

SUSPECT ADVERSE DRUG REACTION REPORTING FORM


(For reporting of Adverse Drug Reaction by Healthcare Professionals & Consumers)
 Hetero Labs Limited, 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018. Telangana, INDIA

*A. PATIENT INFORMATION							ADR Report No. _____ :				
1. Patient Initials _____	2. Age at the time of Event or Date of Birth _____	3. M <input type="checkbox"/> F <input type="checkbox"/> Other <input type="checkbox"/>		4. Weight _____ Kgs Height _____ cms			Argus Case ID/Worldwide Unique No. :				
							Report Type: Initial <input type="checkbox"/> Follow up <input type="checkbox"/>				
*B. SUSPECTED ADVERSE REACTION							12. Relevant tests/ laboratory data with dates				
5. Event/Reaction start date (DD/MM/YYYY)							13. Relevant medical/medication history				
6. Event/Reaction stop date (DD/MM/YYYY)											
7. Describe Event/Reaction with treatment details, if any											
							14. Seriousness of the reaction: No <input type="checkbox"/> Yes <input type="checkbox"/> (if yes, please tick anyone) <input type="checkbox"/> Death (dd/mm/yyyy) <input type="checkbox"/> Life threatening <input type="checkbox"/> Hospitalization (Initial/Prolonged) <input type="checkbox"/> Congenital-anomaly <input type="checkbox"/> Disability <input type="checkbox"/> Other Medically important				
							15. Outcome <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	9. Action taken (please tick)						10. Reaction reappeared after reintroduction (please tick)				
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)	
i											
ii											

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iii														
iv														
11. Concomitant medication(s)														
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):														
Helpline Call/Message Received by:														
(Name and Sign of Receiver)														

Note: Please fill mandatory fields (*)

For ADRs Reporting to Hetero	
Hetero Labs Limited, 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500 018. Telangana, INDIA Tel.: +91 40 23704923/24/25 Fax: +91-40 23813359 Email: ae.pvg@heterodrugs.com (for global cases) drugsafetyindia@heterodrugs.com (for India)	 Call us on Helpline/ 1800-120-8689 (Toll Free) (9:00 AM to 6:00 PM Monday-Friday/ All Working days).