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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **ADVERSE EVENT (AE) REPORT FORM** | | | | | | | | | | | | |
| **Report Type:** ❒ Initial ❒ Follow-up Follow-up No: | | | | | | | | | | | | |
| **Date of AE Report:** | | | | | | | | | | | | |
| 1. **Patient Information** | | | | | | | | | | | | |
| Initials/identifier: | | | | Date of Birth  *(e.g. 01 Jan 1940)* | | | | | Ethnic Origin:  ❒ White ❒ Asian ❒ Black/African American ❒ Other ❒ *Please Specify* | | | |
| Sex: ❒ Male ❒ Female | | | | Height (cm): | | | | | Weight (kg): | | | |
| Pregnant: ❒ Yes ❒ No | | | | Country of occurence: | | | | | Tel. No: | | | |
| 1. **Adverse Event Information** | | | | | | | | | | | | |
| AE term(s): | | | | | | | | | | | | |
| Course of event: | | | | | | | | | | | | |
| ❒ Onset of AE (when AE occurred)*:* | | | | | | | Date: | | | | Time: | |
| Present Status:  ❒ Ongoing → AE currently treated ❒ Yes ❒ No  ❒ Resolved *Please Specify* Date: Time: | | | | | | | | | | | | |
| Case description: Detailed description of the event *(Include related signs/symptoms, course, outcome)* | | | | | | | | | | | | |
| Reason for seriousness: | | | | | | | | | | | | |
| ❒ resulted in death ❒ life-threatening ❒ required inpatient hospitalization or prolongation of existing hospitalization ❒ resulted in persistent or significant disability/ incapability (as per reporter’s opinion)/ congenital anomaly/ birth defect ❒ other medically important event (reporter’s discretion) | | | | | | | | | | | | |
| Intensity: ❒ Mild ❒ Moderate ❒ Severe | | | | | | | | | | | | |
| Reporter’s Causality: [ ] certainly [ ] probably [ ] possibly [ ] unlikely [ ] conditional [ ] unassessable [ ] not related | | | | | | | | | | | | |
| Outcome of AE:  ❒ Completely recovered/resolved ❒ Ongoing ❒ Fatal ❒ Lost to follow-up  ❒ Unknown ❒ Recovered with sequelae → specify: | | | | | | | | | | | | |
| If outcome is fatal:  Cause of death: Date: Time:  Report of Autopsy available?  No  Yes *(Please attach copy to this report)*  Further information: | | | | | | | | | | | | |
| 1. **Drug Details** | | | | | | | | | | | | |
| Name of the drug: Strength: Indication: | | | | | | | | | | | | |
| Route of Admin: Dosage form: Dose: | | | | | | | | | | | | |
| Frequency: Expiry date: | | | | | | | | | | | | |
| Start date: Stop date: Ongoing: ❒ Yes ❒ No | | | | | | | | | | | | |
| Action taken with suspect drug:  ❒ None  ❒ Dosage changed temporarily: Date: ❒ Dosage reduced ❒ Dosage increased  ❒ Drug stop temporarily: Date:  ❒ Drug restarted: Date:  ❒ Drug withdrawn permanently ❒ Dosage not changed ❒ Unknown ❒ Not applicable | | | | | | | | | | | | |
| Additional suspect drug (if any) details as above: | | | | | | | | | | | | |
| Event abated after drug stopped or dose reduced: | | | | Event reappeared after reintroduction of suspect drug: | | | If yes, did reaction recur? | | | | | |
| ❒ Yes ❒ No  ❒ Not applicable | | | | ❒ Yes ❒ No  ❒ Not applicable | | | ❒ Yes ❒ No  ❒ Not applicable | | | | | |
| 1. Patient’s Relevant Medical History (*Supplement attached Yes/No)* | | | | | | | | | | | | |
| *(E.g. concomitant diseases, previous history of present condition, allergy, drug or alcohol abuse)* | | | | | | | | | | | | |
| 1. Concomitant Drugs | | | | | | | | | | | | |
| Drug Name (generic) | Dose/ Unit | Route | Frequency | | | Start date | | Stop date | | Ongoing | | Causal relationship to event |
|  |  |  |  | | |  | |  | | ❒ | | ❒ None  ❒ Possible |
|  | Indication: | | | | | | | | | | | |
|  |  |  |  | | |  | |  | | ❒ | | ❒ None  ❒ Possible |
|  | Indication: | | | | | | | | | | | |
|  |  |  |  | | |  | |  | | ❒ | | ❒ None  ❒ Possible |
| 1. **Reporter Details** | | | | | | | | | | | | |
| Name:  Address:  Country:  Tel. No:  Email: | | | | | Occupation: [ ] Physician [ ] Pharmacist [ ]  Nurse [ ] Consumer [ ] Other, specify: …………  Also reported to: [ ] Regulatory Authority  [ ] Distributor [ ] None  Date : \_\_ / \_\_ / \_\_\_\_\_, Signature: | | | | | | | |
| 1. **Send this report to:** | | | | | 1. **To be filled by the company:** | | | | | | | |
| Global Pharmacovigilance Department, Evolet Healthcare Pvt. Ltd., 201-203, 2nd floor, Tower B, Global Business Park, Sector- 26, Gurgaon, Haryana – 122002, India  (E-mail : phv@evolet.in) | | | | | Date received by receiver: \_\_ / \_\_ / \_\_\_\_\_  Name and sign of receiver:  Safety Report ID: | | | | | | | |

*Note: A supplement paper can be added in case of further information to be reported.*