Advanced Pharmaceutical Industries
مصنع الأدوية المتقدمة

Adverse Drug Reaction (ADR) Reporting Form

A, Patient Details	
Patient initials:	Date of Birth: Day/Month/Year
Sex: ☐ Male ☐ Female [☐ Pregnant ☐ Not Pregnant]	Weight: Height:

B, Suspected Drug/s						
Drug/s Name (Include generic name/s	Manufacturer & Batch No.	Dose route	Dose frequency	Start date	End date	Indication/purpose of use

C, Concomitant Drug/s (Exclude those used to treat reaction)						
Drug/s Name (Include generic name/s	Manufacturer & Batch No.	Dose route	Dose frequency	Start date	End date	Indication/purpose of use

D, Adverse Drug Reaction Description	
Adverse event including relevant tests/lab data and dates	Other relevant history, including preexisting medical. conditions. (Diagnosis, allergies, pregnancy, hepatic, renal etc.)
Date when event started:	Date when event disappeared (if applicable}:

E, Action taken					
☐ Drug Discontinued	☐ Dose reduced	☐ Done Increased	☐ Does not changed	☐ Unknown	☐ Not applicable

F, Outcome of ADR				
The patient: ☐ recovered; Date:	☐ Recovering	☐ No improvement	☐ Died	☐ Unknown
Event subsided after stopping the suspected drug (Dechallenge)		☐ No	☐ Yes	☐ Unknown
Event reappeared after reintroducing to the suspected drug (Rechallenge)		☐ No	☐ Yes	☐ Not applicable
Specific antagonist used		☐ No	☐ Yes, Specify:	

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G, Seriousness of ADR		
☐ Patient died; date:	☐ Life threatening	☐ Hospitalization
☐ Permanent disability	☐ Congenital anomaly	☐ Prolonged hospitalization more than 24 hr.
☐ Required Emergency Room (ER) visit	☐ Required intervention to prevent permanent impairment/damage	
☐ None of the above (Not serious)		
Comments if any:		

H, Reporter Details		
Reporter Name:	Profession/Specialty:	
Center:	Address:	
Phone/Mobile:	E-mail:	
Fax:	Date:	Signature:

Adverse Drug Reaction (ADR) is a response to a medicinal product which is noxious and unintended.
Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

Serious adverse reaction; is an adverse reaction which:

- results in death,
- is life-threatening,
- requires in-patient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability or incapacity or,
- is a congenital anomaly/birth defect.

This form can be used by:

- Physicians
- Pharmacists
- Dentists
- Nurses
- Other healthcare providers

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:

- Advanced Pharmaceutical industries
- 8125 Al Amir Sultan- Al Rawdah | Jeddah
- 23435-2086, KSA
- Phone: +966 12 682 7691
- Email: pv@adv-pharma.com

Thank You