

“Pleksus Farmakovijilans Hizmetleri ve Klinik Arařtırmalar Ltd. řti.” (“Pleksus Pharmacovigilance”) operates as a Contracted Pharmacovigilance Service Provider. As Pleksus Pharmacovigilance, we show the utmost care and sensitivity regarding your personal information and your right to privacy. Therefore, pursuant to Article 10 of the Personal Data Protection Law No. 6698, we would like to inform and enlighten you about our personal data processing activities.

In accordance with the Regulation on the Safety of Medicinal Products and the Guidelines on Good Pharmacovigilance Practices published by the Turkish Medicines and Medical Devices Agency, personal and medical information must be obtained for effective data analysis, such as adverse effect reporting. Accordingly, our company, “Pleksus Farmakovijilans Hizmetleri ve Klinik Arařtırmalar Ltd. řti.”, may record, store, update, process, share with third parties, and transfer your personal data in compliance with the Personal Data Protection Law No. 6698.

DATA CONTROLLER AND REPRESENTATIVE

Pursuant to the Law, **“Pleksus Farmakovijilans Hizmetleri ve Klinik Arařtırmalar Ltd. řti.” (“Pleksus Pharmacovigilance”)**, operating at the address “Barbaros Mahallesi, Tophanelioęlu Caddesi Validebaę Konakları No:72B/41 Üřküdar 34662 İstanbul”, is the Data Controller.

YOUR PERSONAL DATA PROCESSED

Identity Information: Name, surname, gender, date of birth, etc.

Contact Information: Address, telephone number, e-mail address, etc.

Health Information: Medical history, information on concomitant diseases and conditions, such as allergy, pregnancy, smoking/alcohol use, hepatic/renal impairment, diabetes, hypertension, etc.; information regarding congenital anomalies, such as medications used by the mother during pregnancy, diseases to which she was exposed, date of last menstruation; information on medications used; laboratory findings.

Risk Management Information: Risk factors related to adverse events.

Professional Information: Profession and professional experience information.

Other Information: Height, weight, registration number, etc.

PURPOSE OF PROCESSING PERSONAL DATA

Pleksus Pharmacovigilance collects and processes information regarding pharmacovigilance data reported to it by patients, healthcare professionals, and other reporters within the scope of pharmacovigilance activities carried out in accordance with the Regulation on the Safety of Medicinal Products and the Guidelines on Good Pharmacovigilance Practices published by the Turkish Medicines and Medical Devices Agency. The personal data obtained is securely stored in physical or electronic environments in accordance with the Personal Data Protection Law and the retention periods specified in other relevant legislation.

The personal data obtained is protected by Pleksus Pharmacovigilance through administrative and technical measures taken in accordance with all relevant legislation, particularly the Personal Data Protection Law. The purposes of personal data processing by Pleksus Pharmacovigilance are as follows:

- To fulfill the requirements of the activities carried out by our company and the performance of the service, and to enable the relevant persons to benefit from the services offered by our company
- To ensure that the necessary work is carried out by the relevant business units of our company and that related business processes and reports are carried out
- To evaluate requests and complaints
- In accordance with the services offered by our company, to establish, exercise, and protect rights arising from legislation
- To ensure that our company activities are carried out in accordance with company procedures or relevant legislation
- To fulfill information sharing, reporting, and notification obligations stipulated by public institutions and all authorities
- To fulfill information and document retention obligations arising from legal legislation
- To manage our legal processes and to provide you with better and more reliable uninterrupted service your personal data will be processed within the scope of the personal data processing conditions and purposes specified in Articles 5 and 6 of Law No. 6698

METHOD OF COLLECTION OF PERSONAL DATA AND LEGAL BASIS,

For the purpose of carrying out pharmacovigilance activities, the following are used during the collection of personal data obtained by Pleksus Pharmacovigilance:

- The “Interview Record Form” completed verbally over the phone
- The “TÜFAM Adverse Reaction Reporting Form/CIOMS Form” completed by Pleksus Pharmacovigilance employees or healthcare professionals
- Reporting forms determined by service recipients/marketing authorization holders.

