

ALHAKEEM Company for Pharmaceutical and Medical Supply				 ALHAKEEM شركة الحكيم للأدوية ALHAKEEM Co for Pharmaceutical & Medical Supply
Consumers ADR-Reporting Form				
Form No.	AHKM-L4-22-02	Issued date	01/12/2024	
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1. Patient Details

Patient Initials/		<input type="checkbox"/> Gender): Male <input type="checkbox"/> Female <input type="checkbox"/> Other	Age (Year or Month)
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2. Health Information

a. Reason(s) for taking medicine(s)(Disease/Symptoms):

b. Medicines Advised by: Doctor Friends/Relatives
 Pharmacist

Self (Past disease experienced/No past disease experienced)

3. Details of Person Reporting the Side Effect

Name (Optional):

Address:

Telephone No: Email:

4. Details of Medicine Taking/Taken

Name of Medicines	Quantity of Medicines taken (e.g. 250 mg, Two times a day)	Expiry Date of Medicines	Date of Start of Medicines	Date of Stop of Medicines
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form: Tablet Oral Liquids
 Capsule Injection

(If Others Please Specify
)

5. About the Side Effect

When did the side effect dd/mm/yy Side Effect is still Continuing

When did the side effect dd/mm/yy

6. How bad was the Side Effect? (Please ✓ the boxes that Apply)

<input type="checkbox"/>	Did not affect daily activities	<input type="checkbox"/>	Affect daily activities
<input type="checkbox"/>	Admitted to hospital	<input type="checkbox"/>	Death

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Others
7. Describe the Side Effect (What did you do to manage the side effect?)

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**
 - death
 - life-threatening (real risk of dying)
 - hospitalization (initial or prolonged)
 - disability (significant, persistent or permanent)
 - congenital anomaly
 - required intervention to prevent permanent impairment or damage
- **Report even if:**
 - You're not certain the product caused adverse reaction
 - You don't have all the details although point no. 1, 3, 4 & 7 are essentially required.
- **Who can report:**

Please return this form to:

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity. Submission of an ADR report does not have any legal implication on the reporter. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

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- All consumers of the medicines.
- **Where to report:**
- Duly filled in Suspected Adverse Drug Reaction Reporting Form can be sent directly to Pharmacovigilance office
- of Alhakeem Pharmaceuticals (PVAP).
- Call on 00218920920053 to report ADRs or directly mail this filled form to pvap@alhakeem.ly
- **What happens to the submitted information:**
- Information provided in this form is handled in strict confidence. The forms will be sent to mother company to carry out causality assessment of the reported cases. If approved, the case reports are sent back to PV office of Alhakeem. The received case reports are then forwarded to the pharmacovigilance department of the Libyan MOH to Finally submit the data to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the PVAP. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.