شركة ثمار الجزيرة
Thimar AlJazirah Company

Reporting Form

Report Status: ☐ New ☐ Follow- up	**Date of report:** / /
Report Type: ☐ Adverse Drug Reaction ☐ Quality Defect ☐ Lack of Efficacy ☐ Misuse ☐ Abuse ☐ Overdose ☐ Medication error	**Date of ADR receipt / awareness:** / /
Report Source: ☐ Study ☐ Literature ☐ Healthcare Professional ☐ Other (specify):	

*Mandatory fields.

I. REPORTER INFORMATION*

(1)NAME		**(2) ADDRESS**	Country / City:
			Health Institution:
(3) CONTACT Details			**(4) PROFESSION / Qualification**
Phone No.	Email	Fax	☐ Dr ☐ Nurse ☐ Pharmacist ☐ Consumer ☐ Other:

II. PATIENT INFORMATION*

(1) PATIENT INITIAL (first, last)	**(2) Country / City**	**(3) AGE**	**(4) DATE OF BIRTH** (DD/MM/YYYY)	**(5) Gender**	☐Male ☐Female
				Pregnancy:	☐ Yes ☐No
(6) Patient medical record No.	**(7) WEIGHT**	**(8) HIGHT**	**(9) SETTING**	Expected delivery date:	
			☐ Hospital ☐ Out- patient clinic ☐ Home ☐ Nursing home	Consent to Contact at later date if Pregnancy Case	☐ Yes ☐No

III. SUSPECT DRUG(S) INFORMATION*

(1) SUSPECT DRUG(S):	**Generic Name**	**Scientific Name**	**Dosage Form**
	Route of Administration	**Strength**	**Manufacturer Name**
(2) DAILY DOSE(S) / FREQUENCY		**(3) INDICATION FOR USE / REASON FOR USE**	**Batch No & Expiry date**
(4) STARTING DATE AND TIME OF DAY		**(5) STOPPING DATE AND TIME**	**(6) DURATION OF TREATMENT**

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IV. Adverse Drug Reaction*

(1) DESCRIBE ADVERSE REACTION(S), QUALITY DEFECT, PRODUCT EFFICACY	**TYPE OF ADVERSE REACTION**	☐ Serious ☐ non- serious ☐ Expected ☐ non- expected
RELEVANT Info. INCLUDING RELEVANT TESTS / LAB DATA	**(2) REACTION ONSET (Start date & time)**	
(3) STOP DATE & TIME	**(4) DURATION OF REACTION**	

(5) CHECK ALL APPROPRIATE TO ADVERSE REACTION	
☐ PATIENT DIED	☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY	☐ LIFE THREATENING

(6) ADJUSTMENT PLAN/ACTION:	**(7) OUTCOME:**
	☐ Unknown ☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Recovery with Sequelae
(7) DID REACTION ABATE AFTER STOPPING DRUG (De-challenge)?	**(8) DID REACTION REAPPEAR AFTER REINTRODUCTION (Re-challenge)?**
☐ YES ☐ NO ☐ NA	☐ YES ☐ NO ☐ NA

V. CONCOMITANT DRUG(S) AND HISTORY

(1)CONCOMITANT DRUG(S) (exclude those used to treat reaction)	**Generic Name**	**Scientific Name**	**DOSAGE FORM**
	ROUTE(S) OF ADMINISTRATION	**Strength**	**Manufacturer Name**
(2) DAILY DOSE(S)		**(3) INDICATION FOR USE**	**Batch No.**

(4) STARTING DATE AND TIME OF DAY	**(5) STOPPING DATE AND TIME**	**(6) DURATION OF TREATMENT**

(7) OTHER RELEVANT HISTORY (e.g. Co-diseases, diagnostics, allergics, pregnancy with last month of period, etc.)

VI. Causality Opinion

Healthcare professional's causality opinion: Event relationship to Drug/Device:
☐ Possible ☐ Probable ☐ Definite ☐ Unlikely ☐ Unrelated