All of the above-mentioned forms may be received by e-mail, fax, or post. Within this framework, your

personal data is processed under the data processing conditions set out in Article 6(3) of the Personal Data Protection Law, namely:

- c) It is necessary to process the personal data of the parties to a contract, provided that it is directly related to the establishment or performance of a contract.
- ç) It is mandatory for the data controller to fulfill its legal obligation.
- d) The data has been made public by the data subject themselves.
- e) Data processing is mandatory for the establishment, exercise, or protection of a right.
- f) Data processing is mandatory for the legitimate interests of the data controller, provided that it does not harm the fundamental rights and freedoms of the data subject.

The legal bases for obtaining the personal data of patients are the Regulation on the Safety of Medicinal Products and the Guidelines on Good Pharmacovigilance Practices published by the Turkish Medicines and Medical Devices Agency, and other related regulations.

For detailed information, please refer to the “Personal Data Processing and Protection Policy”

PARTIES TO WHOM PROCESSED PERSONAL DATA IS TRANSFERRED AND PURPOSE OF TRANSFER

Your personal data may be shared, in accordance with the fundamental principles set out in the Personal Data Protection Law and within the scope of the personal data processing conditions and purposes specified in Articles 8 and 9 of the Personal Data Protection Law, for the purpose of fulfilling legal obligations stipulated in the legislation regarding the monitoring of drug safety, provided that public interest is observed, with the Ministry of Health, the Turkish Medicines and Medical Devices Agency, business partners and service providers, including suppliers providing storage, archiving, and information technology support, consultants, legally authorized institutions and organizations, and legally authorized private law legal entities.

Pharmacovigilance data may also be entered into the World Health Organization’s database within the scope of the Programme for International Drug Monitoring and Cooperation, in anonymized form.

Some pharmacovigilance data must also be reported to other health authorities in Europe and around the world, including countries with varying levels of data protection. However, although these reports contain detailed information about the event, personal data is included anonymously. The patient’s initials may be included, but the full name is not explicitly reported.

RIGHTS OF THE DATA SUBJECT WHOSE PERSONAL DATA IS PROCESSED

As the personal data owner, we hereby inform you that you have the following rights pursuant to Article 11 of the Law:

- To learn whether personal data is being processed
- To request information if personal data has been processed
- To learn the purpose of processing personal data and whether it is being used in accordance with that purpose

- To know the third parties to whom personal data has been transferred domestically or abroad
- To request correction of personal data if it has been processed incompletely or inaccurately,
- To request deletion or destruction of personal data,
- To request that the correction, deletion, or destruction of personal data be notified to third parties to whom the personal data has been transferred,
- To object to any result arising against the person by analyzing the processed data exclusively through automated systems,
- To request compensation for damages in the event of damage due to the unlawful processing of personal data.

Pursuant to Article 4 of Law No. 6698 on the Protection of Personal Data, the personal data we collect and process must be accurate and, where necessary, up to date. Therefore, if any changes occur in your personal data, you may notify us of your current and accurate personal information through the methods specified below.

IF YOU WISH TO CONTACT US REGARDING YOUR REQUESTS

If the request is made in writing:

You may submit a wet-signed copy of the “GDPR Application Form” available on our website at <https://pleksusfarmakovijilans.com/>, together with a document identifying your identity, in person. You may also apply by proxy with a notarized power of attorney showing that you are authorized to apply regarding the rights listed under Article 11, or you may send your application through a notary public to the address:

“Barbaros Mahallesi, Tophanelioğlu Caddesi Validebağ Konakları No:72B/41 Üsküdar 34662 İstanbul”.

If the request is made electronically:

You may sign the GDPR Application Form with an electronic or mobile signature that has a “secure electronic signature” certificate as defined under the Electronic Signature Law No. 5070 and send it to our Company’s Registered Electronic Mail (KEP) address at pleksusfarmakovijilans@hs04.kep.tr, or you may send it to farmakovijilans@pleksus.com.tr by using the e-mail address that you have previously notified to our Company and that is registered in our systems.

In order to determine whether the application belongs to you and to protect your rights, we may request additional verifications, such as sending a message to your registered e-mail address or contacting you by phone. If the application is made by third parties on behalf of personal data owners, the person making the application must be granted a specially authorized power of attorney issued by a notary public by the data owner.

Your requests submitted to our Company will be responded to in writing or electronically as soon as possible and no later than thirty days, depending on the nature of your request.