Pharmed Limited

Adverse Event Reporting Form

Pharmed Limited
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FOR PHARMED USE ONLY

Pharmed Report No.		Pharmed Received Date (DD/MM/YYYY):	
Worldwide ID No.:		PV Cell Received Date (DD/MM/YYYY):	

Report Type: ☐ Initial ☐ Follow up

A. PATIENT INFORMATION

1. Patient Initials: _ _ _	**2. Date of Birth:** (DD/MM/YYYY)	**3. Age at the time of event:**
4. Sex: ☐ M ☐ F ☐ Other	**5. Height:** ..... Cm.	**6. Weight:**.....Kg.

B. SUSPECTED ADVERSE REACTION

7: Date of Onset: (DD/MM/YYYY)	
8. Date of Recovery: (DD/MM/YYYY)	

9. Description of Reaction or problem and treatment :

13. Relevant tests/laboratory data with dates

14. Relevant medical/medication history (eg. Allergies, race, pregnancy, smoking, alcohol use, hepatic and renal dysfunction etc.

15. Seriousness of the reaction: No ☐ If Yes ☐ (Please tick anyone)

☐ Death (DD/MM/YYYY)	☐ Congenital anomaly
☐ Life threatening	☐ Important Medical Event
☐ Hospitalization (Initial or Prolonged) Start Dates: Stop Dates:	☐ Required immediate intervention to prevent Permanent impairment/damage:
☐ Disability	☐ Other (Specify):

16. Outcome

☐ Fatal	☐ Recovering	☐ Not recovered
☐ Recovered	☐ Recovered with sequelae	☐ Unknown

C. SUSPECTED DRUG

10. Details of Suspected Drug

Sl. No.	Name of the Medicine (Brand/Generic)	Manufacturer (If known)	Batch No./Lot No.	Mfg. Date	Expiry Date	Dose taken	Frequency (OD,BD)	Route of Administration	Therapy Dates		Indication	Action Taken (Drug Withdrawn/ Dose Increased/ Dose Reduced/ Dose not Changed/ Unknown/ Not Applicable)	Causality Assessment
									Date Started	Date Stopped (Tick if its Ongoing)			
1													
2													

11. Reaction reappeared after reintroduction: (Please tick) Yes ☐ No ☐ Unknown ☐ Not Applicable ☐

12. Concomitant medical product including self-medication and herbal remedies with therapy dates (Other medication taken during therapy dates of suspected drug and exclude those used to treat reaction)

Sl. No.	Name of Medicine (Brand/Generic)	Dose taken	Route of adminsitration	Frequency (OD,BD)	Therapy Dates		Indication
					Date Started	Date Stopped (Tick if its Ongoing)	
1							
2							

D. Reporter Details

17. Name:	Address:
Occupation:	
Contact No.:	
E-mail:	PINCODE:
18. Date of this Report (DD/MM/YYYY):	Signature:

Additional Information:

*Information provided in this form is handled in strict confidence.
*Submission of a report does not constitute an admission that medicinal personnel or manufacturer of the product caused or contributed to the reaction.

Adverse Event Reporting Form

ADVICE ABOUT REPORTING

What to report

- Report serious adverse drug reactions.

A reaction is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability (significant, persistent or permanent)
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage
- Medically Significant

- Report non-serious, known or unknown, frequent or rare adverse drug reactions

Who Can Report

- ☛ Any healthcare professional
- ✓ Clinicians / Dentists/ Pharmacists and Nurses
- ☛ Patient/Relative/Friend etc.

Report Even, If :

- You are not certain the product caused adverse reaction/event.
- You don't have all the details.

What happens to the submitted information

Based upon the information submitted in this report, data will be generated which helps in the continuous assessment of Risk-Benefit Ratio of Medicines and strengthens the activities related to Quality, Safety and efficacy of medicinal products.

Where to report?

After filling this form, please return this to the representative of Pharmed Ltd.
Or send scanned copy of the filled form to: **pharmacovigilance@pharmed.in**

Else, send it to:

Pharmed Limited
Pharmacovigilance Cell, Medical Affairs Department,
Pharmed Gardens, Whitefield Road, Bengaluru, Karnataka 560048, India
Direct No.: +91 80 4350 8143/144 (8:30 AM to 5:30 PM, Working Days)
Fax No.: +91 80 28410232

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. The company 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 of the product caused or contributed to the reaction.**