**Adverse Drug Reaction**

**Report Form**

|  |  |  |
| --- | --- | --- |
| Fresenius Kabi India Pvt. Ltd. |  | Email: 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 |