Polfa Warszawa S.A.	MEDICINE SIDE EFFECT REPORTING FORM FOR CONSUMER	2nd EDITION 22/07/2020

REPORT: ☐ INITIAL ☐ FOLLOW-UP

REPORT COMPLETION DD/MM/YYYY	

I. PATIENT DETAILS

WHO EXPERIENCED THE SUSPECTED SIDE EFFECT(S)?

☐ YOU ☐ YOUR CHILD ☐ SOMEONE ELSE.....

PATIENT INITIALS	COUNTRY OF OCCURRENCE OF THE SIDE EFFECT	DATE OF BIRTH OF THE PATIENT DD/MM/YYYY	PATIENT AGE at the time of the side effect	PATIENT GENDER	PATIENT WEIGHT	PATIENT HEIGHT
				☐ FEMALE Is the patient pregnant? ☐ YES ☐ NO ☐ UNKNOWN ☐ MALE		

II. SUSPECTED MEDICINE*

Please provide us with the details about the product that has caused your side effect(s)

NAME OF THE MEDICINE (with dosage)	BATCH NUMBER/ EXPIRATION DATE	DOSAGE (total per day)	SINGLE DOSE	ROUTE OF ADMINISTRATION (e.g. oral, sublingual, intravenous)	WHAT DATE DID YOU START TAKING THE MEDICINE? DD/MM/YYYY	WHAT DATE DID YOU STOP TAKING THE MEDICINE? DD/MM/YYYY	REASON FOR TAKING	WAS THE MEDICINE STOPPED DUE TO SIDE EFFECT(S)?
								☐ YES ☐ NO
								☐ YES ☐ NO
								☐ YES ☐ NO
								☐ YES ☐ NO
								☐ YES ☐ NO
								☐ YES ☐ NO

*A side effect is an unintended and unwanted reaction of a medicine.

ANY OTHER MEDICINES BEING TAKEN AND ADDITIONAL DETAILS

Are any other medicines being taken (including herbal medicines), which you do not suspect of causing the side effect(s)?

☐ YES* ☐ NO

***If YES, please list them in the table below**

NAME OF THE MEDICINE	SINGLE DOSE	DOSAGE (total per day)	ROUTE OF ADMINISTRATION	WHAT DATE DID YOU START TAKING THE MEDICINE? DD/MM/YYYY	WHAT DATE DID YOU STOP TAKING THE MEDICINE? DD/MM/YYYY	REASON FOR TAKING

ADDITIONAL DETAILS

Other information you think might be important, including any other medical condition, any allergies, results of any test performed, pregnancy with the last menstrual period date etc.

III. SIDE EFFECT (S)

SIDE EFFECT EXPERIENCED	START DATE DD/MM/YYYY	END DATE DD/MM/YYYY	TYPE OF REACTION	
			☐ SERIOUS (check the appropriate field/fields)	☐ caused death Cause of death:..... ☐ hospitalization (more than 2 days) or prolonged hospitalization ☐ incapacity or disability ☐ life threatening ☐ congenital anomaly/birth defect ☐ other medically important condition
			☐ NON-SERIOUS (Please select an outcome for side effect)	

DESCRIPTION OF THE SIDE EFFECT (S)

PLEASE SELECT AN OUTCOME FOR SIDE EFFECT
☐ RECOVERED ☐ RECOVERED WITH ABNORMALITY ☐ RECOVERING (DURING TREATMENT) ☐ NOT RECOVERED ☐ CAUSED DEATH ☐ UNKNOWN
WAS ANY TREATMENT RECEIVED FOR SIDE EFFECT? ☐ YES* ☐ NO *What medicines were uses?

WAS THE REACTION ABATED AFTER DISCONTINUED USE OF MEDICINE/REDUCED DOSE?	☐ YES ☐ NO ☐ UNKNOWN
DID THE REACTION REOCCUR AFTER REUSE OF THE MEDICINE?	☐ YES ☐ NO ☐ UNKNOWN

IV. REPORTER DETAILS

First name and surname	**Email address**
Mailing address	**Telephone number**
Do you agree to further contact us in order to supplement the information you have provided?	☐ YES* ☐ NO * Preferred way of contact: ☐ Email address _____ ☐ Telephone number _____

If you feel it is necessary, please contact your physician to fill in the form or confirm the information contained there in and send it to the address below:

Dział Nadzoru nad Bezpieczeństwem Farmakoterapii POLPHARMA Biuro Handlowe Sp. z o.o.
Bobrowiecka 6, 00-728 Warszawa, e-mail: phv@polpharma.com fax: +48 22 364 61 66

PERSONAL DATA CONTROLLER – GENERAL INFORMATION

On the basis of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, hereinafter referred to as: "**GDPR**"), we hereby inform that:

[Controller, data protection officer, contact details]

1. The Controller of your personal data is the Marketing Authorization Holder of the medicinal product which is the subject of the notification, i.e.:
   a. Warszawskie Zakłady Farmaceutyczne Polfa S.A. with its registered office in Warsaw, ul. Karolkowa 22/24, OR
   b. Zakłady Farmaceutyczne Polpharma S.A. with its registered office in Starogard Gdański at ul. Pelplińska 19, OR
   c. Medana Pharma S.A. with its registered office in Sieradz, ul. Władysława Łokietka 10, OR
   d. Herbapol Lublin with its registered office in Lublin, ul. Diamentowej 25, OR
   e. Herbapol Warszawa with its registered office in Pruszków, ul. Ołówkowa 54.

