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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temporarily: Date: ❒ Dosage reduced ❒ Dosage increased ❒ Drug stop temporarily: Date: ❒ Drug restarted: Date: ❒ Drug withdrawn permanently ❒ Dosage not changed ❒ Unknown ❒ Not applicable |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 [ ] NoneDate : \_\_ / \_\_ / \_\_\_\_\_, 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.*