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	☐ Dose increased	☐ Dose 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:	Adress:	
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.

How to report:

- Fill out the reporting form.
- Attach additional information, if needed.
- Use a separate form for each patient.

Please submit completed forms to:

- Tabuk Pharmaceuticals:

KSA	• Tel: +966 11 47 749 46 (Ext: 233) • Email: pv.info@tabukpharmaceuticals.com
Egypt	• Tel:+ (+20) 24037979, (+20) 1552938328 • Email: pv.egypt@tabukpharma.com
Other Countries	• Email: pv.info@tabukpharmaceuticals.com

Thank You