Middle East Pharmaceutical Industries Co. Ltd.
Avalon Pharma

شركة الشرق الأوسط للصناعات الدوائية
أفالون فارما

Pharmacovigilance department

إدارة التيقظ الدوائي

Date received:
Received by:

Adverse Drug Reactions (ADRs) Reporting Form
for Health Care Professionals

A. Patient Details

Patient name or initial (Optional): **Date of birth:** **Height:** **Weight:**

Health Institution: **Medical Record No:** **Age:** **Sex:** □ **M** □ **F**

B. Suspected Drug(s) / Herbal(s) /Cosmetic(s) and all other drugs used.

		Drug name "Generic & Brand"	Batch No.	Dose	Route	Frequency	Start date	End date	Purpose of use
Suspected	1								
	2								
Concomitant	1								
	2								

C. Adverse Drug Reaction

Adverse event including relevant tests/lab data and dates	**Other relevant history, including preexisting medical conditions** *(diagnosis, allergies, pregnancy, hepatic, renal etc)*
Date of event started:	Date of event disappeared, if applicable:

D. Action Taken

□ **Drug withdrawn.** □ **Dose reduced.** □ **Dose increased.** □ **Dose not changed.** □ **Unknown.** □ **Not applicable.**

E. Outcome of ADR (Tick all applicable)

The patient □ **Recovered, date:** □ **Recovering** □**No improvement** □ **Fatal** □**Unknown**

Event subsided after stopping (de-challenge): □**No** □ **Yes** □ **Unknown**

Event reappear after reintroducing (re-challenge): □**No** □ **Yes** □ **Not applicable**

Specific antagonist or treatment used: □**No** □**Yes, specify:**

F. Seriousness of ADR (Tick all applicable)

□ **Patient died, date:** □ **Life threatening** □ **Permanent disability**

□ **Hospitalization** □ **Prolonged hospitalization more than 24 hr.** □ **Congenital anomaly**

□ **Required intervention to prevent permanent impairment/ damage** □ **Required Emergency Room (ER) visit**

□ **Cancer** □ **Others**_____

G. Reporter Details

Reporter name: **Profession (Specialty):**

Address: **E-mail:**

Phone / Mobile: **Date:** **Signature:**

Dear healthcare professional:

- We realize that filling this form requires time to complete but reporting adverse drug reactions are indispensable for safe use of medication. The SFDA can judge the safety of medicinal products in Saudi Arabia only if sufficient information is provided.

- **Confidentiality:** Reporter's and patient's identity are held in strict confidence by Avalon Pharma and protected to the fullest extent of the law, information provided by the reporter will be strictly protected and will not be used in any way against him / her.

- **Adverse Drug Reaction (ADR)** is a response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

- **A serious adverse event or reaction** is any untoward medical occurrence that at any dose result in:

    - Death.
    - Life threatening situation.
    - Inpatient hospitalization (admission or prolongation).
    - Permanent or severe disability.
    - Congenital abnormality.
    - Required intervention to prevent permanent damage.

This form can be used by: • Physician. • Pharmacist. • Dentist. • Nurses. • Other healthcare providers. **Use this form to report adverse reactions from:** • Medications (drugs). • Cosmetic products. • Herbal products.	**How to report:** • Fill out the reporting form. • Attach additional information, if needed. • Use a separate form for each ADR. **Please submit completed forms to:** Pharmacovigilance department ▪ **E-mail:** **Pharmacovigilance@avalon.com.sa**

Thank you

To be filled by Pharmacovigilance department	
Date of receipt information:	**Follow up information requested:** ☐ **Yes** ☐ **No**
By: **Signature:**	☐ **Initial report** ☐ **Follow up report**