

**PRIVACY NOTICE FOR PHARMACOVIGILANCE, MEDICAL INFORMATION, AND  
PRODUCT CLAIMS - DATA PROCESSING NOTIFICATION  
RELATED PERSONNEL**

Dromeinter is required by law to collect safety information (adverse events, adverse reactions, medication errors, misuses, cases of pregnancy) about our products and quality complaints, also counting on the protection of your personal data. This notice explains how we process (collect, use, store, and share) your personal data. We will process any personal data provided by you in accordance with this Notice and in accordance with local law.

At Dromeinter we collect all the safety information of our products in a database. We analyze the data on a regular basis to determine if there is any new information about our products that we need to communicate with authorities, doctors and patients. All of this is done for the purpose of ensuring the safety of our products and our patients.

This Privacy Notice describes the types of Personal Data that may be collected, use, or share your Personal Data; measures you take to protect your Personal Data; and the choices provided to you regarding the use of your Personal Data. This privacy notice applies to Personal Data collected from Patients, Healthcare Professionals, Business Partners, Employees, Ex-Employees, and Third Parties in general through different channels, including physical meetings, digital platforms, or websites that link to this Privacy Policy or other sources, as described below. The scope of this notice is limited to the collection and processing of your personal data for pharmacovigilance tasks and/or product claims. For general information visit the Privacy Policy on our page:

<https://www.dromeinter.com/division-farmaceutica/Pharmacovigilance/?lang=en>

**1. WHO ARE WE?**

The company responsible for processing your personal data is:  
Dromeinter Street between final Ave. Los Próceres and Boulevard  
Morazán,  
DROMEINTER Building No. 4002  
P.O. Box No. 434, Tegucigalpa, Honduras  
**Phone:**(504)2221-5080  
**Fax:**(504)2236-9113

You can contact [farmacovigilancia@dromeinter.com](mailto:farmacovigilancia@dromeinter.com) at any time with questions or concerns about how we process your personal data.

**2. HOW DO WE ACQUIRE YOUR PERSONAL DATA?**

We have access to your personal data from the following sources:

- From you directly
- From health professionals such as nurses, pharmacists or doctors.
- Advertising is available in publications, websites or social networks.

**3. WHY DO WE PROCESS YOUR PERSONAL DATA?**

All personal data provided related to adverse events or other pharmacovigilance activities will be used solely for these purposes. This information is of utmost importance in terms of public health and will be used for the detection, evaluation, understanding and prevention of adverse effects or any other problems related to the use of any medication.

We collect and process your data for such purposes in order to comply with our legal obligations. In addition, we may be asked to report the data to the regulatory authorities. Your data will not be used for purposes other than those mentioned.

We process your personal data for the following purposes:

- To conduct a scientific evaluation of any quality complaints or adverse events related to Dromeinter's drug and/or medical device.
- To archive adverse events in our global pharmacovigilance database, which is regularly analyzed to evaluate generic patterns.
- To evaluate trends associated with quality complaints, including adverse events.

**4. WHAT PERSONAL DATA DO WE PROCESS ABOUT YOU?**

For the purposes described in section 3 above, we may process the following types of personal data:

- Contact details (name, address, telephone and email).
- Data related to race and ethnicity.
- Related health, medication, and/or medical device data you are using.

**5. WHY DO WE HAVE PERMISSION BY LAW TO PROCESS YOUR PERSONAL DATA?**

Our processing of your personal data requires a legislative basis. By law, we are permitted to process your personal data as described in Section 4.

Based on:

- The prior, express and informed consent given by the Owner of the Personal Data in Honduras, Article 19. - Any controller who carries out the processing of personal data must establish and maintain administrative, technical and physical security measures to protect personal data against damage, loss, alteration, destruction or unauthorized use, access or processing.
- The processing of Personal Data is necessary for our compliance with pharmacovigilance and quality legal obligations

**6. HOW DO WE SHARE YOUR PERSONAL DATA?**

We may share your personal data with:

- Health authorities.
- Other entities such as (e.g., business partners or suppliers).
- Companies that provide support (e.g., licensing companies, consultants, technology assistance providers).

It is necessary to manage the global pharmacovigilance database, Dromeinter's product complaints database and comply with the obligation of pharmacovigilance legislation or pharmaceutical safety legislation.

Dromeinter is also required to inform health authorities around the world about certain pharmacovigilance and product-relevant data, including those with a different level of data protection than in the European Union. The reports contain details about the incident, but will only contain limited personal data:

- a) Patients: information provided, including age or date/year of birth (where permitted by regulations) and gender (note that the patient's name will never be provided).
- b) Persons subject to the notification: to follow up on the case.

## **7. HOW LONG DO WE KEEP YOUR PERSONAL DATA?**

Since pharmacovigilance-related information (adverse event reporting) is important for public health reasons, the reports will be retained for a minimum of ten (10) years after the product is withdrawn in the last country in which the product is marketed.

Since information related to product complaints and drug safety is important for public health reasons, complaint records, including personal data contained therein, are retained for a minimum of fifteen (15) years.

## **8. WHAT ARE YOUR RIGHTS?**

In general, you have the following rights:

- You can request verification of the personal data we hold about you.
- You may request a copy of your personal data in a structured, commonly used and machine-readable format.
- You can update or make corrections to your personal data.
- You may submit a complaint about the manner in which your personal data is processed to a personal data processing authority.

Please note that due to our legal obligations under pharmacovigilance legislation, **Dromeinter** may not be able to delete or restrict the processing of your data if it is processed for pharmacovigilance, however, we will respect your rights in accordance with Article 19 above and other regulations amending or supplementing it.

By the law applicable to your country there may be limitations on these rights depending on the circumstances of the data processing activity. Contact us as described in Section 1 with questions or requirements related to these rights.