

DISCLAIMER FOR PROCESSING OF PHARMACOVIGILANCE DATA

We, as Gensenta İlaç Sanayi ve Ticaret Anonim Şirketi (“Gensenta”), care about security of your personal data obtained under pharmacovigilance activities. Recognizing this responsibility, we process your personal data in our capacity as a Data Controller in accordance with the Law No 6698 on Protection of Personal Data (the “Law”) and the relevant legislation within the following framework.

1. Purpose of Collecting and Processing Personal Data

Pharmaceutical companies are required to carry out activities in relation to identification, assessment, description and prevention of adverse reactions (side effects) and other drug-induced problems which are likely to arise during drug use. These activities referred to as pharmacovigilance allow monitoring of drug safety and protection of public health by taking a number of measures at the national or international level if required.

In reporting adverse reactions; general and special categories of personal data, especially concerning personal health, that are collected and processed for effective analysis of safety data and identification of repeated reporting are listed below;

- initials of the patient’s name and surname
- patient’s age/age group and/or date of birth
- patient’s gender
- patient’s weight/height
- patient’s medical history
- medicines used by the patient
- patient’s current medical status (e.g. test results)
- name and contact details of the reporting person for ensuring collection of complete and accurate data to perform a follow-up

2. The Legal Reason for Collecting Personal Data

Your personal data, in any verbal, written, visual or electronic environment, are collected and processed for the purposes mentioned above and for lawful performance of any and all works covered by pharmacovigilance activity of Gensenta and accordingly, in order to enable Gensenta to fulfil its contractual and legal obligations completely and duly. Your personal data of general character are collected and processed on the conditions that such processing is expressly stipulated by law, mandatory for fulfilment of legal obligations of Gensenta and required for legitimate interests of Gensenta. The relevant legislation is listed below:

- Regulation on the Safety of Medicinal Products No 28973
- Good Pharmacovigilance Practices Guideline Module 1 - Management and Reporting of Adverse Drug Reactions
- The Medical Device Regulation No 31499
- Law No 6698 Protection of Personal Data
- Guidelines for Protection of Personal Data in Pharmacovigilance Activities

Processing of pharmacovigilance data which can be considered a special category of personal data by those who are also under confidentiality obligation for pharmacovigilance purposes is considered under protection of public health and preventive medicine activities pursuant to the third paragraph of

Article 6 of the Law No 6698 and such data can be processed without seeking explicit consent of the data subject.

3. Transfer of Personal Data

Your personal data can be shared with the agencies and organizations listed below within the framework of the laws, regulations and guidelines referred to in article 2 and for the purposes explained in article 1.

- Turkish Medicines and Medical Devices Agency
- Regulatory and supervisory agencies and governmental authorities
- Upon written request, judicial authorities and law enforcement officers

4. Retention Period of Personal Data

The personal data mentioned above will only be retained for a period which is reasonably needed for fulfilment of purposes set out in this Disclaimer and required by applicable legislation.

5. Data Security and Right to Application

Your personal data are retained in physical and electronic archives at Gensenta based on available technical and administrative facilities, with great care and in compliance with the legislation.

Pursuant to Article 11 of the Law No 6698 regulating the rights of the data subject, by sending an e-mail to gizlilik@gensenta.com.tr, you are entitled to:

- a) learn whether your personal data have been processed,
- b) obtain information thereof, if processed,
- c) learn the purpose of processing your personal data and whether they have been used for the intended purpose,
- d) learn the third parties to whom your personal data have been transferred within the country/abroad
- e) request rectification if processed incompletely/inaccurately
- f) request erasure/destruction under the terms provided for in Article 7 of the Personal Data Protection Law,
- g) request notification of the transactions made pursuant to subparagraphs (e) and (f) to third parties to whom personal data have been transferred,
- h) object to any unfavorable consequence resulting from analysis of your personal data exclusively by automated systems,
- i) request indemnification in case you suffer any loss due to unlawful processing of your personal data

However, our company may not delete or restrict processing of any data processed for pharmacovigilance pursuant to pharmacovigilance legislation.

Your requests set forth in your application will be settled free of charge as soon as practicable depending on the nature of your request and within thirty days at the latest. However, if such settlement requires any further cost, you may be charged for a fee specified by the Personal Data Protection Board.