

REPORTING AN ADVERSE REACTION TO A MEDICINAL

PRODUCT

PATIENT:	Initials	Date of birth/age	Sex:	F	М	Weight

DESCRIPTION OF ADVERSE SYMPTOMS:	date symptoms first appeared	<u>Classificatio</u> n
		Serious side effects
		□ – death
		– danger to life
		 permanent or significant disability or impairment
		 hospitalization or an extended period in hospital others that the doctor, based on his knowledge, considers severe
Pregnant - Yes □ No □	Outpatient treatment	Statistical code of cause of death
If so – week of pregnancy	Hospital treatment	
	19 · · · I · I · · · · · · ·	

Outcome after discontinuation of drug/medical device

A - recovery without after-effects

F – is undergoing treatment

B – recovery with after-effects

U – unknown

USE OF MEDICINES	Mark 'P' if the	Daily	Route of	Date you	Date you	Reason for
	medication is suspected of causing symptoms	Dosage	administrati on (e.g., oral)	started taking the medicine	stopped taking the medicine	taking the medication

ADDITIONAL INFORMATION: e.g. previous drug reactions, allergies, other diseases, results of additional tests

DETAILS OF REPORTING PERSON:

Name and surname	Specialty
Address	
Telephone: ()	Fax:
Date (day/month/year)	
Signature	

Adverse reaction - a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylexis, diagnosis or therapy of disease or for restoration, correction or modification of physiological function.