ADVERSE EVENT REPORT FORM

1. Patient Details

1.1. Patient Name :

1.2. Date of Birth / Age :

1.3. Gender : ☐ Male ☐ Female ☐ Other

1.4. Weight (in Kg / Lbs) :

1.5. Height (in Ins. / Cms) . :

1.6. Additional Information :

2. Reporter Information (e.g. Healthcare Professional, Lawyer etc)

2.1. Reporter's Name :

2.2. Reporter's Address :

2.3. E-Mail :

2.4. Country :

2.5. Reporter qualification :

☐ Physician ☐ Pharmacist ☐ Other health professional

☐ Lawyer ☐ Non health professional

Please specify : _____

2.6. Phone Number :

2.7. Date :

2.8. Reporter Signature :

3. Suspected Medication

S. No.	Name (Brand / Generic)	Manufacturer	Batch	Expiry	Dose	Route	Frequency	Therapy Dates		Indication	Causality Assessment
								Date Started	Date Stopped		
I											
II											
III											

Did AE improve after stopping or reducing drug? ☐ Yes ☐ No ☐ N/A

Did AE reappear after reintroduction? ☐ Yes ☐ No ☐ N/A

4. Adverse Event Description (Action taken after reaction)

S. No.	Symptom(s)	Start Date	Stop Date	Intensity	Outcome
I				☐ Mild ☐ Mod. ☐ Severe	
II				☐ Mild ☐ Mod. ☐ Severe	
III				☐ Mild ☐ Mod. ☐ Severe	

5. Seriousness: Is the Adverse Event serious?

☐ Yes ☐ No **If yes, please select criteria below:**

Death	Immediately Life-Threatening	In-patient Hospitalization / Prolonging Existing Hospitalization	Resulting in Persistent / Significant Disability or Incapacity	Congenital Abnormality / Birth Defect
☐	☐	☐	☐	☐

If 'Death', Specify Cause: _____

Date of Death _____

Post Mortem / Autopsy Performed?

☐ Yes ☐ No (If 'Yes', Please Attach Findings)

6. Please provide any further relevant information about the Adverse Event, any treatment received, investigations carried out.

Do you consider that there is a reasonable possibility that the event may have been caused by the suspect drug(s)? ☐ Yes ☐ No **Reason** _____

7. Relevant Medical History / Concurrent Diseases

- Please also include drug reaction, allergies, environmental factor , and (or) drug & alocohol abuse

8. Concomitant Medication

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD, BD, etc.)	Therapy Dates		Indication
					Date Started	Date Stopped	
I							
II							
III							

Signature and Name of Receiving Personnel :

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent.

Email the form to: **drugsafety@ikrispharmanetwork.com**

Ikris Pharma Network 905 I-Thum Business Park Plot No. - 40, Block A, Unit No. 5, Tower A Sector 62, Noida 201301 (INDIA)