SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

PHARMACOVIGILANCE CELL

(Pharmaleaf India Private Limited, 2nd Floor, Daarul Awkaf, 6, Cunningham Road, Bangalore -560052, India)

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

Report Type ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials / Patient ID _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

13. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

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

15. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly

☐ Life threatening ☐ Required intervention to Prevent permanent

☐ Hospitalization/Prolonged impairment/damage

☐ Disability ☐ Other (specify)

16. 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. Reaction abated after drug stopped or dose reduced (please tick)					10. Reaction reappeared after reintroduction (please tick)			
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Effect unknown	Dose(if reintroduced)
i									
ii									
iii									
iv									

S.No as per C	11. Action Taken (please tick)					
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
i						
ii						
iii						
iv						

12. 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	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

17. Name and Professional Address:_____
_____
Pin:_____ E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

18. Date of this report (dd/mm/yyyy):

ADVICE ABOUT REPORTING

- Report adverse experiences with medications
- Report serious adverse reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening (real risk of dying)
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report even if:

You're not certain the product caused adverse reaction

You don't have all the details however point nos. 1, 5, 7, 8, 11, 15, 16 & 18 (see reverse) are essentially required.

- Who can report?

Any health care professional (Doctors including Dentists, Nurses and Pharmacists).

- Where to report?

After completing, please return this form to **PHARMALEAF INDIA PRIVATE LIMITED, Pharmacovigilance Cell**

- What happens to the submitted information?

Information provided in this form is handled in strict confidence. PV cell at PHARMALEAF will carry out causality analysis and the data is statistically analyzed and finally submitted to CDSCO.

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 or the product caused or contributed to the reaction.

Please return this form to:

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