 **Adverse Drug Reaction**

**Report Form**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Fresenius Kabi India Pvt. Ltd.** | | |  | Email ID: [fkipl.vigilance@fresenius-kabi.com](mailto:fkipl.vigilance@fresenius-kabi.com) | | | | |
| **MU India Vigilance**  Ninth Floor, AP81, S No 83,  North Main Road, Mundhwa, Pune 411036, Maharashtra, India | | |  | **Office Phone Number:** +91 20 67649000  **Customer Care Number:** +91 9158898288 | | | | |
| **Patient Details** | | |  | **Adverse event** | | | | |
| Initials | | |  |  | | | | |
| Date of Birth |  | |  |  | | | | |
| Age/Age Group |  | |  |  | | | | |
| Gender  F  M | Pregnancy (week) | |  |  | | | | |
| Weight | Height | |  |  | | | | |
| KG | cm | |  | Start date: Stop date: | | | | Duration |
| **Drugs** (Trade name or active substance / dosage form/ Batch No.) | | Application | | | Dosage | Duration of Treatment | | Indication |
| Start | End |
| **1** | |  | | |  |  |  |  |
| **2** | |  | | |  |  |  |  |
| **3** | |  | | |  |  |  |  |
| **4** | |  | | |  |  |  |  |
| **5** | |  | | |  |  |  |  |

Suspected causality with drug No.  1  2 3  4  5 Please tick at least one drug

|  |  |  |
| --- | --- | --- |
| **Medical History and other characteristics**  (e.g. underlying and concomitant diseases, other drugs, allergies, smoking, alcohol, liver-/renal deterioration |  | **Seriousness Criteria of Reaction**  Death (autopsy:  yes  no)  Life threatening  Hospitalization or prolonged hospitalization  Permanent injury or disability  Important medical event  **Outcome of Reaction**  Unknown  Complete recovery  Recovered with sequelae  Not yet recovered  Recovering  **Treatment discontinued due to Adverse Reaction**  Yes  No  No data  **Improvement after discontinuation**  Yes  No  No data  **Reappearance after re-challenge**  Yes  No  No data |
| **Relevant Investigations and Laboratory Data** (with date and normal range) |  |
| **Measures and treatment of adverse reaction** |  |

**In cases of serious Adverse Reactions, it may be helpful to attach doctor and/or hospital discharge letter.**

|  |  |
| --- | --- |
| **Reporter’s Name:** | **Date:** |
| **Address / Institution:** |  |
| **Phone number:** |  |
| **Email:** | **Signature:** |