SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

Pharmacovigilance Operations
Regulatory Department
Systopic Laboratories Private Limited
101, Pragati Chambers, Commercial Complex, Ranjit Nagar,New Delhi-110008, India
Email: regulatory@systopic.com | Contact - 011-48150000(Ext.306)
(Monday to Friday between 8.30 am to 5.30 pm, except on public holidays.)

FOR SYSTOPIC USE ONLY

Report No.:

Report Type: ❑ Initial ❑ Follow up

12. Relevant tests/laboratory data with dates-

A. PATIENT INFORMATION

1. Patient Initials - _____	2. Age at time of Event or Date of Birth - _____	3. M ❑ F ❑ Other ❑	4. Weight _____ Kgs 4. a) Height _____ Cm

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.) -

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy) -

6. Event/Reaction stop date (dd/mm/yyyy) -

6 (A). Onset Lag Time -

7. Describe Event/Reaction with treatment details, if any-

14. Seriousness of the reaction:No ❑ if Yes ❑ (please tick anyone)

❑Death (dd/mm/yyyy)	❑Congenital anomaly
❑Life threatening	❑Disability
❑Hospitalization/Prolonged	❑Other Medically important

15. Outcomes

❑Recovered	❑Fatal
❑ Recovering	❑ Recovered with sequelae
❑ Not recovered	❑ 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 Date Started	Therapy Date stopped	Indication	Causality Assessment
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	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect Unknown	Dose (if reintroduced)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										
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	Therapy dates Indication Date Stopped	Indication
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):

Sign. and Name of Receiver-

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

*use separate page for more information