Report an adverse event

Pharmaceutical products need to be as safe as possible and fully compliant with regulatory guidelines. Therefore, in the development of pharmaceutical products, the evaluation of safety and efficacy of these products is mandatory. Several studies need to be performed. These studies are highly regulated and thoroughly monitored, reviewed and evaluated both by Pharming and the Health Authorities.

All pharmaceutical products, e.g. Ruconest, can cause side effects. However, not all side effects (adverse events) associated with the use of pharmaceutical products can be detected during clinical development, not even by the most comprehensive clinical trials. Capturing as many of these adverse events, however rare they may be, from worldwide sources is of paramount importance for continued patient safety.

For Pharming as a global pharmaceutical company, ensuring patient safety is our number one goal, beyond mere compliance with worldwide regulations. By reporting adverse events for Pharming medicinal products you help us to ensure the safety of our products. Your information will also enable Pharming to fulfill its reporting requirements to Health Authorities, which requires that Pharming provides information on adverse events with our products.

In case you experience or suspect any adverse event following the administration of our product(s), please contact Pharming via:

UK, EU and Rest of World territories:
Phone (24/7 availability): +31 (0)71 5247 110
e-mail: safety@pharming.com
Fax: +31 (0)85 0643 382

US and US territories:
Phone (Monday to Friday 6.00 a.m. to 4.00 pm): +1 (800) 930-5221
e-mail: safetyUS@pharming.com
Fax: +1 201-389-8092

You can also report (suspected) adverse events to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch

General information

At Pharming Group N.V. (“we” ”us” ”Pharming”)we are committed to protecting your personal data. We take data privacy seriously and treat all your personal data in accordance with the Pharming Privacy Notice, the General Data Protection Regulation and all other applicable laws that regulate the collection, storage, processing, access and transfer of personal data.

What does this Notice Cover?

This Pharmacovigilance Privacy Notice explains how Pharming collects and processes your personal data for the purposes of pharmacovigilance related activities. The scope of this Notice is limited to the collection and processing of your personal data for pharmacovigilance and or medical information inquiries. For general information about data processing at Pharming, please visit, *Pharming Website Privacy Notice.*

Please read this Privacy Policy carefully and contact us if you have any questions.

What is Pharmacovigilance?

Pharmacovigilance means the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions and other medicine related problems. For Pharming to comply with applicable Pharmacovigilance regulations and legislation, we must maintain pharmacovigilance systems, including a safety database. The data relating to adverse reactions is used by Pharming to monitor the safety of our products and detect any change in the risk benefit analysis.

What information do we collect?

Patients: We collect personal data about you when you, or a third party, provides information to Pharming an adverse event that has affected you. If you are reporting the adverse event yourself, please also refer to the Reporters section below:

The Personal data that we may collect about you when you are the subject of an adverse event is:

- Name or initials;
- Address (Country only);
- Age and date of birth;
- Gender;
- Weight and height;
- Details of the products causing the reaction, including the dosage you have been taking or were prescribed;
- Details of other medicines or remedies you are taking or were taking at the time of the reaction, including the dosage you have been taking or were prescribed, the batch number the period of time you were taking that medicine;
- Details of the adverse event you suffered, the treatment you received for that event, and any long-term effects the event has caused to your health;
- Other medical history considered relevant by the reporter, including clinical study information, lab reports, medication history and patient history.

Some of this information may be considered "sensitive personal data" under the General Data Protection Regulation because it pertains to your health or other sensitive data about you (i.e. ethnicity).

This information is only processed where relevant and necessary to document your adverse event properly and for the purposes of meeting our pharmacovigilance requirements.

Reporting individuals: Pharming must ensure that reports of adverse events are traceable and available for follow up. If you are the reporter of the adverse reaction, we may collect the following information about you:

- Name;
- Contact details (address, email, phone number);
- Profession (this may determine the questions you are asked about the adverse event); and
- Relationship with the subject of the report.

Why do we collect this information?

Any personal information provided to Pharming related to adverse events or other activities related to pharmacovigilance will be used solely for these purposes. This information is important for public health and will be used for the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem.

Legal basis for processing

The legal basis for processing personal data is compliance with Pharming's legal obligations under the General Data Protection Regulation.

Keeping your personal data safe

Pharming has security measures in place to prevent your personal data from being improperly accessed, lost, used, modified or disclosed in an unauthorized manner. Pharming's service providers and employees have restricted access to your personal data. They will only use your personal data in accordance with our instructions and must keep your person information confidential. If Pharming suspects there is a security breach, we will notify you and the appropriate organizations in accordance with our legal requirements.

How we share your Personal Data

We share your information with Pharming affiliates, third parties, and service providers who may assist Pharming in pharmacovigilance processes such as receipt and follow up of reported adverse events, regulatory reporting and signal evaluation.

All companies dealing with your personal information agree to process your personal data in accordance with this Privacy Policy. **We are also obligated to submit the data to the applicable authorities for managing and analyzing information on suspected adverse reactions.**

Personal data may also be disclosed to a third party such as a health authority if we are required to do so because of an applicable law, court order or governmental regulation. Pharming will not disclose the collected data for commercial purposes.

Transfers of your Personal Data outside the EEA

Your personal data may be transferred to companies in countries that operate and are located outside of the EU/EEA (Europe). When transferring personal data to countries outside of Europe,

Pharming uses standard contractual clauses approved by the European Commission to ensure a sufficient level of protection for your personal data.

Your rights

You have the right to view the personal information that we hold about you. You may contact Pharming to inquire whether our register contains your personal data. Subject to legal exceptions.

After you have supplied enough search criteria, Pharming will search for your data in our register. If data that can be identified as your personal data is found, you will be given a copy of it or you will be given a notice that the register contains no data which can be identified as your personal data.

You may also request Pharming to complete or correct any inaccurate personal data held about you, or to correct or delete any data that is erroneous, unnecessary or incomplete or request a restriction to the processing of your personal data. You make such a request by contacting us at gdprcompliance@pharming.com or via the contact information provided below.

Retention of Personal Data

Pharming is required to store all information including the personal data regarding safety of medical products for at least ten years after the end of the expiration of the marketing authorization or