„LABORATORIUM GALENOWE OLSZTYN" Sp. z o. o.
ADVERSE DRUG REACTION REPORT FORM

24h tel +48 604 44 66 58; fax +48 22 841 16 71; email: lgo@sciencepharma.pl

For internal use only at Laboratorium Galenowe Olsztyn Sp. z o.o.	**No.**
Date of receipt by the entity in charge/Date of publication receipt by the entity in charge	
Report received by:	Recipient's signature _____

1) PATIENT INFORMATION

Please provide at least one answer about the patient.

Initials	Date of birth or age	Gender Female Male	Body weight (kg)	Height (cm)

2) CONTACT INFORMATION FOR THE PERSON SUBMITTING

Please state full name and telephone number or email address of the person submitting the form.

First name, last name	Address (street, city/town, country)*	
Telephone no. E-mail	Qualifications of the person submitting Doctor Other medical practitioner Pharmacist Non-Practitioner Patient Medical publication author	
Date of receipt of the notification	Signature of the person submitting**	Reported to drug-control authorities? Yes No Unknown
*Medical practitioners should provide their practice address. ** Signature required only when the form is submitted on paper		

3) INFORMATION ABOUT ADVERSE EFFECTS OF THE MEDICATION

General description:					
Adverse effects/Diagnosis: *If there is no medical diagnosis available, please list all symptoms.*	**What is the connection between adverse effects and medical product use***	**Date of adverse effects observed**	**Date of adverse effects ending or how long the adverse effects lasted**	**Results****	**Is the adverse effect serious*** (Yes/No)?** *If 'Yes', please explain****

4)

Please choose the most appropriate answer:

***Connection:** **1 –** Very likely; **2** – Likely; **3** – Possible; **4** – Unlikely, **5** – No connection; **6** – Unknown

****Result:** **1** – Return to health; **2** – Return to health, but with lasting consequences; **3** – During treatment; **4** – Did not regain health; **5** – Death; **6** – Unknown

*****Seriousness:** **1** – Death ; **2** – Life-threatening; **3** – Hospitalisation; **4** – Lasting or serious disability; **5** – Birth defect/Foetal damage; **6** – Other serious medical event

4) INFORMATION ABOUT MEDICATION(S) SUSPECTED TO HAVE CAUSED ADVERSE EFFECTS

Name of medication and/or active substance	**Indication(s)**	**Serial no.**	**Expiry date**	**Dosage, route of administration, pharmaceutical form**	**Start date of administration**	**End date of administration**	**Any actions taken***
*** Please choose the appropriate number: 1** - Reduced dosage; **2** - Increased dosage; **3** – Medication withdrawn ; **4** – Medication administered again; **5** - No action taken; **6** - Unknown							

5)

Providing relevant information in Tables 5-7 can facilitate the analysis of reported adverse effects. For this reason, we encourage you to provide as much information as possible below.

5) IMPORTANT INFORMATION

Adverse effects *Please list the symptoms*	Did adverse effects remit after the medication was withdrawn or the dosage was reduced?			
	Yes	No	Unknown	Not applicable
	Yes	No	Unknown	Not applicable
Adverse effects *Please list the symptoms*	Did adverse effects occur again after the medication was administered for the second time?			
	Yes	No	Unknown	Not applicable
	Yes	No	Unknown	Not applicable
In case of death, please list the reason and date of death:				
Was the postmortem examination performed?	Yes (If 'Yes', please attach the results/report)		No	

6)

6) OTHER MEDICATION USED (drugs interacting with the suspected medication should be listed in Table 4)

Name of medication and/or the active substance	Indication(s)	Dosage, route of administration, pharmaceutical form	Therapy type[#]	Start date of administration	End date of administration
[#]C – medication administered at the same time; T – medication administered to combat adverse effects; P – medication withdrawn before adverse effects were observed					

7)

7) MEDICAL HISTORY: PAST AND CURRENT ILLNESSES

Cigarettes	Alcohol	Allergies (To what?)

8)

Laboratorium Galenowe Olsztyn z o.o. (ul. Spółdzielcza 25A, 11-001 Dywity) will process any data provided in the notification form as your data administrator. Your personal information will be processed with accordance to regulations as per Article 6 (1) (c) and Article 9 (2), and Regulation (EU) 2016/679 of 27th April 2016. Any data provided in this form will be processed only to fulfil the obligations for monitoring of health and safety of use of medical products with accordance to regulations as per Regulation (EU) 520/2012 of 19th June 2012. It is necessary to provide the submitting person's information in order for the report form to be accepted. Your data will be accessed only by the entities authorised to do so by the law. You have the right to access your personal data and to update it. Your personal information shall be retained as long as the product is authorised and for 10 years after the marketing authorisation has ceased to exist. If you decide the processing of your personal data is violating the GDPR law, you have the right to complain to the Data Protection Supervisor authority.