جمجوم فارما
Jamjoom Pharma

Pharmacovigilance
التَيقُظ الدوائي

ADVERSE DRUG REACTION REPORTING FORM

1. PARTICULARS OF PATIENT*

Patient Initials: …… Country: …… Date of Birth: …… *Age (At the time of event): ……..…...

Weight (kg): …… Height (cm): …… Patient address: ……. *Sex: □ Male □ Female

*Pregnant: □ Yes □ No Not applicable…… Pregnancy week: …….

2. ADVERSE EVENT*

Date of reaction started*: …… Date of recovery (If applicable): ……

Describe the Reaction(s) or problem*:

3. SERIOUSNESS OF THE REACTION

Tick appropriate box with reference to the adverse drug reaction:

□ Life threatening
□ Death (date): …….
□ Congenital anomaly
□ Requires or prolongs hospitalization
□ Permanently disabling or incapacitating
□ Other medically important condition (Please Specify):

4. OUTCOME OF THE REACTION

□ Fatal (Death)
□ Recovering
□ Recovered
□ Continuing
□ Unknown
□ Other (Please Specify): ……

5. SUSPECTED MEDICATIONS or DRUGS*

Brand Name*	**Generic Name***	**Manufacturer**	**Batch No.**	**Strength**	**Dose*** (Amount of medicine taken)	**Route*** (Oral, Parental, Ophthalmic, etc.)	**Dosage form*** (Tablet, Capsule, Cream, etc.)	**Purpose of use** (Indication)	**Duration of treatment** (days/month etc.)	**Drug discontinued or dose reduced** (De-challenge)	**Reaction stopped after drug discontinuation** (Yes/No/NA)	**Reaction reappeared after re-administration** (Yes/No/NA)

6. *CONCOMITANT MEDICATIONS (Other than suspect drugs) *

Concomitant medical product including self-medication and herbal remedies with therapy dates (exclude those used to treat the reaction):

7. MEDICAL HISTORY

Other relevant history including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc.)

Have you experienced the same side effect before with the same medicine? Yes No

8. RELEVANT TESTS / LABORATORY DATA WITH DATES

9. *PRIMARY REPORTER DETAILS (Patient/Physician/Pharmacist/Nurse/Dentist/ Other healthcare professional) *

Name*: ……. Qualification*: …… Reporter organization: …….

Address: ……. Town: ……State or province: ……. *Country: …… Phone No.*: ……

Email: …….

10. SECONDARY REPORTER DETAILS (Med. Rep. / Distributer/ etc.)

Name: ……. Qualification: …… Reporter organization: …….

Address: ……. Town: …… State or province: …… Country: ……

Phone No.: …… Email: ……

11. CAUSALITY ASSESSMENT – DRUG REACTION CORELATION (By Primary reporter only)

☐ Certain ☐ Possible ☐ Probable ☐ Not related ☐ Unassesable ☐ Unknown

12. DATE OF THIS REPORT (dd/mm/yy):

Confidentiality & Data Privacy: The patient's identity is held in strict confidence and protected to the fullest extent. Jamjoom staff is not expected to and will not disclose the reporter's identity in response to a request from the public.

- By providing your data, you consent to the collection, processing, and submission of your information to regulatory authority, when required.
- You acknowledge that your data will be handled in accordance with applicable data protection and privacy laws and may be shared with the authorized entities.
- This data will be retained for a period of 10 years for regulatory compliance and related purposes

Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

ADVICE ABOUT REPORTING

- **Report on adverse experiences with medications:**
- **A reaction is serious when the patient outcome is**: 1) Death 2) Life threatening 3) Requires or prolongs hospitalization 4) Permanently disabling or incapacitating 5) Congenital anomaly
- **Report even if:**
- You're not certain the product caused adverse reaction
- You don't have all the details, however, point nos. 1, 2, 5, 6, 9, and Points with (*) marks are essentially required.