Aflofarm	**FORM REGARDING EXPOSURE TO MEDICINAL PRODUCT DURING PREGNANCY**	Phone 48 42 / 22 53 100 e-mail: PV@aflofarm.pl

In case of suspicion of an adverse reaction, please fill-out an additional suspect adverse drug reaction 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. _MEDICINES USED DURING PREGNANCY.

Name of the medicine or active substance:	Therapeutic indication:	Administration route:	Batch no. and expiry date:
Posology:	Therapy start date:	Therapy end date:	Other information:

2. INFORMATION ON THE REPORTING PERSON.

Full name:	Address:	
Phone no.: E-mail:	Classification of the reporting person: ☐ Physician ☐ Another medical practitioner ☐ Pharmacist ☐ Patient ☐ Publication author	
Date and signature of the reporting person:	Stamp of the reporting person:	Report to relevant authorities: ☐ Yes ☐ No ☐ No information

3. INFORMATION ON THE MOTHER.

Initials:	Birth date / age:	Body weight (kg):	Race: ☐ White ☐ Other ☐ Black ☐ Asian	
Is the pregnancy going on?: ☐ Yes ☐ No	Duration in weeks: Pregnancy end date:			
Expected date of childbirth:			Due date:	
Diagnosis:	☐ USG		☐ Pregnancy test	☐ Gynaecological examination
Medical history (mother's state of health, allergies, alcohol, cigarettes, drugs, other):			Were there complications during pregnancy?: ☐ No ☐ Yes Which?.....	

4. INFORMATION ON LABOR.

☐ Natural delivery ☐ C-section ☐ Forceps delivery ☐ Miscarriage ☐ Not provided
☐ Termination
Reason for termination:……
☐ Stillbirth
☐ Delivery at term – gestational age (in weeks):
☐ Delivery before term – gestational age (in weeks):
☐ No information

Additional information:

5. INFORMATION ON THE CHILD.

☐ Healthy child ☐ Stillbirth	☐ Newborn complications ☐ Multiple pregnancy	☐ Congenital / perinatal trauma	☐ Death of a child after birth
Delivery date:	Body weight: Length:	Sex: ☐ Female ☐ Male	Other information:
Apgar score:			
Additional information about the child's health:			

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;

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 12a 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 all times you also have the right to access the content of the personal data, the right to correct such data, the right to limit the processing. Declarations regarding the exercise of these rights should be submitted to the email address of the Data Protection Officer appointed by the Controller: daneosobowe@aflofarm.pl. If, despite our support, you consider that personal data are processed in violation of the provisions of applicable law, you have the right to lodge a complaint to the supervisory authority (i.e. the President of the Office for Personal Data Protection).

The personal data provided will not be subject to any profiling or automated decision-making processes, nor will it be transferred to third countries.