PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Xolair PFS, Solution for Injection

Active ingredient:
Each Xolair PFS syringe contains 150 mg/ml omalizumab.
Inactive and allergenic ingredients: see section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Allergic asthma:
Xolair is indicated for patients aged 6-12 years with persistent severe asthma and patients aged 12 years and above with moderate to severe persistent asthma, who have a positive skin test or a lab response to a perennial respiratory allergen and whose symptoms are not adequately controlled with inhaled corticosteroids. Xolair has shown reduced incidence of asthma flare-ups in these patients.

Limitations of use:
Xolair is not indicated for relief of acute bronchospasm or of status asthmaticus (asthma attack that lasts for more than 24 hours). Xolair is not indicated for treatment of other allergic conditions.

Chronic rhinosinusitis (inflammation of the nose and sinuses) with nasal polyps:
Xolair in combination with intranasal corticosteroids is indicated for the treatment of severe chronic rhinosinusitis with nasal polyps in adults (18 years of age and older) who did not achieve adequate control of the disease with intranasal corticosteroids.

Chronic spontaneous urticaria:
Xolair is indicated as an adjunct treatment for chronic spontaneous urticaria in adult and adolescent (12 years of age and older) patients with an inadequate response to H1 antihistamine treatment.

Therapeutic group: Medicines for obstructive airway diseases, other systemic medicines for obstructive airway diseases.

Xolair works by blocking a substance called immunoglobulin E (IgE) that is produced by the body.
IgE contributes to a type of inflammation that plays a key role in causing allergic asthma, chronic rhinosinusitis with nasal polyps and chronic spontaneous urticaria. Nasal polyps are small lumps in the nasal mucosa. Xolair helps to reduce their size and improves symptoms including nasal congestion, loss of sense of smell, post-nasal drip and runny nose.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient omalizumab or to any of the additional ingredients contained in the medicine (listed in section 6 "Further Information").

If you think you may be allergic to one of the ingredients, tell your doctor since you should not be given Xolair.

Special warnings regarding use of the medicine:
Before treatment with Xolair, tell the doctor if:
- you have kidney or liver problems.
- you have a disorder where your own immune system attacks parts of your own body (autoimmune disease).
- you are travelling to a region where infections caused by parasites are common, since Xolair may weaken your resistance to such infections.
- you have had a previous severe allergic reaction (anaphylaxis) caused, for example, by a medicine, an insect bite or food.
- you have ever had an allergic reaction to latex. The needle cap of the syringe may contain latex.

Xolair does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore, Xolair should not be used to treat such symptoms.
Xolair is not intended for the prevention or treatment of other types of allergy conditions, such as sudden allergic reactions, hyperimmunoglobulin E syndrome (Job's syndrome, an inherited immune disorder), aspergillosis (a fungus-related lung disease), food allergy, eczema or hay fever, since Xolair has not been studied in these conditions.

Pay attention to signs of allergic reactions and other serious side effects
Xolair may cause serious side effects. You must look out for signs of these conditions while using Xolair. Seek medical care immediately if you notice signs indicating severe allergic reactions or other serious side effects. Such signs are listed under "Serious side effects" in section 4. The majority of the severe allergic reactions occur within the first 3 doses of Xolair.

Children and adolescents:
Allergic asthma
Xolair is not intended for children under 6 years of age. Use of the medicine in children under 6 years of age has not been studied.
Chronic rhinosinusitis with nasal polyps
Xolair is not intended for children and adolescents under 18 years of age. Use of the medicine in patients under 18 years of age has not been studied.
Chronic spontaneous urticaria
Xolair is not intended for children under 12 years of age. Use of the medicine in children under 12 years of age has not been studied.

Drug interactions:
If you are taking, have recently taken, or may take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor, nurse or pharmacist. Particularly if you are taking:
- medicines to treat an infection caused by a parasite, as Xolair may reduce the effect of your medicines.
- inhaled corticosteroids and other medicines for allergic asthma.

Pregnancy and breastfeeding:
If you are pregnant, think you may be pregnant or are planning to become pregnant, tell your doctor before starting to use Xolair. Your doctor will discuss with you the benefits and potential risks of using this medicine during pregnancy.
If you become pregnant while using the medicine, tell your doctor immediately.
Xolair can pass into breast milk. If you are breastfeeding or plan to breastfeed, tell your doctor before using Xolair.

