ADVERSE DRUG REACTION REPORT

Confidential

Drug side effect is a noxious and unintended responses to a medicinal product related to any dose or route of administration.

To be valid, the report has to include at least:

1. Patient details
2. Suspected adverse drug reaction description
3. Suspected medicinal product/active substance details
4. Reported details

Additional data will help to assess the causal relationship between the drug administration and adverse reaction occurrence.

1. Please provide your personal data

Name: .....

Phone number: .....

E-mail: .....

2. Data of the patient who experienced adverse reaction

Initials	Birth date	Age		F	M
			Sex	☐	☐

Was the patient pregnant or breast-feeding while taking the drug?

Pregnancy: ☐ no ☐ yes, week: .....

Breast-feeding: ☐ no ☐ yes

3. Please describe the adverse reactions

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Tax ID No. 778-00-21-575, Share Capital: PLN 6,000,000.00

4. Please write the date of occurrence of adverse reactions: .....

5. Please list the drugs suspected for causing the adverse reaction

Name	Dose	Indication	Treatment duration (from... to...)	Action taken
				☐ drug withdrawal ☐ dose reduction ☐ treatment continuation
				☐ drug withdrawal ☐ dose reduction ☐ treatment continuation
				☐ drug withdrawal ☐ dose reduction ☐ treatment continuation

6. Did the adverse reaction abate after stopping the drug/dose reduction?

☐ yes ☐ no ☐ unknown

7. Did reaction reappear after reintroducing drug?

☐ yes ☐ no ☐ unknown

8. Did the patient take this drug previously?

☐ yes ☐ no ☐ unknown

If "yes", did the same reaction appear?.....

9. Did the same reaction appear after another drug intake?

☐ yes ☐ no ☐ unknown

If "yes", please specify.....

10. Did patient develop the same reaction regardless of drug use?

☐ yes ☐ no ☐ unknown

11. Was symptomatic treatment of the adverse reaction? If „yes", please specify

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12. Please specify other concomitant medications and dates of administration (from/to)

13. Other relevant information (diseases, medical procedures, drugs, allergies, earlier symptoms, laboratory test results, diagnostic test results, past medical history, etc.)

We hereby kindly inform you that the administrator of the personal data provided by you in the report is Biofarm Sp. z o.o. with the registered office in Poznań, ul. Wałbrzyska 13, 60 - 198 Poznań, Tax ID No. 7780021575, REGON No. 008029300, National Court Register No. KRS 0000120050 (hereinafter Biofarm).

We process your personal data solely for the purpose of pharmacovigilance of Biofarm's medicinal products. The legal basis for processing your personal data is Art. 6 Sec. 1 c) 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 - GDPR), i.e. providing the reported information on adverse drug reactions to the appropriate authorities, constituting the legal obligation of the administrator. Your personal data will be processed solely for the purposes related to the fulfilment of pharmacovigilance obligations. For this purpose, they may be provided to the competent national authorities or to the EU Eudravigilance database. In such a case, the recipient of your personal data is obliged to protect the received data in accordance with the applicable law. Your personal data will be processed for a period not longer than specified in the pharmacovigilance regulations. Providing your personal data is voluntary, but necessary for processing the above-mentioned report, with the exception of healthcare professionals, who are obliged to report adverse drug reaction by the applicable legal regulations governing their profession. Due to legal requirements, Biofarm, as the administrator, may not be able to remove the information collected in connection with the adverse drug reactions report, unless it is untrue. However, you have the right to request access to your personal data, rectification or limitation of theirs processing and the right to object to the processing, as well as the right to transfer them. Requests within the above-mentioned scope should be sent in writing by traditional mail to the address of Biofarm provided above or electronically to the following e-mail address: bezpieczenstwo@biofarm.pl

Moreover, you have the right to lodge a complaint with the competent supervisory authority for the protection of personal data.

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