**Adverse Drug Reaction**

**Report Form**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Fresenius Kabi India Pvt. Ltd. | | |  | Email: [fkipl.vigilance@fresenius-kabi.com](mailto:fkipl.vigilance@fresenius-kabi.com) | |
| MU India Vigilance | | |  | Phone: +91 20 26634701 – 7 Fax: +91 20 26634710 | |
| A wing, 5th Floor, Ashoka Plaza, Pune -411014, India | | |  |  | |
| 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 |