



MINISTRY OF HEALTH OF THE REPUBLIC OF ARMENIA
Scientific Centre of Drug and Medical Technology Expertise after academic E. Gabrielyan
REPORT #

OF ADVERSE REACTION OR MANUFACTURING PROBLEM OF MEDICINAL PRODUCT

A. INFORMATION ABOUT PATIENT						
1. Name, surname	2. Age or date of birth	3. Sex <input type="checkbox"/> M <input type="checkbox"/> F	4. Weight (KGs)	5. Height(cm)		
B. ADVERSE REACTION OR MANUFACTURING PROBLEM						
1. <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Manufacturing problem		2. Date of event (day/mo/yr)		3. Date of report (day/mo/yr)		
4. Description of adverse reaction or manufacturing problem						
5. Adverse reaction diagnosis methods used						
6. Short description and peculiarities of disease, laboratory data				<input type="checkbox"/> smoking <input type="checkbox"/> allergy <input type="checkbox"/> alcohol use <input type="checkbox"/> concomitant disease _____ _____ _____		
				<input type="checkbox"/> pregnancy <input type="checkbox"/> genetic factors <input type="checkbox"/> organ and system dysfunction <input type="checkbox"/> other		
7. Outcome of adverse reaction						
<input type="checkbox"/> Recovery without sequela <input type="checkbox"/> Recovery with sequela <input type="checkbox"/> Not recover yet <input type="checkbox"/> Death related to ADR		<input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or incapacity <input type="checkbox"/> Required intervention of medical personnel <input type="checkbox"/> Hospitalization- initial or prolonged		<input type="checkbox"/> Congenital anomaly/Birth defect <input type="checkbox"/> Outcome is unknown <input type="checkbox"/> Other		
C. SUSPECTED MEDICINAL PRODUCT(S)						
1. Name, manufacturer, batch number, expiry date	2. Dosage form	3. Dose		4. Route of administration	5. Indications for use	6. Therapy dates (duration) from / to
		single/daily				
D. ASSOCIATED TREATMENT (exclude those used to treat adverse reaction)						
1. Name, manufacturer, batch number, expiry date	2. Dosage form	3. Dose		4. Route of administration	5. Indications for use	6. Therapy dates (duration) from / to
		single/daily				
E. INFORMATION ABOUT REPORTER						
1. Name, address, phone		2. Profession <input type="checkbox"/> Doctor <input type="checkbox"/> Pharmacist <input type="checkbox"/> Other		3. Occupation		

F. ADDITIONAL INFORMATION

1. Whether the same medicinal product was administered before? If yes, what kind of adverse reactions were observed?

not administered before

same reactions

unknown

other -----

2. Whether event abated after use stopped?

yes

no

unknown

3. Whether event reappeared after reintroduction?

yes

no

unknown

there was no reintroduction

4. Whether event abated after dose reduced?

yes

no

unknown

there was no dose reduction

G. ANALYSIS OF REPORT

1. Relation between adverse reaction and suspected medicinal product

definite

probable

possible

doubtful

conditional

impossible to classify

2. Adverse reaction type

serious

expected

not serious

unexpected

3. Status of medicinal product

registered

not registered

humanitarian aid

clinical trial

Reports can be send to Scientific Center of Drug and Medical Technology Expertise department of monitoring of side and adverse effect of medicinal products by the following address:

0051, Yerevan, 49/4 Komitas av.

Tel: (+374 10) 23 16 82, 23 08 96 # 123

Fax: (+374 10) 23 21 18

Hot line: (+374 10) 20 05 05, (+374 96) 22 05 05

e-mail: vigilance@pharm.am

Online version of this report can be found at:

web: <http://www.pharm.am>

*You can help million of patients
by reporting about suspected
side and adverse effects of
medicinal products.*