Driving and operating machinery:
It is unlikely that Xolair will affect your ability to drive and operate machinery.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation in accordance with the doctor's instructions.
Check with the doctor, nurse or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
Xolair is given in an injection under the skin (subcutaneous injection).
Instructions for injection by healthcare professionals are detailed in English at the end of the leaflet in the section **"Information for the healthcare professional"**.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:

Allergic asthma and chronic rhinosinusitis with nasal polyps
Your doctor will decide on the Xolair dosage you need and how often the medicine will be given to you. This will depend on your body weight and the results of blood tests carried out before the start of the treatment to measure the IgE level in your blood.
You will receive between one and four injections each time, once in two weeks or once in four weeks.
Continue taking your current medicine for asthma and/or chronic rhinosinusitis with nasal polyps during the course of treatment with Xolair. Do not stop taking any other medicine for asthma or chronic rhinosinusitis with nasal polyps without speaking to your doctor.
You may not see an immediate improvement after starting treatment with Xolair. In patients with chronic rhinosinusitis with nasal polyps, the effect was seen 4 weeks after starting treatment. In patients with asthma, it usually takes between 12 and 16 weeks until the full effect is achieved.

Chronic spontaneous urticaria
You will receive two injections of 150 mg each time, every four weeks.
Continue taking your current medicine for chronic spontaneous urticaria during the course of treatment with Xolair. Do not stop taking any medicine without first speaking to your doctor.

Use in children and adolescents
Allergic asthma
Xolair can be given to children and adolescents aged 6 years and older, who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high-dosage steroid inhalers and beta-agonist inhalers. The doctor will calculate the Xolair dosage your child needs and how often it needs to be given. This will depend on his body weight and the results of his blood tests carried out before the start of the treatment to measure IgE level.
Chronic rhinosinusitis with nasal polyps
Xolair should not be given to children and adolescents under 18 years of age.
Chronic spontaneous urticaria
Xolair can be given to adolescents aged 12 years and older, who are already receiving antihistamines, but whose chronic spontaneous urticaria symptoms are not well controlled by these medicines. The dosage for adolescents aged 12 years and older is identical to that of adults.

Do not exceed the recommended dose.

Mode of administration
Instructions on how to use and inject Xolair are provided in English later in the leaflet, in the section **"Information for the healthcare professional"**.
Xolair will be given to you as an injection under the skin (subcutaneous) by a doctor or nurse.
Carefully follow all the instructions that will be given to you by your doctor or nurse.

If you forgot to take the medicine
If you missed an appointment, contact your doctor or clinic/medical center as soon as possible to re-schedule.
Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine
Do not stop treatment with Xolair unless your doctor tells you to do so. Interrupting or stopping treatment with Xolair may cause your symptoms to come back.
However, if you are being treated for chronic spontaneous urticaria, your doctor may periodically stop treatment with Xolair so that your symptoms can be evaluated. Follow your doctor's instructions.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor, pharmacist or nurse.

4. SIDE EFFECTS

As with any medicine, use of Xolair may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. The side effects caused by Xolair are usually mild to moderate but may sometimes be serious.

Serious side effects:
Seek medical attention immediately if you notice any signs of the following side effects:

Rare side effects – effects that occur in 1-10 users in 10,000:
- Severe allergic reactions (including anaphylaxis). Symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue, larynx, windpipe or other parts of the body, rapid heartbeat, dizziness and lightheadedness, confusion, shortness of breath, wheezing or trouble breathing, bluing of the skin or lips, collapse and loss of consciousness.
  If you have a history of severe allergic reactions (anaphylaxis) unrelated to Xolair, you may be at a higher risk of developing a severe allergic reaction following use of Xolair.
- Systemic lupus erythematosus (SLE). Symptoms may include muscle pain, joint pain and swelling, rash, fever, weight loss and fatigue.

Side effects of unknown frequency (effects whose frequency has not been determined yet):
- Churg-Strauss syndrome or hypereosinophilic syndrome. The symptoms may include one or more of the following: swelling, pain or rash around blood or lymph vessels, high level of a specific type of white blood cells (excess eosinophils), worsened breathing problems, nasal congestion, heart problems, pain, numbness, tingling in the arms and legs.
- Low blood platelet count with symptoms such as bleeding or bruising more easily than normal.
- Serum sickness. Symptoms may include one or more of the following: joint pain with or without swelling or stiffness, rash, fever, swollen lymph nodes, muscle pain.

Additional side effects include:
Very common side effects – effects that occur in more than 1 user in 10:
- Fever (in children).

Common side effects – effects that occur in 1-10 users in 100:
- Reactions at the injection site, including pain, swelling, itching and redness.
- Pain in the upper part of the stomach.
- Headache (very common in children).
- Upper respiratory tract infections, such as pharyngitis and cold.
- Pressure or pain in the cheeks and forehead (sinusitis, headaches caused by the sinuses).
- Joint pain.
- Feeling dizzy.

Uncommon side effects – effects that occur in 1-10 users in 1,000:
- Feeling sleepy or tired.
- Tingling or numbness of the hands or feet.
- Fainting, low blood pressure while sitting or standing (postural hypotension), flushing.
- Sore throat, coughing, acute breathing problems.
- Nausea, diarrhea, indigestion.
- Itching, hives, rash, increased sensitivity of the skin to sun.
- Weight gain.
- Flu-like symptoms.
- Swollen arms.

