

**Notice pursuant to art. 13 et seq. of EU Regulation 679/2016
for the processing of personal data**

In accordance with art. 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 in Via del Mare 36 – 00071 Pomezia (RM), (hereinafter "Holder"), as holder of the Treatment informs you that your data will be processed in the following ways:

1) Subject, method of treatment and legal basis

Holder treats personal identifying information (e.g. without limitation, name, surname, fiscal code, address, telephone number, e-mail address, reference Banking and payment, VAT, images, photographs and videos) communicated by you at the conclusion and conduct of contracts for services concluded with the owner.

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 "interested"; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more elements characteristic of his physical identity, physiological, genetic, psychic, economic, cultural or social

«Processing»: any operation or set of operations, carried out 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, organisation, structuring, storage, processing, selection, blocking, adaptation or modification, extraction, consultation, use, communication by transmission, dissemination or any other form of making available disposition, comparison or interconnection, limitation, cancellation or destruction.

2) Purpose of data processing

The data and information (the "Data") you provide will be used for pharmacovigilance purposes, to comply with the obligations imposed on us by Italian and European regulations regarding the safety and efficacy of pharmaceuticals.

This legislation requires us to report to health authorities information 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 submitted indicating only the patient's initials, age or date of birth and gender.

Your contact details will be used in case additional data is needed or to respond to your further requests. The data may also be used, where necessary, to ascertain, exercise or defend a right in judicial or administrative proceedings.

In any case, information regarding age, gender or ethnic and cultural origins will be used exclusively for the purpose of enabling the Data Controller to verify compliance with the law and its best application in terms of equal opportunities, non-discrimination and correct human resources management.

The data Controller will process personal data for the time necessary to fulfill the aforementioned purposes.

3) Data retention

The Data will be stored, implementing the security measures required by law, at our archives and IT services and/or at 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 from time to time based on the circumstances of the case and the type of data.

For the purposes of internal management of pharmacovigilance obligations, data retention shall be ensured for the entire duration of the marketing authorization of the medicinal product concerned by the report and for the following ten years from the moment in which the authorization expires.

4) Access to data

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

to employees and collaborators of the Owner or of the companies that manage the Pharmacovigilance service, in their capacity as data processors and/or managers and/or system administrators;

to subjects authorized to fulfill the pharmacovigilance obligations imposed by law and to subjects obliged to carry out Pharmacovigilance activities, such as AIFA, holders of Marketing Authorizations, Local Health Units, Regions, Hospital Pharmacovigilance Office, etc.

5) Data transfer

Personal data is located and stored on our servers, which are physically located within the European Union. It is in any case understood that the holder, if necessary, will have the right to move the servers even in the territories outside the European Union. In that case, the holder shall ensure that the transfer of data in the non-EU territories will be made in accordance with the applicable legal provisions by stipulating, if necessary, agreements guaranteeing an adequate level of protection and/or adopting the Standard contractual clauses provided by the European Commission.

6) Rights of data subject

Data subjects are granted the rights referred to art. 15 to 20 of the GDPR. By way of example, each data subject may therefore:

- obtain confirmation that a processing of personal data concerning him or her is ongoing or not;
- if processing is ongoing, obtain access to personal data and processing information as well as request a copy of the personal data;
- obtain correction of inaccurate personal data and integration of incomplete personal data;
- obtain, if one of the conditions set forth in art. 17 of the GDPR exists, the deletion of personal data concerning him or her;
- obtain, in the cases provided for in art. 18 of the GDPR, the limitation of processing;
- receive personal data concerning him or her in a structured, commonly used and machine-readable format and request their transmission to another data controller, if technically feasible.

7) Right to object

Each data subject has the right to object at any time to the processing of his personal data carried out in pursuit of a legitimate interest of the data controllers.

In the event of an objection, your personal data will no longer be processed, unless there are legitimate grounds for processing that outweigh the interests, rights and freedoms of the data subject or for verification, the exercise or defence of a right in court.

8) Right to lodge a complaint with the Data Protection Authority

Each data subject may lodge a complaint with the Data Protection Authority if he/she believes that the rights he/she holds pursuant to the GDPR have been violated, according to the methods indicated on the Data Protection Authority's website accessible at: www.garanteprivacy.it.

9) How to exercise rights

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

10) Holder, manager and appointees

The owner of processing is I.B.N. SAVIO S.r.l., with registered office in Via del Mare 36 - 00071 Pomezia (RM) as specifically listed at the beginning of this document. An updated list of data processors and persons in charge to treatment is kept at the registered office of the Holder.

11) Minors

Holder's services are not intended for children under the age of 18 and the Holder does not intentionally collect personal information related to minors. In the event that information about minors is unintentionally recorded, the Holder will delete them in a timely manner, at the request of the users.