## ADVERSE EVENT (AE) REPORT FORM
(For all countries)

**Report Type:** ❒ Initial ❒ Follow-up Follow-up No:

**Date of AE Report:**

**Please fill and return this form to Alde Medi Impex Ltd., First Floor, 71/2C, Rama Rd, Moti Nagar, Block C, Najafgarh Road Industrial Area, New Delhi, Delhi, 110015, India, within 24 hours of knowledge of Adverse event.**

**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:** |

**2. Adverse Event Information**

**AE term(s):**

**Course of event:**

| | | |
|---|---|---|
| ❒ Onset of AE or date and time when AE occurred*:* | **Date:** | **Time:** |
| ❒ Onset of AE or date and time when event became serious, if applicable: | **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:_____

**Lab test Details (with dates, results and normal range):** _____

**3. Drug Details**

**Name of the drug:**_____**Strength:**_____**Indication:**_____

**Route of Admin:**_____**Dosage form:**_____**Dose:**_____

**Frequency:**_____**Expiry date: DD/MM/YYYY**

**Start date:(dd.mmm.yyyy) Stop date:(dd.mmm.yyyy) Ongoing:**

**Action taken with suspect drug:**
❒ None
❒ Dosage changed temporarily: Date:_____❒ Dosage reduced ❒ Dosage increased

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| ❒ Drug stop temporarily: Date:_____<br>❒ Drug restarted: Date:_____<br>❒ 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<br>❒ Not applicable | | ❒ Yes ❒ No<br>❒ Not applicable | | | | ❒ Yes ❒ No<br>❒ Not applicable | |
| **4. Patient's Relevant Medical History** (*Supplement attached Yes/No)* | | | | | | | |
| *(E.g. concomitant diseases, previous history of present condition, allergy, drug or alcohol abuse)*<br>_____ | | | | | | | |
| ***5.*** **Concomitant Drugs** | | | | | | | |
| **Drug Name (generic)** | **Dose/ Unit** | **Route** | **Frequency** | **Start date** | **Stop date** | **Ongoing** | **Causal relationship to event** |
| | | | | | | ❒ | ❒ None<br>❒ Possible |
| | **Indication:** | | | | | | |
| | | | | | | ❒ | ❒ None<br>❒ Possible |
| | **Indication:** | | | | | | |
| | | | | | | ❒ | ❒ None<br>❒ Possible |
| **6. Reporter Details** | | | | | | | |
| **Name:**<br>**Address:**<br>**Country:**<br>**Tel. No:**<br>**Email:** | | | | **Occupation:** [ ] Physician [ ] Pharmacist [ ] Nurse [ ] Consumer [ ] Other, specify: ……<br>**Also reported to:** [ ] Regulatory Authority [ ] Distributor [ ] None<br>**Date : __ / __ / _____, Signature:** | | | |
| **7. Send this report to:** | | | | **8. To be filled by Manufacturer:** | | | |
| **Alde Medi Impex Ltd.,**<br>**First Floor, 71/2C, Rama Rd, Moti Nagar, Block C, Najafgarh Road Industrial Area, New Delhi, Delhi, 110015, India**<br>**Email: pv@aldemedi.com**<br>**24*7 mobile number: 9958165585** | | | | **Date received by receiver: __ / __ / _____**<br>**Name and sign of receiver:**<br>**Safety Report ID:** | | | |