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:

2. 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:

3. 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❒ Drug stop temporarily: Date:_____ ❒ Drug restarted: Date:_____ ❒ Drug withdrawn permanently ❒ Dosage not changed ❒ Unknown ❒ Not applicable		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

4. Patient's Relevant Medical History (*Supplement attached Yes/No)*

(E.g. concomitant diseases, previous history of present condition, allergy, drug or alcohol abuse)

_____

5. 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

6. Reporter Details

Name: Address: Country: Tel. No: Email:	Occupation: [ ] Physician [ ] Pharmacist [ ] Nurse [ ] Consumer [ ] Other, specify: …… Also reported to: [ ] Regulatory Authority [ ] Distributor [ ] None Date : __ / __ / _____, Signature:
7. Send this report to:	**8. To be filled by the company:**
ALDE MEDI IMPEX LTD First Floor, 71/2C, Rama Rd, Moti Nagar, Block C, Najafgarh Road Industrial Area, New Delhi, Delhi, 110015, India (E-mail : pv@aldemedi.com)	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.