


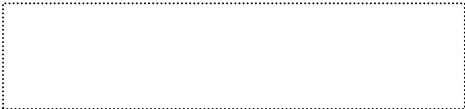
**RESTRICTED CIRCULATION**

	<p><b>OPES HEALTHCARE PVT. LTD.</b></p> <p><b>Ahmedabad, Gujarat</b></p>
<b>TITLE</b>	<b>ADVERSE EVENT REPORTING FORM</b>


<b>A. Patient Details</b>			
Patient Initials		Gender (M/F)	
DOB (DD MMM YYYY)		Age (years)	
Weight (Kgs)		Height (cms)	
Ethnicity / Race		Country:	
<b>B. Reporter Details</b>			
Reporter Initials		Phone Number	
Healthcare Professional	<input type="checkbox"/> No <input type="checkbox"/> Yes (Please Specify):	Postal Code	
E-mail ID		State	
Address		Country:	

<b>C. Suspect Drug Details</b>							
<b>1. Suspect Product Name (Brand Name/Generic Name):</b>							
Strength		Dosage from		Route			
Start date, Time		Stop Date, time		Frequency			
Indication:		Action Taken:		<input type="checkbox"/> Ongoing <input type="checkbox"/> Drug Withdrawn <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown <input type="checkbox"/> Dose reduced <input type="checkbox"/> Temporarily stopped			
<b>2. Suspect Product Name (Brand Name/Generic Name):</b>							
Strength		Dosage from		Route			
Start date, Time		Stop Date, time		Frequency			
Indication:		Action Taken:		<input type="checkbox"/> Ongoing <input type="checkbox"/> Drug Withdrawn <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown <input type="checkbox"/> Dose reduced <input type="checkbox"/> Temporarily stopped			

<b>D. Other Drug Details</b>								
Sr. No.	Past drug/ Concomitant Drug	Strength	Dosage from	Route	Frequency	Start date, Time	Stop date, Time	Indication
1								
2								
3								
4								
5								



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<b>E. Details of Adverse Drug Events</b>							
<b>1. Adverse Event (Verbatim):</b>							
<b>Severity</b>	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<b>Start date</b>		<b>Stop Date</b>		<b>Event Serious</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Seriousness</b>	<input type="checkbox"/> Fatal <input type="checkbox"/> Life-Threatening	<input type="checkbox"/> Hospitalization or prolongation of hospitalization					
<b>Criteria</b>	<input type="checkbox"/> Persistent or significant disability or Incapacity	<input type="checkbox"/> Congenital Anomaly		<input type="checkbox"/> Other IME			
<b>Causality</b>	<input type="checkbox"/> Definite <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> Unrelated						
<b>Outcome</b>	<input type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovering/ resolving <input type="checkbox"/> Not recovered/not resolved; <input type="checkbox"/> Recovered/resolved with sequelae						
	<input type="checkbox"/> Fatal; <input type="checkbox"/> unknown						
<b>2. Adverse Event (Verbatim):</b>							
<b>Severity</b>	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<b>Start date</b>		<b>Stop Date</b>		<b>Event Serious</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Seriousness</b>	<input type="checkbox"/> Fatal <input type="checkbox"/> Life-Threatening	<input type="checkbox"/> Hospitalization or prolongation of hospitalization					
<b>Criteria</b>	<input type="checkbox"/> Persistent or significant disability or Incapacity	<input type="checkbox"/> Congenital Anomaly		<input type="checkbox"/> Other IME			
<b>Causality</b>	<input type="checkbox"/> Definite <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> Unrelated						
<b>Outcome</b>	<input type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovering/ resolving <input type="checkbox"/> Not recovered/not resolved; <input type="checkbox"/> Recovered/resolved with sequelae						
	<input type="checkbox"/> Fatal; <input type="checkbox"/> unknown						
<b>3. Adverse Event (Verbatim):</b>							
<b>Severity</b>	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	<b>Start date</b>		<b>Stop Date</b>		<b>Event Serious</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Seriousness</b>	<input type="checkbox"/> Fatal <input type="checkbox"/> Life-Threatening	<input type="checkbox"/> Hospitalization or prolongation of hospitalization					
<b>Criteria</b>	<input type="checkbox"/> Persistent or significant disability or Incapacity	<input type="checkbox"/> Congenital Anomaly		<input type="checkbox"/> Other IME			
<b>Causality</b>	<input type="checkbox"/> Definite <input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely <input type="checkbox"/> Unrelated						
<b>Outcome</b>	<input type="checkbox"/> Recovered/resolved <input type="checkbox"/> Recovering/ resolving <input type="checkbox"/> Not recovered/not resolved; <input type="checkbox"/> Recovered/resolved with sequelae						
	<input type="checkbox"/> Fatal; <input type="checkbox"/> unknown						

<b>In case of Hospitalization</b>	
<b>Date of Admission</b>	<b>Date of Discharge</b>

<b>F. For Fatal Outcome</b>			
<b>Date of Death</b>		<b>Time Of Death</b>	
<b>Autopsy Report</b>		<b>Death Certificate</b>	



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<b>Cause(s) of Death</b>	
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**G. Laboratory Tests Performed**

Sr. No.	Test Name	Date of Test performed	Result	Reference Range
1				
2				
3				

**H. Medical History / Concurrent Conditions**

Sr. No.	Description	Type*	Start Date	Stop Date
1				
2				
3				
*	1 - Past History (Surgical procedures); 2 - Concurrent Condition			

**ADVICE ABOUT VOLUNTARY REPORTING**

**WHERE TO REPORT**

**Postal Address**

Opes Healthcare Private Limited  
411 and 412, Block A,  
Navratna Corporate Park, Ambli road,  
Ahmedabad-380058, Gujarat, India.

**OR**

✉ **Email:** [safety@opeshealthcare.com](mailto:safety@opeshealthcare.com)

☎ **Phone Number:** 02717-465326 (Ext: 777)

**INSTRUCTION TO FILL THE REPORTING FORM**

- Use clear and legible handwriting
- Fill in the sections that apply to your report
- Attach additional pages if needed
- Use a separate form for each patient and event
- Provide contact details (information is used for follow-up, if necessary. Your identity will remain confidential)
- Avoid information such as personal IDs to protect privacy.

**Note:** If you have any questions while filling the form, please contact our Pharmacovigilance team at above email ID/Phone number.