(hereinafter each separately referred to as the "Controller").

2. You can contact the Controller in writing to the above addresses. The Controller has appointed a Data Protection Officer, whom you may contact in all matters relating to the personal data protection, by writing to: Bobrowiecka 6, 00-728 Warszawa, by sending an e-mail to: dpo@polpharma.com or by telephone on: 22 364 63 11.
3. Where an adverse reaction has occurred following the use of a medicinal product, the adverse reaction may be reported to the Pharmacovigilance Risk Assessment Unit, ul. Bobrowiecka 6, 00 -728 Warszawa, tel: 22 364 61 00, email: phv@polpharma.com

[Purpose and legal basis for personal data processing]

4. Your personal data will be processed:
   a. for the purpose necessary for ensuring high standards of quality and safety of medicinal products by Controller and, in particular, monitoring the safety of medicinal products, including the keeping of records of individual adverse reactions to medicinal products and the reporting of individual adverse reactions to medicinal products to the competent authorities– on the basis of:
      - data concerning health will be processed pursuant to Article 9(2)(i) of the GDPR, i.e. processing is necessary for reasons related to the public interest in the field of public health in the form of ensuring high standards of quality and safety of medicinal products pursuant to the provisions of law, i.e. pursuant to Article 36e(1) of the Polish Pharmaceutical Law Act;
      - other personal data will be processed pursuant to Article 6(1)(c) of the GDPR, i.e. processing is necessary to fulfil the legal obligation imposed on the Controller pursuant to Article 36e(1) of the Pharmaceutical Law Act;

   b. contacting the attending physician and obtaining additional information from the attending physician in connection with adverse reactions to the medicinal product - pursuant to Article 6(1)(c) of the GDPR, i.e. processing is necessary to fulfil the legal obligation imposed on the Controller pursuant to Article 36e(1) of the Pharmaceutical Law Act;
   c. determination, investigation or defence of possible claims between you and the Administrator with regard to health data pursuant to Article 9(2)(b) of the GDPR, i.e. processing is necessary for the determination, investigation or defence of claims; in the case of other personal pursuant to Article 6(1)(f) of the GDPR, i.e. on the basis of the legitimate interest pursued by the Administrator, which is the possibility to pursue claims.
5. You will not be subject to automated decision-making, including decisions based on profiling.
6. Provision of Your personal data is voluntary.

[Categories of personal data recipients]

7. Your personal data may be disclosed to the following entities: attending physician (if consent is granted to contact with the attending physician), employees, IT service providers, providers of consulting and legal services.
8. Your personal data will be processed by Polpharma Biuro Handlowe Sp. z o.o. with its registered office in Warsaw (00-728) ul. Bobrowiecka 6, entered into the Register of Entrepreneurs of the National Court Register under number 0000043523, by the District Court for the capital city of Warsaw, XIII Commercial Division of the National Court Register, Tax Identification Number 5252113462, REGON 014824664, share capital: PLN 6,187,000 under the entrustment agreement.
9. Your personal data may be made available to entities and bodies authorized to process such data under the law, in particular to the President of the Office of Medicinal Products, Medical Devices and Biocidal Products, the European Medicines Agency and other competent authorities of the Member States of the European Union, in which the Controller has obtained a marketing authorisation for a medicinal product.
10. The Controller does not intend to transfer your personal data outside the European Economic Area or to an international organisation.

[Personal data storage period]

11. Your personal data shall be processed for the period necessary to achieve the purposes for which the data are processed or until an objection is raised (if the processing is based on the legitimate interest of the Controller) or until the withdrawal of consent (if the processing is based on the given consent) - depending on which of the events occurs earlier.
12. After the expiry of the aforementioned period, personal data shall be stored for 10 years from the expiry date of the medicinal product series to which the application referred or until the claims expiry or until you have objected to the processing (if the processing is based on legitimate interest of the Controller) or have withdrawn your consent (if the processing is based on consent) – whichever occurs first

[Rights]

13. You have the right to:
    a. access to data concerning you, the right of rectification, erasure, restriction of processing, the right to object to the processing of data;
    b. transfer personal data, i.e. to receive from the controller personal data in a structured, commonly used machine-readable format;
    c. to the extent that the processing of your personal data is based on consent, the right to withdraw consent to the processing of your personal data at any time. The withdrawal of consent shall not affect the lawfulness of the processing carried out on the basis of consent prior to its withdrawal.
14. In order to exercise the above rights, you need to contact the Controller or the Data Protection Officer, using the aforementioned contact details (contact details provided above).
15. You also have the right to lodge a complaint with a personal data protection supervisory authority (President of the Personal Data Protection Office), if you believe that the data processing violates the GDPR.