ADVERSE DRUG REACTION REPORTING FORM

A. Patient Details

Patient Initial:_____ Sex: ☐ M ☐ F ☐ Other	Date of Birth or Age (Yrs.):_____	Weight: _____Kg Pregnant : ☐ Yes ☐ No	☐ Adverse event ☐ Product Complaint

Other relevant history including pre-existing medical conditions
(e.g. allergies, smoking, alcohol use, hepatic renal dysfunction etc.):

Source: ☐ Patient ☐ Healthcare professional ☐ Other_____

B. Suspected Adverse Reaction/ ADR Details

Date of AE observed: DD /MM/YYYY Date of recovery: DD /MM/YYYY	Description of the adverse events (including sign and symptoms with specific diagnosis; dosage, duration & start date of treatment and action taken):

C. Drug Details

Sr. No.	Name (Brand and/or Generic)	Manufacturer	Batch/Lot No.	Exp. Date	Dose & Route	Therapy Dates		Reason for use or prescribed for
						Date Started	Date Stopped	
1								
2								
3								

Sr. No. as per C	Action Taken (Pleasetick)					Reaction reappeared after re-introduction (Please tick)			
	Drug Withdrawn	Dose Increased	Dose Reduced	Unknown	If changed Specify Dose	Yes	No	Unknown	If reduced Specify Dose
1									
2									
3									

D. Details of Concomitant Medication

E. Reporter Details

Name and address: _____

Email:_____ Tel. No.:_____

Send the report to the below address

INDOCO REMEDIES LIMITED

R&D Centre, R-92/93, T.T.C. Industrial Area, M.I.D.C., Thane Belapur Road, Rabale, Navi Mumbai 400 701

Toll Free No.: 1800-313-3636

Email: safetyindia@indoco.com

Prescriber Details:

Name of Prescriber:_____

Sign with date and stamp:

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

INSTRUCTIONS TO COMPLETE THE REPORTING FORM

Section 1 - Patient Details

- In patient Initial, write first letter of the name and first letter of the surname (e.g. Pradeep Sharma-PS).
- Provide personal information (Gender, Age).

Section -2 Health Information

- Provide reason(s) for taking medicines and medicines advised by (Doctor, Pharmacists, Friends/ Relatives and Self).

Section 3 - Details of Person Reporting the Side Effect

- Provide the name (optional), address; telephone no. and email are necessary to assess the report.

Section 4 - Details of the Medicines Taking/Taken

- Give all details about the Medicines (Name of Medicines, Quantity of Medicines taken, Expiry Date, start and stop date of Medicines) that have caused side effect.
- Please provide Dosage form (Tablets, Capsule, injections, Oral liquid) and if others, please specify.

Section 5 - About the Side Effect

- Provide side effect start and stop dates and also specify whether the side effect still continues.

Section 6 - How bad was the Side Effect

- Please tick marks the appropriate boxes that apply.

Section 7- Describe the Side Effect

- Please describe the details of side effect and what treatment was taken to manage the side effect.