Rare side effects – effects that occur in 1-10 users in 10,000:
- Parasitic infection.

Side effects of unknown frequency (effects whose frequency has not been determined yet):
- Muscle pain and joint swelling.
- Hair loss.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult a doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.
In addition, they can be reported to Novartis via the following email address: Safetydesk.israel@novartis.com.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**
  Store refrigerated (2°C-8°C). Do not freeze. Store in the original package to protect from light.
  Can be stored at a temperature of up to 25°C for up to 48 hours before use.
- Do not use packages that are damaged or look as if they were tampered with.
- Do not use the preparation if the syringe fell on a hard surface or fell after removing the needle cap.
- Do not shake the syringe.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
L- arginine hydrochloride, L-histidine hydrochloride monohydrate, L-histidine, Polysorbate 20 and Water for injections.
The syringe needle cap may contain latex.

What the medicine looks like and the contents of the package:
A pre-filled syringe containing a clear to slightly opaque, colorless to brown-pale yellow solution.
Each package contains one 0.5 ml (75 mg omalizumab) pre-filled syringe or one 1 ml (150 mg omalizumab) pre-filled syringe.
The 0.5 ml (75 mg omalizumab) pre-filled syringe has a blue syringe shield, while the 1 ml (150 mg omalizumab) pre-filled syringe has a purple syringe shield.
Not all package sizes may be marketed.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B. 9240, Tel Aviv.

Revised in July 2025.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 177 91 37147

מידע לצוות הרפואי

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

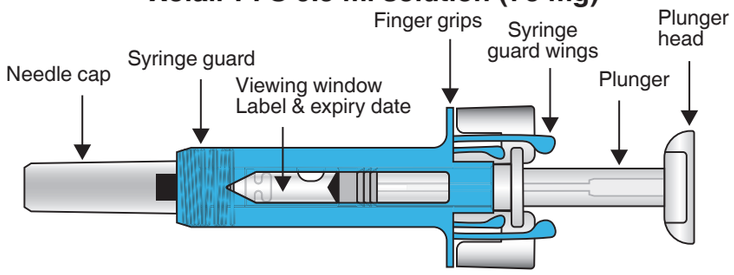
המידע הבא מיועד לאנשי הצוות הרפואי בלבד:
المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط:

The following information is intended for healthcare professionals only:

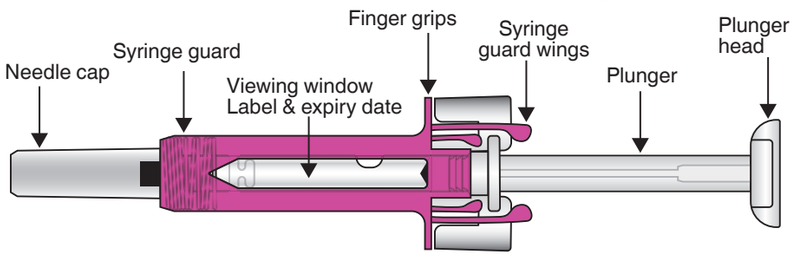
INSTRUCTIONS FOR USE OF XOLAIR PRE-FILLED SYRINGE

Read ALL the way through these instructions before injecting. The box contains Xolair pre-filled syringe(s) individually sealed in a plastic tray.

Xolair PFS 0.5 ml solution (75 mg)



Xolair PFS 1 ml solution (150 mg)



After the medicine has been injected, the syringe guard will be activated to cover the needle. This is intended to protect against accidental needlestick injuries.

Other items you need for your injection:

- Alcohol swab
- Cotton ball or gauze
- Sharps disposal container

Important safety information

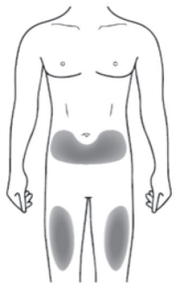
Caution: Keep the syringe out of the sight and reach of children.

- The needle cap of the syringe may contain dry rubber (latex), which should not be handled by anyone who is sensitive to this substance.
- Do not open the sealed outer box until you are ready to use this medicine.
- Do not use this medicine if either the seal on the outer box or the seal of the plastic tray is broken, as it may not be safe for you to use.
- Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.
- Never leave the syringe where others might tamper with it.
- Do not shake the syringe.
- Be careful not to touch the syringe guard wings before use. If the wings are touched, the syringe guard may be activated too early.
- Do not remove the needle cap until just before you give the injection.
- The syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.

