

Adverse Drug Reaction Form

Global Vigilance Centre
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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: Occupation:	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						
6						

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"**.

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D. Adverse Reaction(s) [please describe the reaction(s) and any treatment given]:

Start date: _____ Stop date: _____ Duration: _____

Non-Serious

Serious

If, serious, check Seriousness Criteria of Reaction(s)

Death (autopsy: yes no)

life threatening

hospitalization or prolonged hospitalization

permanent injury or disability

important medical event

Outcome:

unknown

complete recovery

recovered with sequelae

not yet recovered

recovering

Fatal

Treatment discontinued due to Adverse Reaction

yes no no data

Improvement after discontinuation

yes no no data

Reappearance after re-challenge

yes no no data

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

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:

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ADVICE ABOUT REPORTING

A. What to report

Report serious adverse drug reactions. A reaction is serious when the patient outcome is:

1. Death
2. Life-threatening
3. Hospitalization (initial or prolonged)
4. Disability (significant, persistent or permanent)
5. Congenital anomaly
6. Required intervention to prevent permanent impairment or damage

Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines.

B. What happens to the submitted information

1. Information provided in this form is handled in strict confidence. The causality assessment is carried out at Fresenius Kabi by using WHO-UMC scale. The analysed forms are forwarded to the PvPI/CDSCO for further analysis.
2. The information generated based on these reports helps in continuous assessment of the benefit-risk ratio of medicines.