 **Adverse Drug Reaction**

 **Report Form**

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| **Fresenius Kabi India Pvt. Ltd.** |  | Email ID: 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.**

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