



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002								FOR AMC/NCC USE ONLY				
Report Type <input type="checkbox"/> Initial <input type="checkbox"/> Follow up								AMC Report No. : _____				
A. PATIENT INFORMATION								Reg. No. /IPD No. /OPD No./GR no. : _____				
1. Patient Initials _____			2. Age at time of Event or Date of Birth _____			3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>			Worldwide Unique No. : _____			
4. Weight _____ Kgs								12. Relevant tests/ laboratory data with dates				
B. SUSPECTED ADVERSE REACTION								13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)				
5. Date of reaction started (dd/mm/yyyy)								14. Seriousness of the reaction: No <input type="checkbox"/> if Yes <input type="checkbox"/> (please tick anyone)				
6. Date of recovery (dd/mm/yyyy)								<input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Congenital-anomaly				
7. Describe reaction or problem								<input type="checkbox"/> Life threatening <input type="checkbox"/> Required intervention to Prevent permanent impairment/damage				
								<input type="checkbox"/> Hospitalization/Prolonged				
								<input type="checkbox"/> Disability <input type="checkbox"/> Other (specify)				
								15. Outcomes				
								<input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered				
								<input type="checkbox"/> Fatal <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Unknown				
C. SUSPECTED MEDICATION(S)												
S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment	
								Date started	Date stopped			
i												
ii												
iii												
iv												
S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)					
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unkn own	Yes	No	Effect unknown	Dose (if reintroduced)		
i												
ii												
iii												
iv												
11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)												
S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication					
					Date started	Date stopped						
i												
ii												
iii												
Additional Information:						D. REPORTER DETAILS						
						16. Name and Professional Address: _____						
						Pin: _____ E-mail _____						
						Tel. No. (with STD code) _____						
						Occupation: _____ Signature: _____						
						17. Date of this report (dd/mm/yyyy): _____						

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Pharmacovigilance staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

National Coordination Centre Pharmacovigilance

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**Pharmacovigilance Programme of
India for Assuring Drug Safety by
Centaur Pharmaceuticals Pvt Ltd.**

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
 - Death
 - Life-threatening
 - Hospitalization (initial or prolonged)
 - Disability (significant, persistent or permanent)
 - Congenital anomaly
 - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to Pharmacovigilance department.
- Call on Helpline 022-67609341 to report ADRs.
- Or can directly mail this filled form to pharmacovigilance@centaurlab.com

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at Pharmacovigilance department by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

**For ADRs Reporting or for any doubt/queries,
contact Pharmacovigilance department on
Call helpline: 022-67609341
(9:00 AM to 4:30 PM, Mon to Friday)**

**Whatsapp on: +91 7506875056
Email on: pharmacovigilance@centaurlab.com**

**For more information visit us at:
<https://www.centaurpharma.com/>**



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Centaur Pharmaceuticals Pvt. Ltd.