

Information under the Articles 13 et seq. of EU Regulation 679/2016 for the processing of personal data

This information is provided to you as a data subject or as someone authorized to communicate personal data to us on behalf of the data subject, in accordance with the provisions of Regulation (EU) 2016/679 - also known as "GDPR".

In accordance with Articles 13 et seq. of EU Regulation 679/2016 (hereinafter GDPR) on the protection of personal data, I.B.N. Savio S.r.l., with registered office at Via del Mare 36 - 00071 Pomezia (RM), (hereinafter "Controller"), as Data Controller, informs you that your personal data will be processed in the manner described below.

1) Subject, processing methods and legal basis

The Data Controller processes the personal identification data (for example, by way of example and not limited to, name, surname, tax code, address, telephone number, email address) communicated by you. The data is processed using computer or paper means.

For the purposes of this regulation (Art. 4 "Definitions") the following definitions apply:

«personal data»: any information relating to an identified or identifiable natural person "data subject"; an identifiable natural person is one who can be identified, directly or by application, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person

"processing": any operation or set of operations, performed with or without the aid of automated processes and applied to personal data or sets of personal data, even if not recorded in a database, such as collection, recording, organization, structuring, storage, processing, selection, blocking, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

The legal bases for processing are:

- a) the data subject has given consent to the processing of their personal data for one or more specific purposes;
- b) processing is necessary for compliance with a legal obligation to which the controller is subject;
- c) processing is necessary to protect the vital interests of the data subject or of another natural person.

2) Purpose of Data Processing

The data and information (the "Data") you provide will be used for Pharmacovigilance purposes, i.e. to fulfill the obligations imposed on us by Italian and European legislation regarding the safety and efficacy of medicines. This legislation requires us to transmit information to health authorities about possible adverse reactions resulting from the use or exposure to our medicinal product and to respond to any requests from the competent authorities; reports are transmitted indicating only the patient's initials, age or date of birth, and gender. Your contact details will be used in case further data are needed or to respond to your further requests. The data may also be used, where necessary, to establish, exercise or defend a right in court or administrative proceedings. In any case, information regarding age, gender or ethnic and cultural origins will be used exclusively to allow the Controller to verify compliance with the law and its best application in terms of equal opportunities, non-discrimination and proper management of human resources. The Controller will process personal data for the time necessary to fulfill the purposes mentioned above.

3) Data storage

The Data will be stored, with the implementation of the security measures required by law, in our archives and IT services and/or in the archives of our Pharmacovigilance service provider, whose archives may be located abroad, including in countries outside the European Union. The retention

period will be determined on a case-by-case basis depending on the circumstances and the type of data. For internal management purposes of pharmacovigilance obligations, data retention is guaranteed for the entire duration of the marketing authorization of the medicinal product concerned by the report and for ten years after the authorization expires.

4) Access to data

Your data may be made accessible, for the purposes set out in this information and specified above, to the following subjects:

to employees and collaborators of the Data Controller or of the companies that manage the Pharmacovigilance service, in their capacity as persons in charge and/or responsible for processing and/or system administrators;

to subjects authorised to fulfil the pharmacovigilance obligations imposed by law and to subjects obliged to carry out Pharmacovigilance activities, such as AIFA, holders of Marketing Authorisations, Local Health Units, Regions, Hospital Pharmacovigilance Offices, etc.

5) Data transfer

Personal data is located and stored on our servers, which are physically located within the European Union. In any case, it is understood that the Data Controller, if necessary, will have the right to move the servers to territories outside the European Union. In this case, the Data Controller hereby ensures that the transfer of data to non-EU territories will take place in accordance with the applicable legal provisions, stipulating, if necessary, agreements that guarantee an adequate level of protection and/or adopting the standard contractual clauses provided by the European Commission.

6) Rights of access, deletion, limitation and portability

The interested parties are granted the rights set forth in Articles 15 to 20 of the GDPR. By way of example, each interested party may therefore:

- obtain confirmation as to whether or not personal data concerning them is being processed;
- if processing is in progress, obtain access to the personal data and information relating to the processing as well as request a copy of the personal data;
- obtain the rectification of inaccurate personal data and the integration of incomplete personal data;
- obtain, if one of the conditions set forth in Article 17 of the GDPR exists, the erasure of personal data concerning them;
- obtain, in the cases set forth in Article 18 of the GDPR, the limitation of processing;
- receive the personal data concerning them in a structured, commonly used and machine-readable format and request their transmission to another controller, if technically feasible.

7) Right to object

Each interested party has the right to object at any time to the processing of his/her personal data carried out for the pursuit of a legitimate interest of the Data Controllers. In the event of objection, his/her personal data will no longer be processed, unless there are legitimate reasons to proceed with the processing that prevail over the interests, rights and freedoms of the interested party or for the establishment, exercise or defense of a right in court.

8) Right to lodge a complaint with the Guarantor

Each interested party may lodge a complaint with the Guarantor for the Protection of Personal Data if he or she believes that his or her rights under the GDPR have been violated, according to the methods indicated on the Guarantor's website accessible at: www.garanteprivacy.it.

9) How to exercise your rights

You may exercise your rights at any time by sending a registered letter with return receipt to I.B.N. Savio S.r.l., with registered office in Via del Mare 36 - 00071 Pomezia (RM).

10) Owner, manager and persons in charge

The Data Controller is I.B.N. Savio S.r.l., with headquarters at Via del Mare, 36 - 00071 Pomezia (RM) as expressly stated at the beginning of this document. The updated list of data processors and persons authorized to process data is maintained at the headquarters of the Data Controller.

11) Minors

The Owner's Services are not intended for children under the age of 18, and the Owner does not intentionally collect personal information related to minors. In the event that information about minors is unintentionally recorded, the Owner will promptly delete it upon user request.