

Pharmed Limited

Adverse Event Reporting Form



| Pharmed Limited Pharmacovigilance Cell, Medical Affairs Department, Pharmed Gardens, Whitefield Road, Bengaluru, Karnataka 560048 India Direct No.: +91 80 4350 8143/144 Fax No.: +91 80 28410232 E-mail: pharmacovigilance@pharmed.in | | | | 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: <input type="checkbox"/> Initial <input type="checkbox"/> Follow up | | | | 13. Relevant tests/laboratory data with dates | | | | | | | | | |
| A. PATIENT INFORMATION | | | | | | | | | | | | | |
| 1. Patient Initials: _____ | | 2. Date of Birth: (DD/MM/YYYY) | | | | | | | | 3. Age at the time of event: | | | |
| 4. Sex: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other | | 5. Height: Cm. | | 6. Weight:.....Kg. | | | | | | | | | |
| B. SUSPECTED ADVERSE REACTION | | | | 14. Relevant medical/medication history (eg. Allergies, race, pregnancy, smoking, alcohol use, hepatic and renal dysfunction etc. | | | | | | | | | |
| 7. Date of Onset: (DD/MM/YYYY) | | | | | | | | | | | | | |
| 8. Date of Recovery: (DD/MM/YYYY) | | | | | | | | | | | | | |
| 9. Description of Reaction or problem and treatment : | | | | 15. Seriousness of the reaction: No <input type="checkbox"/> If Yes <input type="checkbox"/> (Please tick anyone) | | | | | | | | | |
| | | | | <input type="checkbox"/> Death (DD/MM/YYYY) | | | <input type="checkbox"/> Congenital anomaly | | | | | | |
| | | | | <input type="checkbox"/> Life threatening | | | <input type="checkbox"/> Important Medical Event | | | | | | |
| | | | | <input type="checkbox"/> Hospitalization (Initial or Prolonged) | | | <input type="checkbox"/> Required immediate intervention to prevent Permanent impairment/damage: | | | | | | |
| | | | | Start Dates: Stop Dates: | | | | | | | | | |
| <input type="checkbox"/> Disability | | | <input type="checkbox"/> Other (Specify): | | | | | | | | | | |
| | | | | 16. Outcome | | | | | | | | | |
| <input type="checkbox"/> Fatal | | <input type="checkbox"/> Recovering | | <input type="checkbox"/> Not recovered | | | | | | | | | |
| <input type="checkbox"/> Recovered | | <input type="checkbox"/> Recovered with sequelae | | <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable <input type="checkbox"/> | | | | | | | | | | | | | |
| 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 administration | Frequency (OD,BD) | Therapy Dates | | Indication | | | | | | |
| | | | | | Date Started | Date Stopped (Tick if its Ongoing) | | | | | | | |
| 1 | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | |
| D. Reporter Details | | | | | | | | Additional Information: | | | | | |
| 17. Name: | | | | Address: | | | | | | | | | |
| Occupation: | | | | | | | | | | | | | |
| Contact No.: | | | | | | | | | | | | | |
| E-mail: | | | | PINCODE: | | | | | | | | | |
| 18. Date of this Report (DD/MM/YYYY): | | | | Signature: | | | | | | | | | |
| *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 health-care professional
- ✓ Clinicians / Dentists/
Pharmacists and Nurses
- ☞ Non health-care professional
- ✓ 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.**