

Managed Access Programs / Post-Study Drug Supplies

Patient Consent

Dear Patient,

Your treating physician is submitting a request to Novartis for your treatment or your child's/ward's treatment. This privacy notice describes how Novartis Pharma AG, Lichtstrasse 35, 4056 Basel, Switzerland, processes your personal information in connection with your request under the Managed Access Program / Post-Study Drug Supplies program as the controller. For questions relating to privacy in Israel, you may also contact Novartis Israel Ltd., 6 Tozeret Haaretz Street, Tel Aviv, Israel, at dataprivacy.israel@novartis.com.

In this privacy notice, references to “we” or “us” mean Novartis. “You” means the patient whose data is processed as described in this document. If you receive this document because your treating physician has submitted a request for access to treatment for your child or ward, the term ‘you’ refers to your child or ward for whom the request is being made.

What data do we collect and what happens with it?

When submitting the request for access to your treatment, your treating physician is required to share certain data about you with Novartis (hereinafter referred to as “your data”).

Novartis receives personal information relating to you, including limited identifying details where required, and health information / highly sensitive medical information needed to review and manage the request, such as your medical condition and the information about the treatment you have received so far. Providing the requested information is voluntary. However, if the minimum personal information and medical information needed to review the request, manage the treatment supply, or comply with legal and safety obligations is not provided, Novartis may be unable to process the request or arrange treatment supply.

In case your treating physician requests a re-supply of the treatment for you, additional information about the treatment efficacy may also be requested. Other data, such as your initials, may be collected only if required by local laws or regulatory authorities. Novartis does not receive your directly identifiable information such as your name or address unless it is required for the shipment of your treatment as per the country requirements – in such case your name and contact details may be required for the shipment.

Novartis will process your personal information only for the specific purposes described in this notice and as otherwise required by applicable law, namely to manage the request; evaluate medical suitability and eligibility; arrange shipment where applicable; comply with pharmacovigilance, safety, and other legal / regulatory requirements; and keep required records:

Novartis may also further anonymize your data, which means that the data can no longer be linked back to you. Anonymized data may be used by Novartis for other purposes such as writing scientific publications and educational papers and may share it with others including external partners or health authorities.

Who can see your data?

Your data can be seen by:

- Institutional review boards or ethics committees,

- Novartis and their representatives,
- Third parties hired by Novartis to provide services related to the management of the request and other purposes outlined in this document,
- Health Authorities.

The people and organizations listed in the section above are required to keep your data confidential.

Your personal information may be processed in, accessed from, or stored outside Israel, including by Novartis group companies and service providers in Switzerland and other jurisdictions relevant to the program. Where personal information is transferred outside Israel, Novartis will use the transfer mechanism and safeguards required under applicable Israeli law. Where the transfer relies on your consent, this is included in the consent section below.

Novartis collects and uses your data based on your consent and to meet its legal obligations. Novartis will keep your personal information for 15 years, or for a longer period if required by applicable law, patient safety requirements, or regulatory record-retention obligations.

What are your privacy rights?

Subject to applicable laws and regulations, you have the right to request to review the personal information held about you and request correction or update of personal information that is incorrect, incomplete, unclear or outdated; request a copy of your personal information, where applicable; and withdraw your consent at any time, without affecting processing already carried out before the withdrawal. Any additional rights will apply only to the extent available under applicable law and subject to legal or regulatory restrictions.

Novartis may be restricted by law in following requests related to your privacy rights, it may e.g. not be possible to erase certain data, where data needs to be available for health authority purposes.

If you have any questions about your data or want to exercise your privacy rights, please contact your treating physician or Novartis Israel Ltd. at dataprivacy.israel@novartis.com. If you contact Novartis directly, Novartis may need additional information to verify your identity before handling your request.

You can also contact the Novartis data protection officer at the email address **global.privacy_office@novartis.com** or writing per post mail to “Global Data Privacy Office, Novartis Pharma AG, Lichtstrasse 35, 4056 Basel, Switzerland”. If you reach out directly to Novartis, and not through your physician, Novartis may know your identity. In addition to the rights above, you may have the right under applicable law to file a complaint with the ~~authority~~ Israeli Privacy Protection Authority.

This form will be retained by your physician.

By signing below, I confirm that I have read and understood this privacy notice. I consent to Novartis processing my personal information, including my health / highly sensitive medical information, for the purposes described in this notice. Where relevant, I also consent to the transfer of my personal information outside Israel as described in this notice.

Typed/printed name of **Patient /**
Parent/Guardian

Signature

Date