HETERO

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 □ F □ Other □ 4. Weight_____Kgs	**Argus Case ID/Worldwide Unique No. :** **Report Type: Initial □ Follow up □**

B. SUSPECTED ADVERSE REACTION	12. Relevant tests/ laboratory data with dates
***5. Event/Reaction start date (DD/MM/YYYY)**	
***6. Event/Reaction stop date (DD/MM/YYYY)**	
***6 (A). Onset Duration Time**	
***7. Describe Event/Reaction with treatment details, if any**	13. Relevant medical/medication history
	14. Seriousness of the reaction: No □ if Yes □(please tick anyone) □ Death □ Congenital-anomaly □ Life threatening □ Disability □Hospitalization Initial/Prolonged □ Other Medically important
	15. Outcomes □ Recovered □ Recovering □ Not recovered □ Fatal □ Recovered with sequelae □ 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	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)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.

For ADRs Reporting to Hetero

- ***Hetero Helpline (Toll Free) :*** 180-020-01303 *(9:00 AM to 6:00 PM, Monday-Friday/ All working days)*
- **E-mail:** ae.pvg@heterodrugs.com

Call us on Hetero Helpline or Send your report by mail to/

Hetero Labs Limited,
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