Storage of Xolair PFS

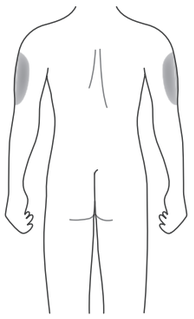
- Store this medicine sealed in its outer box to protect it from light. Store in the refrigerator between 2°C and 8°C. DO NOT FREEZE.
- Remember to take the syringe out of the refrigerator and allow it to reach room temperature (25°C) before preparing it for injection (it will take about 30 minutes). Leave the syringe in the box to protect it from light. The total time that the syringe is kept at room temperature (25°C) before use must not exceed 48 hours.
- Do not use the syringe after the expiry date which is stated on the outer box and syringe label. If it has expired, return the entire pack to the pharmacy.

The injection site



The injection site is the place on the body where you are going to use the syringe.

- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 5 centimeters around the navel (belly button).
- If you need to give more than one injection for the full dose, choose a different injection site each time you inject.
- Do not inject into areas where the skin is tender, bruised, red or hard. Avoid areas with scars or stretch marks.



If a healthcare professional is giving the injection, the outer upper arms may also be used.

Preparing Xolair PFS

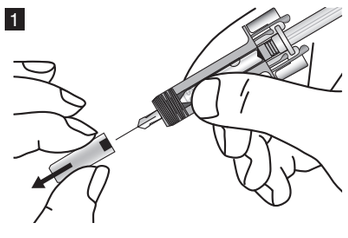
Note: Depending on the dose prescribed by the doctor, you may need to prepare one or more pre-filled syringes and inject the contents of them all. The following table gives examples of how many injections of each dose strength is needed for a given dose:

Dose	Syringes needed for the dose
75 mg	1 blue
150 mg	1 purple (150 mg)
225 mg	1 blue (75 mg) + 1 purple (150 mg)
300 mg	2 purple (150 mg)
375 mg	1 blue (75 mg) + 2 purple (150 mg)
450 mg	3 purple (150 mg)
525 mg	1 blue (75 mg) + 3 purple (150 mg)
600 mg	4 purple (150 mg)

1. Take the box containing the syringe out of the refrigerator and leave it **unopened** for about 30 minutes so that it reaches room temperature (leave the syringe in the box to protect it from light).
2. When you are ready to use the syringe, wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Remove the plastic tray from the box and peel back the paper cover. Gripping the middle of the blue/purple syringe guard, lift the syringe out of the tray.
5. Inspect the syringe. The liquid should be clear to slightly cloudy. Its color may vary from colorless to pale brownish-yellow. You may see an air bubble, which is normal. DO NOT USE if the syringe is broken or if the liquid looks distinctly cloudy or distinctly brown, or contains particles. In all these cases, return the entire pack to the pharmacy.
6. Holding the syringe horizontally, look into the viewing window to check the expiry date printed on the label. Note: It is possible to rotate the inner part of the syringe assembly so that the label can be read in the viewing window. DO NOT USE if the product has expired. If expired, return the entire pack to the pharmacy.

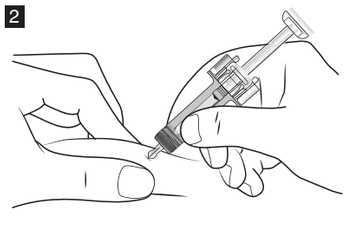
How to use Xolair PFS

1



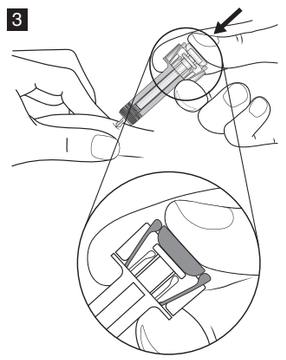
Carefully remove the needle cap from the syringe. Discard the needle cap. You may see a drop of liquid at the end of the needle. This is normal.

2



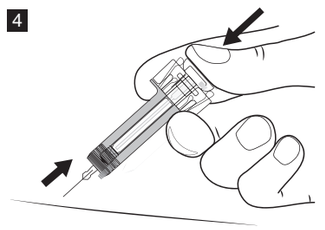
Gently pinch the skin at the injection site and insert the needle as shown. Push the needle all the way in to ensure that the medicine can be fully administered.

3



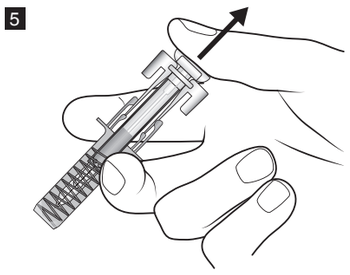
Hold the syringe as shown. **Slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the syringe guard wings.

4



Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site.

5



Slowly release the plunger and allow the syringe guard to automatically cover the exposed needle.

There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 30 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

Disposal instructions

Dispose of the used syringe immediately in a sharps container (closable, puncture-resistant container). For the safety and health of you and others, needles and used syringes **must never** be re-used. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Do not throw away any medicines via wastewater or household waste.