Pharmacovigilance Privacy Notice

This Pharmacovigilance Privacy Notice describes how we collect and use Personal Data to fulfil our duty to monitor the safety of all FERRING medicines, also known as our pharmacovigilance obligations. This Pharmacovigilance Privacy Notice also describes how we fulfil our commitment to applicable national and European privacy data protection law.

Why do we collect information on you?

For the purpose of safety (pharmacovigilance) reporting, FERRING is legally obliged to collect specific Personal Data in relation to individuals who use our products.

When you, your doctor or a third party provide FERRING with information on an adverse event experienced with the use of our products, we collect and process Personal Data where relevant and necessary to document the adverse event properly and to meet our pharmacovigilance obligations. These obligations exist to allow FERRING and regulatory authorities to manage adverse events and make efforts to prevent similar events from happening in the future.

What information do we collect about you?

The Personal Data that we may collect about you when you are the subject of an adverse event:
- Name and/or initials
- Age and date of birth
- Gender
- Weight and height
- Details of the product causing the adverse event
- The reason you have been taking or were prescribed the product
- Details of other medicines or remedies you are taking or were taking at the time of the reaction
- The reason you have been taking the other medicines and any subsequent changes in your medicines
- Details of the reaction you suffered, the treatment you received for that reaction, and any long-term effects the reaction has caused to your health
- Medical history considered relevant, including documents such as laboratory reports
- Additional information about your ethnicity, religion and sexual orientation if considered relevant for the use of the product and the reaction you experienced

The Personal Data that we may collect about you when you are the reporter of an adverse event:
- Name
- Contact details (which may include your address, e-mail address, phone number or fax number)
- Profession (this information may determine the questions you are asked about an adverse event)
- Relationship with the subject of the report

If you are also the subject of a report, this information will be combined with the information you provide in relation to the adverse event. We will only collect the minimum data required for the purposes of fulfilling our pharmacovigilance obligations.

Most of the information we request from you must be provided to us, otherwise we will not be able to assist you or adequately process your report for pharmacovigilance purposes.

What do we use the information for?

Pharmacovigilance laws require us to collect information about the safety of our products. As a result, we must keep sufficient information to allow us to investigate adverse events and to request additional information. We will compare the information about the adverse event with information about other adverse events received by FERRING to properly analyse and assess the safety of the product(s) over time and to update the safety information available to patients, prescribers and regulatory authorities. In order to do this, we keep the information for the period permitted by the applicable law.

FERRING will only use Personal Data collected for pharmacovigilance for this purpose, and will not hold or process this data for any other purpose.

Will you need to give your consent?

FERRING is committed to ensuring that appropriate consent is obtained before collecting or processing personal or sensitive data. However, as data collected to fulfil pharmacovigilance obligations is collected and processed for reasons relating to our legal obligations, public interest and public health, it is not subject to the same consent requirements as other sectors. Therefore, consent is not required.

With whom do we share the information?

We share the information with regulatory authorities such as the European Medicines Agency, The US Food & Drug Administration and Medicines & Healthcare products Regulatory Agency in the UK, in accordance with national pharmacovigilance laws in the countries, where we market our product.

We may also share the information with other pharmaceutical companies, who are our co-marketing, co-distribution or other license partners, where pharmacovigilance obligations for a product require such exchange of information. This means that your information will be shared outside of your country to countries that may have other requirements for data protection.

We may publish information about the safety of our products. We will remove identifiers from any publications, so that no individual can be identified.

We may also transfer data to a third party in the event of a sale, assignment, transfer, or acquisition of the company or a specific product or therapeutic area, in which case we would require the buyer, assignee or transferee to treat that Personal Data in accordance with applicable data protection law.

Where will the data be held and will it be transferred to another country?

Our pharmacovigilance obligations require us to review patterns across adverse event reports received from all countries, where we market our products. To meet these requirements, information provided as part of an adverse event report is kept under secure conditions in the local FERRING office in the country/region of the report and is transferred to FERRING headquarters. Upon transfer, only the minimum data required is included. Any names and contact details of patients and reporter are hidden, meaning that only information on age/age group, date of birth and gender is transferred in addition to the information concerning the reaction and the health of the patient.

How will we ensure the security and protection of your Personal Data?

FERRING takes all available and appropriate measures to secure Personal Data from accidental loss and from unauthorised access, use, alteration or disclosure. Additionally, we take further information security measures including access controls, stringent physical security and robust information collection, storage & processing practices.

What are your rights?

FERRING will give effect to your rights under data protection law where pharmacovigilance law permit. Your rights as a data subject are the following:

- Right to access and rectification: You have the right to request a copy of the information we hold about you, as well as the right to request corrections, if the data is incorrect. We may require you to provide proper identification before we comply with any request to access or correct Personal Data.
- Right to erasure and restriction of processing: For legal reasons, we cannot delete information that has been collected and processed as part of an adverse event report unless it is inaccurate
However, you may have the right to restrict the processing of your Personal Data, if, for example, you believe the data is incorrect.
- Right to data portability: You have the right to request that we transfer the Personal Data we hold about you to another party, except if this cannot be permitted for reasons of public interest.
- Right to object: As the data collected as part of an adverse event report is processed for reasons of public health and interest, you cannot object to the use of the data.

If you would like further information about your rights as a data subject, please contact us using the contact information provided at the end of this notice.

You also have the right to complain to the data protection supervisory authority in your country.

Whom to contact?

Personal Data submitted to FERRING is stored locally in the country of origin as well as in the FERRING global safety database on servers situated within the EEA. The servers are owned and maintained by FERRING Pharmaceuticals A/S, whose principal place of business is at Kay Fiskers Plads 11, DK-2300 Copenhagen S, Denmark.

If, at any time, you have questions concerning the information that we hold about you, please contact the FERRING office in the country/region to where the data was initially reported.

If you would like to contact us on how to exercise your rights as a data subject or for any other enquiries regarding data privacy, please contact the FERRING Global Privacy Office by e-mail at privacy@ferring.com by post at Chemin de la Vergognausaz 50, 1162, St-Prex, Switzerland.

For enquires in Malaysia, you may also contact Regulatory Affairs at 03-7960 3032.