Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Xolair® 150 mg, powder and solvent for solution for injection

Active ingredient:

omalizumab 150 mg

Inactive ingredients and allergens: see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Allergic asthma:

Xolair is indicated for patients 6 to 12 years of age with severe persistent asthma and for patients 12 years of age and older with moderate to severe persistent asthma, who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.

Limitations of use:

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

Chronic rhinosinusitis (inflammation of the nose and sinuses) with nasal polyps:

Xolair is indicated as add-on therapy with intranasal corticosteroids for the treatment of adults (18 years of age and older) with severe chronic rhinosinusitis with nasal polyps for whom therapy with intranasal corticosteroids does not provide adequate disease control.

Chronic spontaneous urticaria:

Xolair is indicated as add-on therapy for the treatment of chronic spontaneous urticaria in adult and adolescent (12 years and above) patients with inadequate response to H1 antihistamine treatment.

Therapeutic group: obstructive airway disease medicines, other systemic medicines for obstructive airway disease.

Xolair works by blocking a substance called immunoglobulin E (IgE) which 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 growths on the lining of the nose. Xolair helps to reduce the size of the polyps and improves symptoms including nasal congestion, loss of sense of smell, post-nasal drip (mucus in the back of the throat) and runny nose.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient omalizumab or any of the other ingredients of this medicine (listed in section 6).

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

Special warnings about using this medicine

Before using Xolair, tell your 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 - Xolair may weaken your resistance to such infections.
- you have had a previous severe allergic reaction (anaphylaxis) for example resulting from a medicine, an insect bite, or food.

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 meant to prevent or treat other allergy-type conditions, such as sudden allergic reactions, hyperimmunoglobulin E syndrome (an inherited immune syndrome), aspergillosis (a fungus-related lung disease), food allergy, eczema or hay fever, because Xolair has not been studied in these conditions.

Look out for signs of allergic reactions and other serious side effects

Xolair can potentially cause serious side effects. You must look out for signs of these conditions while you use Xolair. Seek medical help immediately if you notice any signs indicating possible serious side effects. Such signs are listed under "Serious side effects" in section 4. Most serious 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. Its use 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. Its use 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. Its use in children under 12 years of age has not been studied.

Drug Interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor 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, breastfeeding, and fertility:

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor before you start using Xolair. Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy.

If you become pregnant while being treated with this medicine, tell your doctor immediately.

Xolair may pass into breast milk. If you are breast-feeding or plan to breast-feed, tell your doctor before using Xolair.

Driving and using machines:

It is unlikely that Xolair will affect your ability to drive and use machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

Allergic asthma and chronic rhinosinusitis with nasal polyps

Your doctor will decide how much Xolair you need and how often you will be given it. This depends on your body weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in your blood.

You will be given 1 to 4 injections at a time, either every two weeks, or every four weeks.

Keep taking your current asthma and/or chronic rhinisinusitis with nasal polyps medicine during Xolair treatment. Do not stop taking any asthma and/or chronic rhinisinusitis with nasal polyps medicine without talking to your doctor.

You may not see an immediate improvement after beginning Xolair therapy. In patients with chronic rhinisinusitis with nasal polyps, the effect has been seen 4 weeks after the start of the treatment. In asthma patients it usually takes between 12 and 16 weeks to have the full effect.

Chronic spontaneous urticaria

You will be given two 150 mg injections at a time every four weeks.

Keep taking your current medicine for chronic spontaneous urticaria during Xolair treatment. Do not stop taking any medicine without talking to your doctor first.

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 dose steroid inhalers and beta-agonist inhalers. Your doctor will work out how much Xolair your child needs and how often it needs to be given. This will depend on your child's weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in his/her blood.

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 dose for adolescents aged 12 years and above is the same as for adults.

Do not exceed the recommended dose.

How Xolair is given

Instructions on how to use Xolair are given below in the section "Information for the healthcare professional".

Xolair will be given to you by a doctor or nurse as an injection just under the skin (subcutaneously).

Carefully follow all instructions given by your doctor or nurse.

If you forget to take this medicine

Contact your doctor or clinic/healthcare center as soon as possible to schedule a new appointment.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Do not stop treatment with Xolair unless your doctor tells you to. Interrupting or stopping the treatment with Xolair may cause your symptoms to come back.

However, if you are being treated for chronic spontaneous urticaria, your doctor may stop Xolair treatment from time to time so that your symptoms can be assessed. Follow your doctor's instructions.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Xolair may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them. The side effects caused by Xolair are usually mild to moderate but can occasionally be serious.

Serious side effects:

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

Rare side effects - affect 1-10 in 10,000 users

- Severe allergic reactions (including anaphylaxis). Symptoms may include rash, itching or hives on the skin, swelling of the face, lips, tongue, voice box, windpipe or other parts of the body, fast heartbeat, dizziness and light-headedness, confusion, shortness of breath, wheezing or trouble breathing, blue skin or lips, collapsing and losing consciousness.

