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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **\***A. PATIENT INFORMATION | | | | | | | | | | | | **ADR Report No. :** | | | | | |
| **1. Patient Initials** | | **2. Age at the time of Event or Date of Birth** | | | | | 3. M □ F □ Other □ | | | | | **Case ID/Worldwide Unique No. :** | | | | | |
| 4. Weight Kgs  Height cms | | | | | **Report Type: Initial □ Follow up □** | | | | | |
| **\***B. SUSPECTED ADVERSE REACTION | | | | | | | | | | | | 12. Relevant tests/ laboratory data with dates | | | | | |
| **5. Event/Reaction start date (DD/MM/YYYY)** | | | | | | | | | | | |
| **6. Event/Reaction stop date (DD/MM/YYYY)** | | | | | | | | | | | |
| **7. Describe Event/Reaction with treatment details, if any** | | | | | | | | | | | |
| 13. Relevant medical/medication history | | | | | |
| 1. Seriousness of the reaction: No □ Yes □   (if yes, please tick anyone)   * + Death (dd/mm/yyyy) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   + Life threatening   + Hospitalization (Initial/Prolonged)   + Congenital-anomaly   + Disability   + Other Medically important | | | | | |
| 15. Outcome   * 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 | | Frequenc y (OD,  BD, etc.) | Therapy dates | | | Indication | Causality Assessment |
| Date started | | Date stopped |
| i |  | |  | |  | |  |  | |  | |  |  | |  |  |  |
| ii |  | |  | |  | |  |  | |  | |  |  | |  |  |  |
| iii |  | |  | |  | |  |  | |  | |  |  | |  |  |  |
| iv |  | |  | |  | |  |  | |  | |  |  | |  |  |  |
| S.No 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| Drug withdrawn | Dose increased | | Dose reduced | | Dose not changed | | | Not applicable | | Unknown | | Yes | No | | Effect unknown | Dose (if reintroduced) |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 |  |  | |  | |  | | |  | |  | |  |  | |  |  |

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| iii |  | |  |  | |  |  | |  | |  |  | |  |  |
| iv |  | |  |  | |  |  | |  | |  |  | |  |  |
| 11. Concomitant medication(s) | | | | | | | | | | | | | | | |
| 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** | | | | | |
| 16. Name and Professional Address:  Pin:\_ E-mail Tel.No.(with STD code) Occupation:\_ Signature:\_ | | | | | |
| 17. Date of this report (DD/MM/YYYY): | | | | | |
| **Helpline Call/Message Received by:**  (Name and Sign of Receiver) | | | | | |

Note: Please fill mandatory fields (\*)

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| --- | --- |
| **For ADRs Reporting to Shilpa** | **For ADRs Reporting to PvPI** |
| **Telephone:**  Please call us on the numbers below.   |  | | --- | | Telephone and WhatsApp : +91 9866307771 |   **Email:**    [Mail Us: Pharmacovigilance@shilpamedicare.com](mailto: Toll Free No. PvPI: Mail Us: Pharmacovigilance@shilpamedicare.com ) | **Call on PvPI Helpline/ 1800 180 3024 (Toll Free)**  **(9:00 AM to 6:00 PM)**  **Monday-Friday/ All Working days).**  **E-mail: pvpi.ipc@gov.in**  **ADR Mobile App: “ADR PvPI”** |