



ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ
В СФЕРЕ ЗДРАВООХРАНЕНИЯ

**NOTICE OF A SIDE EFFECT, ADVERSE REACTION
OR ABSENCE OF THE EXPECTED THERAPEUTIC
EFFECT OF
THE DRUG PRODUCT**

Primary

Additional information to the notice
No. _____ dated _____

Patient Information													
Patient full name (patient ID No.)*						Sex	M		F		Weight, kg		
Age		Pregnancy		gestational age		weeks							
Hypersensitivity reaction		No		Is allergic to									
Treatment				outpatient		in-patient		self-medication					
Drugs suspected of causing an adverse reaction													
	Drug invented name*	Manufacturer		Batch number	Dosage, route of administration	Therapy start date	Therapy end date		Indication				
1													
2													
3													
Adverse reaction								Adverse reaction onset date					
Description of the reaction* (provide all the details, including laboratory findings)								AE seriousness criteria:					
								Fatal					
								Life-threatening condition					
								Inpatient hospitalization or prolonged hospitalization					
								Disability					
								Congenital abnormalities					
								Medically important condition					
Adverse Event Resolution Date								Not applicable					
Actions Taken													
No treatment		Suspected Drug Withdrawal				Dose reduction							
Non-drug treatment (including surgery)													
Drug therapy													
Outcome													
Recovered or resolved				Recovering or resolving				Not recovered or not resolved					
Recovered/Resolved with Sequelae													
Fatal		Unknown				Not applicable							
Was the withdrawal of the drug associated with the recovery from AE?				No		Yes		No drug withdrawal				Not applicable	
Was the drug repeatedly prescribed?		No		Yes		Outcome				Not applicable			

Other drugs taken within the last 3 months, including the self-administered drugs (self-medication)

	Drug invented name	Manufacturer	Batch number	Dosage, route of administration	Therapy start date	Therapy end date	Indication
1							
2							
3							
4							
5							

The reporting person data

<input type="checkbox"/>	Physician	<input type="checkbox"/>	Other healthcare professional	<input type="checkbox"/>	Patient	<input type="checkbox"/>	Other
Phone number/e-mail:*							
Full name							
Position and place of employment							
Notice date							

*** mandatory field**

A notice can be sent:

- by e-mail: pharm@roszdravnadzor.ru,
- by fax: +7(495)698-15-73,
- on the website npr.roszdravnadzor.ru
- correspondence address: Slavyanskaya Ploshchad, 4, bldg. 1., Moscow, 109074