  If you have a history of severe allergic reactions (anaphylaxis) that are unrelated to Xolair, you may be more at 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 (the frequency of these effects has not been established yet)

- Churg-Strauss syndrome or hypereosinophilic syndrome. 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 (marked eosinophilia), worsening problems with breathing, 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.

Other side effects include:

Very common side effects - affect more than one in ten users

- fever (in children)

Common side effects - affect 1-10 in 100 users

- reactions at the injection site including pain, swelling, itching and redness
- pain in the upper part of the abdomen
- headache (very common in children)
- upper respiratory tract infection, such as inflammation of the pharynx and common cold
- feeling of pressure or pain in the cheeks and forehead (sinusitis, sinus headache)
- pain in joints
- feeling dizzy

Uncommon side effects - affect 1-10 in 1,000 users

- 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 increase
- flu-like symptoms
- swollen arms

Rare side effects - affect 1-10 in 10,000 users

- parasitic infection

Side effects of unknown frequency (the frequency of these effects has not been established yet)

- muscle pain and joint swelling
- hair loss

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:**

  Keep refrigerated (2°C-8°C). Do not freeze.

  Storage conditions after reconstitution by your healthcare provider: keep refrigerated (2°C-8°C) up to 8 hours.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Vial with powder:

Sucrose, L-histidine HCl monohydrate, L-histidine, polysorbate 20.

Ampoule with solvent:

Water for injection.

What the medicine looks like and what is the contents of the pack:

Powder: white to off-white powder packaged in a glass vial.

Solvent: clear, colorless liquid (water for injections) in a 2 ml glass ampoule.

The powder is reconstituted in the water before it is injected by a doctor or nurse.

The reconstituted solution contains 125 mg/ml omalizumab (150 mg in 1.2 ml).

The reconstituted solution is colorless to pale yellowish-brown, clear to slightly opalescent.

Each pack contains one vial with powder and one ampoule of solvent.

Registration holder and importer's name and address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in November 2020.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 132-61-31124

מידע לצוות הרפואי

מלומות للطاقم الطبي

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for healthcare professionals only:

The lyophilised medicinal product takes 15-20 minutes to dissolve, although in some cases it may take longer. The fully reconstituted medicinal product will appear clear to slightly opalescent, colourless to pale brownish-yellow and may have a few small bubbles or foam around the edge of the vial. Because of the viscosity of the reconstituted medicinal product care must be taken to withdraw all of the medicinal product from the vial before expelling any air or excess solution from the syringe in order to obtain the 1.2 ml.

To prepare Xolair 150 mg vials for subcutaneous administration, please adhere to the following instructions:

1. Draw 1.4 ml of water for injections from the ampoule into a 3 ml syringe equipped with a large-bore 18-gauge needle.
2. With the vial placed upright on a flat surface, insert the needle and transfer the water for injections into the vial containing the lyophilised powder using standard aseptic techniques, directing the water for injections directly onto the powder.
3. Keeping the vial in an upright position, vigorously swirl it (do not shake) for approximately 1 minute to evenly wet the powder.
4. To aid in dissolution after completing step 3, gently swirl the vial for 5-10 seconds approximately every 5 minutes in order to dissolve any remaining solids.

   Note that in some cases it may take longer than 20 minutes for the powder to dissolve completely. If this is the case, repeat step 4 until there are no visible gel-like particles in the solution.

   When the medicinal product is fully dissolved, there should be no visible gel-like particles in the solution. Small bubbles or foam around the edge of the vial are common. The reconstituted medicinal product will appear clear to lightly opalescent, colourless to pale brownish-yellow. Do not use if solid particles are present.
5. Invert the vial for at least 15 seconds in order to allow the solution to drain towards the stopper. Using a new 3-ml syringe equipped with large-bore, 18-gauge needle, insert the needle into the inverted vial. Keeping the vial inverted position the needle tip at the very bottom of the solution in the vial when drawing the solution into the syringe. Before removing the needle from the vial, pull the plunger all the way back to the end of the syringe barrel in order to remove all of the solution from the inverted vial.
6. Replace the 18-gauge needle with a 25-gauge needle for subcutaneous injection.
7. Expel air, large bubbles, and any excess solution in order to obtain the required 1.2 ml dose. A thin layer of small bubbles may remain at the top of the solution in the syringe. Because the solution is slightly viscous, it may take 5-10 seconds to administer the solution by subcutaneous injection.

   The vial delivers 1.2 ml (150 mg) of Xolair. For a 75 mg dose, draw up 0.6 ml into the syringe and discard the remaining solution.
8. The injections are administered subcutaneously in the deltoid region of the arm, the lower abdomen (but not the area 5 centimetres around the navel), or the thigh.