Aflofarm	SUSPECT ADVERSE DRUG REACTION REPORT	Phone +48 42 / 22 53 100 e-mail: PV@aflofarm.pl

☐ Initial report ☐ Follow-up report

Name of person who received report _____ **Signature** _____

Receipt date _____

(To be completed by MAH below)

Number of report _____

Date received by MAH _____

Name of person who received report _____

Signature _____

1. PATIENT DETAILS.

Initials:	Date of birth / age:	Sex: ☐ Famale ☐ Male	Body mass (kg): _____	Race: ☐ White ☐ Other ☐ Black ☐ Asian

2. REPORTER DETAILS.

Name and surname:	Address:	
Phone number: E-mail:	Report source: ☐ Physician ☐ Other medically qualified person ☐ Pharmacist ☐ Patient ☐ Literature	
Date and signature of reporter:	Stemp of reporter:	Reported to the component authorities: ☐ Yes ☐ No ☐ No information

3. REACTION INFORMATION.

Diagnosis or symptoms if there is no diagnosis:	Reaction onset:	End date or duration:	Results: ☐ Recovery ☐ Recovery with significant disability ☐ During treatment ☐ Patient died ☐ No recovery ☐ No information	
Description of reaction(s):	Severity of adverse drug reaction: ☐ Mild ☐ Medium ☐ Severe ☐ No information		Did reaction abate after stopping or decreasing drug's dose: ☐ Yes ☐ No ☐ No information	Did reaction reappear after reintroduction: ☐ Yes ☐ No ☐ No information

4. REACTION INFORMATION.

Is it serious adverse drug reaction: ☐ Yes ☐ No	If yes, mark the result: ☐ Death ☐ Life-threatening ☐ Hospitalisation or its prolongation ☐ Persistent or significant disability or incapacity ☐ Congenital anomaly / birth defect ☐ Medically important event or reaction	Cause of death:
		Were autopsy: ☐ Yes ☐ No ☐ No information
Casuality: ☐ Very likely ☐ Likely ☐ Possible ☐ Unlikely ☐ No casuality ☐ No information		

5. SUSPECT DRUG(S) INFORMATION.

Name of drug or active substance:	Indication:	Batch numer:	Expiry date:
Posology:	Start date:	End date:	Other information:

6. OTHER MEDICINAL PRODUCTS.

Name of drug or active substance:	Indications:	Therapy type*:	Posology, form, route of administration:	Other information:

*C – concomitant drug, T– drug used to treat adverse reaction, P– drug stopped before experiencing the adverse reaction.

7. MEDICAL HISTORY.

☐ Smoking ☐ Alcohol ☐ Allergy ☐ Others:

In accordance with the provisions of the Regulation (UE) no. 2016/679 of the European Parliament and of the Council (UE) 2016/679 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: GDPR) we inform you that the Controller of the personal data provided by you in the above form is Aflofarm Farmacja Polska Sp. z o.o. with its registered office in Pabianice at 133/151 Partyzancka Street, 95-200 Pabianice, phone: +48 42 22 53 100, email: aflofarm@aflofarm.pl (Aflofarm). Aflofarm has appointed a Data Protection Officer, who can be contacted by mail to the Aflofarm address and by email to: daneosobowe@aflofarm.pl.

The personal data provided will be processed by Aflofarm exclusively for the purpose of:

a) monitoring of the safety of medicinal products, including keeping a register of reports and the reporting of individual adverse reactions to competent authorities in the scope of:
   - health data that will be processed on the basis of **Article 9(2)(i) of GDPR**, i.e. in situations where processing is necessary for reasons related to public interest in the field of public health in terms of ensuring high standards of quality and safety of health care,
   - other personal data that will be processed on the basis of **Article 6(1)(c) of GDPR**, i.e. in situations where processing is necessary to fulfill the legal obligation incumbent on the Controller under the provisions of the Act of 6 September 2001 on Pharmaceutical Law;

b) establishing, investigating or defending any claims between you and the Administrator regarding health data pursuant to art. 9 point 2 letter f) GDPR and in the case of other data pursuant to art. 6 point 1 letter f) GDPR, i.e. based on a legitimate interest pursued by the Administrator, which is the possibility of pursuing or defending claims.

The recipients of the personal data provided will be Aflofarm employees and associates, entities acting in the name and on behalf of Aflofarm, including entities providing support and maintenance of information systems, as well as domestic and foreign entities and bodies authorized to process such data on the basis of legal regulations, in particular the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, the European Medicines Agency and other authorities of the European Union Member States, in which the Controller obtained the marketing authorisation for a medicinal product.

Your personal data will be processed for a period no longer than it is required by the provisions on the supervision of the safety of medicinal products or the provisions on the limitation period of claims.

Your personal data will be kept for the period necessary in the light of the applicable provisions of pharmaceutical law, including the period of archiving documents, i.e. for the entire period of the product's marketing authorisation and for 10 years after the expiry of the marketing authorisation for this product, in accordance with Article 12 of the Commission Implementing Regulation (EU) no. 520/2012 of 19 June 2012 on pharmacovigilance activities referred to in Regulation (EC) no. 726/2004 of the European Parliament and of the Council and in Directive 2001/83/EC of the European Parliament and of the Council.

Providing personal data is voluntary, however, it is necessary for the lawful reporting of an adverse reaction (legal basis: Article 36e(1) of the Act of 6 September 2001 on Pharmaceutical Law), with the exception of persons performing medical profession, in respect of which the relevant provisions of law regulating the rules of the profession provide for the obligation to report adverse reactions to medicinal products.

At any time you shall have the right to access the data content, the right to rectify it, the right to delete data, the right to limit processing, the right to raise objections and the right to transfer data. Statements regarding the exercise of rights should be submitted to the e-mail address of the Data Protection Inspector appointed by the Administrator: daneosobowe@aflofarm.pl. If, despite our support, you believe that personal data are processed in breach of applicable law, you have the right to lodge a complaint with the supervisory authority (i.e. the President of the Personal Data Protection Office).The personal data provided will not be subject to any profiling or automated decision-making processes, nor will it be transferred to third countries.