

Privacy Information Notice in case of adverse event reports, quality claims and medical enquiries

Introduction

This privacy notice is issued on behalf of the **Stemline Companies of the Menarini Group** (hereinafter collectively referred to as the “Company” or “we”).

It applies to all individuals who contact any of the Stemline Companies via our call center (phone), email, or during direct interactions with Company personnel (for example, during meetings, conferences, or events).

Contact details and DPO

The Data Controller for the processing of your personal data is the Stemline Company that is the Marketing Authorization Holder or the sales dealer/promoter of the product to which your request, report, or communication refers.

The name and address of the Company (Data Controller) is indicated in the leaflet included with the medicine's package. The list and contact details of the **Stemline Companies** belonging to the Menarini Group are available at the following link: <https://www.menarini.com/en-us/countries>

The Data Protection Officer (**DPO**) of the Menarini Group can be contacted by email at: dpo@menarini.com

What data we process

The data we process include both your 'common' data (e.g., name, surname, telephone number) and 'special categories' of data, in particular information that may reveal your health status or the health status of a patient or consumer. This also covers any information you share during telephone calls or other correspondence (collectively “**Data**”).

If you call our call centre, please note that your number may be automatically detected and the call centre may record your conversation for quality purposes. In addition, recordings of messages left on our voicemail will be linked to your phone number. Please note that if you provide information about third parties, you must first provide them with this privacy policy and, where required by law, obtain their prior informed consent.

Why we process your Data and how

We inform you that your Data may be processed by the Data Controller for the following purposes:

1. management of your requests, which may include:
 - (i) requests for medical information;
 - (ii) complaints about the quality of our products;
 - (iii) reporting of adverse events (e.g., pharmacovigilance). The full Pharmacovigilance Privacy Notice is available [here](#).

The legal basis for the processing for abovementioned purposes is the pursuit of a **public interest in the field of public health**, consisting of ensuring high standards of quality and safety of healthcare and medicines or medical devices.

2. performing internal statistical analyses on the effectiveness of our services and the quality of our products. The legal basis for the processing for this purpose is our **legitimate interests**, provided that these interests do not override your fundamental rights.
3. your Data may be processed by the Company to establish/defend legal claims or to enforce the Menarini Group Code of Conduct. The legal basis for processing for this purpose is our **legitimate interests to establish, exercise or defend legal claims** or whenever courts are acting in their judicial capacity.

All your Data is processed manually or electronically, on paper or using automated tools, in any case suitable for ensuring the security and confidentiality of your Data.

Required/optional Data

We require your Data only to the extent necessary to manage your report/claim or request described above. If you do not provide this essential Data, we may be unable to process your request. Providing optional Data (if any) is not mandatory and will not affect our ability to provide services or handle your requests.

How we process your Data

In accordance with applicable privacy laws, we minimize the use of personal identification data, i.e., we only process it to the extent necessary to achieve the purposes indicated in this document. The Data will be retained for the time necessary to pursue the actual purposes for which it was collected and, in any case, for no longer than the period indicated below:

- Pharmacovigilance: for as long as the product is authorized plus ten (10) years after the marketing authorization has ceased in the last country where the product is used, unless national laws requires longer retention periods;
- Quality: the time strictly necessary to resolve the complaint and a maximum of one (1) year after the last contact with the patient/customer; said term could be extended up to ten (10) years in accordance to local provisions that may differ from country to country. In exceptional circumstances (e.g. such as in case of (i) recall from the market of the concerned products; (ii) litigation or legal defence needs, etc.) it is possible that Data may be stored for longer periods, in any event no longer than necessary to achieve the goals for which they were collected.;
- Medical information: one (1) year after the last contact with the patient/customer; said term could be extended in accordance to local provisions that may differ from country to country. In exceptional circumstances (e.g. such as in case of (i) recall from the market of the concerned products; (ii) litigation or legal defence needs, etc.) it is possible that Data may be stored for longer periods; in such circumstances, the Data is anonymized/deleted ten (10) years after the marketing authorization has been withdrawn in the last country where the product is used.

Once the maximum retention term has been reached, your Data may be anonymized and be kept only for statistical reasons (art. 6.1.(f) of the GDPR) or simply erased.

How we ensure the security and quality of your personal Data

The Company is committed to ensuring the security of your Data and to implementing the technical and organizational measures required by applicable laws and internal policies to prevent data loss, unauthorized access, or misuse. Your Data is protected through a range of technological and procedural safeguards; for instance, they are stored on secure servers in restricted-access, protected locations.

Who can access the Data

The Data will be collected and processed by a third party provider, appointed by Stemline to carry out the activities and acting as Data Processor. Authorized staff of the Data Controller handling personal data belong to the following categories: administrative personnel, customer service personnel (for example, depending on the case, call center staff or personnel handling medical information requests, quality complaints, or pharmacovigilance reports), IT technicians, product managers, as well as personnel who need to process data to perform their work duties, including members of Supervisory Bodies for carrying out their oversight activities and for enforcing the Menarini Group Code of Conduct.

Data may also be communicated, outside your country (“Third Countries”), to other companies of the Menarini Group for the same purposes and/or for administrative purposes. Furthermore, the Data may be communicated, also to Third Countries, to: (i) institutions, authorities, and public bodies for their institutional purposes; (ii) professionals, independent consultants—operating individually or in association—and other third parties and service providers who provide commercial, professional, or technical services to the Company (for example, IT and cloud computing service providers), including outsourced call centers, for the achievement of the purposes described above; (iii) third parties in the event of mergers, acquisitions, business or branch transfers, audits, or other extraordinary operations.

Such recipients will process only the Data necessary for their tasks and undertake to use it solely for the purposes indicated above and in compliance with the law. Data may also be communicated to recipients required by applicable law. Except as indicated above, Data will not be shared with third parties (whether natural or legal persons) who do not provide any technical, professional, or commercial service to the Data Controller, and will not be communicated to unauthorized parties.

Recipients process Data as independent controllers, processors, or authorized personnel, as applicable, for the purposes indicated above and in accordance with applicable data protection laws.

Where Data is transferred to Third Countries, including to countries whose data protection standards may differ from those of the country where the data were originally collected, such transfers are carried out using appropriate safeguards designed to ensure an adequate level of protection. These safeguards may include contractual measures, internal policies, or other recognized compliance mechanisms.

You may request additional information about these safeguards by contacting the details provided above.

Your rights

You may exercise at any time your rights, including the right to know whether we are processing your Data, to verify its content, origin, accuracy, and location (including any Third Countries where it may be held), to request a copy, to request correction, and, where provided by applicable law, to obtain the restriction of processing, erasure, or to object to processing, by writing to the postal address indicated above or via email to dpo@menarini.com.

You may also contact the DPO to raise any concerns you consider inappropriate regarding the processing of your Data. You may also lodge a complaint with the data protection authority in your country.