

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 Directorate, Raj Bhawan, Connaught Place, New Delhi 110028							FOR AMC/NCC USE ONLY				
A. PATIENT INFORMATION							AMC Report No. _____				
1. Patient Initials _____		2. Age at time of Event or Date of Birth _____		3. M ☐ F ☐ Other ☐			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 (Yes ☐ No ☐ ☐ Death (dd/mm/yyyy) ☐ Congenital anomaly ☐ Life threatening ☐ Required intervention to prevent permanent impairment/damage ☐ Hospitalization/Prolonged ☐ Disability ☐ Other (specify) _____				
6. Date of recovery (dd/mm/yyyy) _____											
7. Describe reaction or problem _____											
C. SUSPECTED MEDICATION(S)							15. Outcomes ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Fatal ☐ Recovered with sequelae ☐ Unknown				
S.No	B. 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	
								Date started	Date stopped		
i											
ii											
iii											
iv											
5. No. as per C	9. Action Taken						10. Reaction reappeared after reintroduction				
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)	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)							D. REPORTER DETAILS				
17. Causality Assessment: Additional information: _____							16. Name and Professional Address: _____ Pin: _____ E-mail: _____ Tel. No. (with STD code): _____ Occupation: _____ Signature: _____				
							18. Date of this report (dd/mm/yyyy): _____				

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme 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 of the product caused or contributed to the reaction.

How To Report Adverse Drug Reaction

Clemens Wendtner



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