



ALRAI Pharmaceutical Industries Co. (L.L.C)

Form No.:PV-FRM-0001
Revision No.: 0

Pharmacovigilance

Individual Case Safety Report (ICSR) Form

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1- PATIENT INFORMATION

Patient Initials	Gender	Age	Weight	Height	Pregnancy?
	<input type="checkbox"/> Male <input type="checkbox"/> Female				<input type="checkbox"/> No <input type="checkbox"/> Yes, week.....

2- SUSPECTED PRODUCT INFORMATION

Generic Name	Scientific Name	Daily Dose	Indication	Batch Number	Date	
					From	To

3- ADVERSE EVENT INFORMATION

Adverse Event Onset Date	Describe the Reaction

Tick appropriate box with reference to the adverse drug reaction (if applicable):

- Require hospitalization Prolonged hospitalization Death, date.....
- Life threatening Congenital anomaly Permanent disability
- Required intervention to prevent permanent impairment / damage Other.....

Did Reaction Disappear?	Did Reaction Reappear After Reintroduction of Drug?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know

Action Taken With Suspect Drug	Patient Status
<input type="checkbox"/> Discontinued due to AE <input type="checkbox"/> Dose increased <input type="checkbox"/> Dose decreased <input type="checkbox"/> Other (please specify)..... <input type="checkbox"/> None	<input type="checkbox"/> Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> Not recovered <input type="checkbox"/> Unknown

4- CONCOMITANT DRUGS AND MEDICAL HISTORY

Concomitant drugs (exclude drugs used to treat reaction) and medical history any diseases that the patient has (for example: Diabetes, Hypertension, etc...)

Concomitant Disease(s)	Other Relevant History (e.g., diagnostics, allergies, etc.)

Drug Name	Daily Dose	Indication	Date	
			From	To



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5- TREATING PHYSICIAN INFORMATION

Name	Phone / Mobile	Profession	Date of the Report

Place of Practice	Address of Practice	Email

Additional Information or Notes (if there)

6- FOR PHARMACOVIGILANCE DEPARTMENT

Case Tarcker No.	Receiving Date / Sign	Notes
ICSR / /		