

ADVERSE EVENT REPORTING FORM

PATIENT INFORMATION:

| | | | | | | | | |
|----------|---------------|-------|------|-----|--------------------------|--------------------------|--------|--------|
| Initials | Date of Birth | | | Age | Sex: F | M | Weight | Height |
| | Day | Month | Year | | <input type="checkbox"/> | <input type="checkbox"/> | | |
| | | | | | | | | |

ADVERSE EVENT INFORMATION:

| | |
|--|---|
| Date of onset of symptoms: | Classification (for medical professionals) |
| Description of symptoms: | |
| Outcome: | |
| Were you pregnant while taking the medication? | |

Was the adverse event serious?

YES

NO

Check all points corresponding to the reaction:

death

life-threatening event

permanent or significant disability or impairment

hospital stay or prolonged hospital stay

other

recovery without lasting effects

recovery with lasting effects

undergoing treatment of symptoms

other:

No

Yes; if yes, indicate the week of pregnancy:
.....

Information about the medication suspected of causing an adverse reaction

| Medication Name | Mark 'P' if the medication is suspected to have caused the symptoms | Dosage <i>(e.g., 20 mg twice daily)</i> | Route of administration <i>(e.g., oral)</i> | Start date of taking the medication | End date of taking the medication | Reason for taking the medication <i>(e.g., hypertension)</i> |
|-----------------|---|--|--|-------------------------------------|-----------------------------------|---|
| | | | | | | |

ADDITIONAL INFORMATION: e.g., previous reactions to the medication, allergies, other diseases, results of additional tests

INFORMATION ABOUT OTHER MEDICATIONS BEING TAKEN

REPORTING PERSON'S INFORMATION:

Name:

Phone*:

Address:

E-mail:

Date and signature

REPORTING PERSON'S INFORMATION (for medical professionals):

| | |
|---------------------------|--------------------|
| Name: | Specialisation: |
| Address of the workplace: | |
| Phone*: | Fax: |
| E-mail: | Date and signature |

*providing this information is voluntary

Personal Data Processing Information

The controller of your personal data is Polfarmex S.A., based in Kutno, ul. Józefów 9, 99-300 Kutno, hereinafter referred to as: Polfarmex S.A.

Why and on what basis will Polfarmex S.A. process personal data?

Your personal data will be processed to receive and register a report of an adverse drug reaction and to forward this information to the relevant authority. The legal basis for processing your personal data for the aforementioned purposes is Article 6(1)(c) of the GDPR, i.e., processing is necessary to comply with a legal obligation, and Article 9(2)(i) of the GDPR, i.e., processing is necessary for reasons of public interest in the field of public health to ensure high standards of quality and safety of medicinal products. The legal obligation arises from Articles 36d, 36e, and 36g of the Pharmaceutical Law Act of 6 September 2001. Providing the data is necessary to fulfil the legal obligations imposed on the controller; without the required data, it is not possible to receive and register the report. For communication with the reporter, the data is processed based on the controller's legitimate interest under Article 6(1)(f) of the GDPR. If additional contact details are provided, the data is processed based on the reporter's voluntary consent by voluntarily providing the data under Article 6(1)(a) of the GDPR.

Polfarmex S.A. will share your personal data with other entities entrusted with processing personal data on behalf and for the benefit of Polfarmex S.A. Moreover, Polfarmex S.A. will, in fulfilling the aforementioned legal obligation, share your personal data with the European Medicines Agency. Polfarmex S.A. will only share personal data with other recipients when required by law.

Your data will not be transferred to third countries.

How long will Polfarmex S.A. process the data?

Your personal data will be processed for the duration of the marketing authorisation for the medicinal product and for 10 years after its expiration.

What rights do you have regarding your data?

You have the right to:

- Access your personal data and receive a copy of the personal data being processed;

- Correct any incorrect data;
- Request the deletion of data (the right to be forgotten) in cases provided for in Article 17 of the GDPR;
- Request the restriction of data processing in cases specified in Article 18 of the GDPR;
- Object to the processing of data in cases specified in Article 21 of the GDPR;
- Transfer the provided data processed in an automated manner.

If you believe that your personal data is being processed unlawfully, you may file a complaint with the supervisory authority (PUODO, ul. Stawki 2, Warsaw).

Contact

If you need additional information regarding the protection of personal data or wish to exercise your rights, please contact:

Data Protection Officer:

Jakub Treugut, e-mail: iod@polfarmex.pl

Polfarmex S.A. with its registered office in Kutno, ul. Józefów 9, 99-300 Kutno