontinuation**
☐ hospitalization or prolonged hospitalization	☐ recovered with sequelae	☐ yes ☐ no ☐ no data
☐ permanent injury or disability	☐ not yet recovered	**Reappearance after re-challenge**
☐ important medical event	☐ recovering	☐ yes ☐ no ☐ no data

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

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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: