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2. Omalizumab

Omalizumab

Pronunciation: *OH ma LIZ oo mab***Brand name:** [Xolair](#)**Dosage form:** Autoinjector (75 mg/0.5 mL, 150 mg/mL, 300 mg/2), Prefilled syringe (75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL), vial for reconstitution (150 mg)**Drug class:** [Selective immunosuppressants](#)Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Jan 24, 2025.[Uses](#) [Side effects](#) [Warnings](#) [Before taking](#) [Dosage](#) [Interactions](#) [FAQ](#)

What is omalizumab?

Omalizumab (Xolair) injection is used to reduce the risk of severe food allergy reactions ([anaphylaxis](#)) and help improve allergic [asthma](#), [nasal polyps](#), and chronic hives.

Omalizumab is given as an injection under the skin every 2 to 4 weeks and can be self-injected using a pen (autoinjector) or a prefilled syringe. Omalizumab is an anti-IgE antibody that works by blocking a protein from your immune system called IgE, which helps to reduce allergy symptoms. **Omalizumab is a preventative medicine** that reduces symptoms caused by allergies; **it does not treat acute asthma or emergency allergic reactions**, including anaphylaxis.

Omalizumab FDA approval was granted on June 20, 2003, for Genetech and Novartis Pharmaceutical.

Omalizumab brand name is Xolair.

What is omalizumab used for?

Omalizumab is used to treat:

- **food allergies to reduce allergic reactions** including anaphylaxis after accidentally eating food you are allergic to. Omalizumab can be used for IgE-mediated food allergy in adults and children aged 1 year and older. May be given repeatedly and should be used in conjunction with food allergen avoidance. It should not be used for the emergency treatment of allergic reactions, including anaphylaxis.
- **moderate to severe asthma** that is caused by allergies for adults and children who are at least 6 years old. It can be used if asthma symptoms are not controlled by asthma-inhaled steroid medicine. It is not a rescue medicine for treating an asthma attack.
- **chronic hives with no known cause (chronic spontaneous urticaria)** in adults and children who are at least 12 years old. It can should only be used if antihistamine medicines have been tried but were not successful. It should not be used for other forms of hives.
- **nasal polyps** in people 18 years of age and older as an add-on medicine if medicines called nasal corticosteroids

have not worked well

How does omalizumab work?

If you have allergies, your overactive immune system produces antibodies called Immunoglobulin E (IgE) which bind to receptors on cells in the immune system (mast cells). When you are exposed to the allergen (food, dust, grass) the allergen binds to IgE on the cells which sets off an allergic reaction triggering the release of chemicals like histamine, which causes the allergic reaction.

Omalizumab mechanism of action is by blocking the binding of IgE to receptors on cells, which in turn stops the release of the chemicals responsible for allergy symptoms. Omalizumab also reduces the number of IgE receptors on cells, resulting in further improvement of allergy symptoms.

Omalizumab side effects

Common omalizumab side effects

Common omalizumab side effects include:

- fever;
- rash;
- nausea, vomiting, diarrhea, stomach pain;
- Itching or a skin rash;
- headache;
- dizziness;
- joint pain usually in arms or legs, bone fractures;
- ear pain, ear infection;
- Swelling in sinuses, nose or throat;
- Throat infection
- nose bleeds
- injection site reaction with pain, bruising, swelling, or irritation where the medicine was injected; or
- cold symptoms such as stuffy nose, sneezing, sinus pain, cough, sore throat.

The common omalizumab side effects vary depending on the condition being treated and the age group of the patient.

Serious omalizumab side effects

Some people using omalizumab have had a severe, life-threatening allergic reaction either right after the injection or hours later. Allergic reactions may occur even after using the medication regularly for a year or longer.

Get emergency medical help if you have any signs of an allergic reaction to omalizumab:

- hives, itching;

- anxiety or fear, feeling like you might pass out;
- flushing (warmth, redness, or tingly feeling);
- chest tightness, wheezing, cough, feeling short of breath, difficult breathing;
- fast or weak heartbeats; or
- swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have:

- ongoing nausea or vomiting, severe or watery diarrhea;
- trouble breathing;
- numbness or tingling in your arms or legs;
- fever, muscle pain, and rash within a few days after receiving an injection;
- signs of an ear infection - fever, ear pain or full feeling, trouble hearing, drainage from the ear, fussiness in a child;
- heart attack symptoms - chest pain or pressure, pain spreading to your jaw or shoulder; or
- signs of a blood clot - sudden numbness or weakness, problems with vision or speech, coughing up blood, swelling or redness in an arm or leg.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

 [Omalizumab side effects](#) (more detail)

Related/similar drugs

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Dupixent may be used to treat eczema, eosinophilic or oral-corticosteroid-dependent asthma, chronic ...

Reviews & ratings

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Prednisone

Prednisone is used to treat allergic disorders, ulcerative colitis, psoriasis and arthritis. Learn ...

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Warnings

Some people using this injection have had a severe, life-threatening allergic reaction either right after the injection or hours later. Allergic reactions may occur even after using this injection regularly for a year or longer.

Get emergency medical help if you have any signs of an allergic reaction to omalizumab: hives, rash; anxiety or fear; flushing (warmth, redness, or tingly feeling); feeling like you might pass out; chest tightness, wheezing, feeling short of breath, difficult breathing; fast or weak heartbeats; swelling of your face, lips, tongue, or throat.

Asthma is often treated with a combination of different drugs. Use all medications as directed by your doctor. Read the medication guide or patient instructions provided with each medication. Do not change your doses or medication schedule without your doctor's advice.

If you also use an oral steroid medication, do not stop using the steroid suddenly or you may have unpleasant withdrawal symptoms. Talk with your doctor if any of your asthma medications do not seem to work as well in treating or preventing attacks. Your symptoms may not improve right away once you start receiving omalizumab. For best results, keep receiving the injection as directed. Talk with your doctor if your symptoms do not improve after a few weeks of treatment.

Omalizumab should not be used for the emergency treatment of allergic reactions, including anaphylaxis. It is only used in food allergy to reduce the risk of allergic reactions.

Use omalizumab regularly to get the most benefit. Get your prescription refilled before you run out of medicine completely.

Before taking this medicine

You should not use this medicine if you are allergic to omalizumab, or any of the inactive ingredients. See the bottom of this document for a full list of ingredients. To make sure omalizumab is safe for you, tell your doctor if you have:

- any signs of infection (fever, swollen glands, general ill feeling)
- any other allergies (foods, pollens, etc.)
- an infection caused by parasites (such as giardia, malaria, leishmaniasis, hookworm, pinworm, toxoplasmosis, and many others)
- past or present cancer
- a history of heart attack or stroke
- if you are receiving allergy shots
- if you have ever had a severe allergic reaction (anaphylaxis)
- if you have a latex allergy, as the needle cap on the prefilled syringe contains a type of natural rubber latex.

Using this injection may increase your risk of certain types of cancers of the breast, skin, prostate, or salivary gland. Talk to your doctor about your individual risk.

While you are using this medicine, you may also have an increased risk of becoming infected with parasites (worms) if you live in or travel to areas where such infections are common. Talk with your doctor about what to look for and how to treat this condition.

Pregnancy

Tell your doctor if you are pregnant or plan to become pregnant during treatment. If you become pregnant while using this injection, call your doctor.

If you are pregnant, your name may be listed on a pregnancy registry. This is to track the outcome of the pregnancy and to evaluate any effects of omalizumab on the baby.

Breastfeeding

It is not known whether omalizumab could harm a nursing baby. Tell your doctor if you are breastfeeding or planning to breastfeed a baby..

How should I use omalizumab?

Before you start treatment with this medicine, your doctor may perform an allergy skin test or blood test to make sure this medicine is right for you.

Omalizumab is given as an injection under the skin (subcutaneous injection). When you first start your treatment, the injection will be given to you by your healthcare provider.

You will be watched closely for a short time after receiving the injection to make sure you do not have an allergic reaction to the medication.

Your healthcare provider may decide that the injections can be administered by you or a caregiver, and you will receive training on the right way to prepare and inject this medicine. Do not try to inject omalizumab until you have been shown the right way to use the prefilled syringe injections.

For children 12 years of age and older, the prefilled syringe may be self-injected under adult supervision. For children 6 to 11 years of age, the prefilled syringe should be injected by a caregiver.

Omalizumab is usually given every 2 or 4 weeks, depending on what condition you are treating.

Your condition may be treated with a combination of drugs. Use all medications as directed by your doctor. Read the medication guide or patient instructions provided with each medication. Do not change your doses or medication schedule without your doctor's advice.

If you also use a steroid medicine, do not stop using it suddenly, or you may have unpleasant withdrawal symptoms. Talk with your doctor if any of your asthma medications do not seem to work as well in treating or preventing attacks.

While using this medicine, you may need frequent medical tests, such as allergy tests and lung function tests. Your stools may also need to be checked for parasites, especially if you travel.

Your condition may not improve right away. For best results, keep receiving the medication as directed. Talk with your doctor if your symptoms do not improve after a few weeks of treatment.

Omalizumab Prefilled Syringe instructions:

- Take the carton containing the prefilled syringe out of the refrigerator. Set aside the carton for at least 15 to 30 minutes so the prefilled syringe can warm up on its own to room temperature. Leave the prefilled syringe in the carton to protect it from light.
- Do not speed up the warming process using any heat sources such as warm water or a microwave.
- Check the contents of the prefilled syringe for particulate matter and discoloration prior to administration. The solution should be clear and colorless to pale brownish yellow. Do not use the prefilled syringe if the medicine is cloudy, discolored, or contains particles.
- Check the number of prefilled syringes needed for the patient's dosage.
- For patients requiring more than 1 injection to complete a full dose, administer each injection at least 1 inch apart from other injection sites.
- Use the injection within 4 hours after taking it out of the refrigerator.
- Administer subcutaneous injection into the thigh or abdomen, avoiding the 2-inch (5 cm) area directly around the navel. The outer area of the upper arms may be used only if the injection is being given by a caregiver or healthcare provider. The injection may take 5-10 seconds to administer.

- Dispose of the used syringe in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

For more instructions, including diagrams for all Xolair device types and how to inject, see [Xolair Instructions For Use](#).

Omalizumab dosing information

Usual omalizumab dose for food allergy (IgE-Mediated):

Dose: 75 mg to 600 mg subcutaneously every 2 or 4 weeks.

- Determine the dosage and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and the person's body weight (kg).
- See the dose determination chart in the prescribing information.

Usual adult and pediatric dose for asthma:

Dose: 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks. Dose and frequency of injection is based on weight and pre-treatment IgE levels.

Comments:

- Interruptions lasting less than 1 year: Dose based on serum IgE levels obtained at the initial dose determination.
- Interruptions lasting 1 year or more: Retest total serum IgE levels for dose determination.
- Periodically reassess the need for continued therapy based on the patient's disease severity and level of asthma control.

Use: Management of moderate to severe persistent asthma in patients (12 Years and Older) who are inadequately controlled with inhaled corticosteroids and with a positive skin test or in vitro reactivity to a perennial aeroallergen.

Usual Adult Dose for Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Dose: 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks. The dose and frequency of injection are based on weight and pre-treatment IgE levels. Click on the link below "Detailed Xolair dosage information" for dose details.

Comments:

- Periodically reassess the need for continued therapy based upon the patient's disease severity and level of symptom control.
- Interruptions lasting less than 1 year: Dose based on serum IgE levels obtained at the initial dose determination.
- Interruptions lasting 1 year or more: Retest total serum IgE levels for dose determination.

Use: As an add-on maintenance treatment for Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

Usual Adult Dose for Chronic Spontaneous Urticaria (CSU):

Dose: 150mg or 300 mg subcutaneously every 4 weeks.

Comments:

- Dosing is not dependent on IgE levels or body weight.
- Avoid administering more than 150 mg per injection site.
- The appropriate duration of therapy for CSU has not been evaluated. Periodically reassess the need for continued therapy.

Use: Chronic idiopathic urticaria in patients remaining symptomatic after H1 antihistamine treatment..

i [Detailed Omalizumab dosage information](#)

Xolair formulations

Xolair Autoinjector (single-dose prefilled): 75 mg/0.5 mL, 150 mg/mL and 300 mg/2 mL

Prefilled syringe (single-dose): 75 mg/0.5 mL, 150 mg/mL, and 300 mg/2 mL

Single-dose vial for reconstitution: 150 mg lyophilized powder

What happens if I miss a dose?

Call your doctor for instructions if you miss an appointment for your injection.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What other drugs will affect omalizumab?

Other drugs may interact with this medicine including prescription and over-the-counter medicines, vitamins, and herbal products. Tell each of your healthcare providers about all medicines you use now and any medicine you start or stop using.

It is important to tell your doctor or healthcare provider if you have any of the following: allergy shots (a series of injections given regularly to prevent the body from developing allergic reactions to specific substances) and medications that suppress your immune system. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

This list is not complete. Many other drugs may interact with Xolair, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

i [Omalizumab drug interactions](#) (more detail)

Does omalizumab interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

omalizumab

+

Enter a drug name

Add

Storage

- Store in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep your unused prefilled syringes in the original carton until use to protect them from light.
- The Xolair prefilled syringe can be removed and placed back in the refrigerator if needed. The total combined time out of the refrigerator may not exceed 2 days.
- Do not use the prefilled syringe if it is exposed to temperatures above 77°F (25°C) and discard it in a sharps disposal container.
- Do not freeze. Do not use if prefilled syringes have been frozen.
- Keep this medicine out of direct sunlight.
- Do not use this medicine if it is past the expiration date.

Ingredients

Active ingredient: omalizumab

Inactive ingredients:

Xolair Prefilled syringe or autoinjector: L-arginine hydrochloride, L-histidine, L-histidine hydrochloride monohydrate, and polysorbate 20.

Xolair Vial: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 20 and sucrose.

Manufacturer

Manufactured by:

- Genentech, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990. U.S. License No.: 1048.

Jointly marketed by:

- Genentech USA, Inc., A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990.
- Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936-1080.

Omalizumab Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for omalizumab.

Xolair (omalizumab) - Genentech, Inc.



Formulation type	Strength
Autoinjector	150 mg/mL
Autoinjector	300 mg/2 mL
Autoinjector	75 mg/0.5 mL
Pre-Filled Syringe	150 mg/mL
Pre-Filled Syringe	300 mg/2 mL
Pre-Filled Syringe	75 mg/0.5 mL
Single-Dose Vial	150 mg

View [Xolair](#) information in detail.

Popular FAQ

Is Xolair an immunosuppressant?



How long before Xolair starts working?



How does Xolair work?



Does Xolair cause weight gain?



What is omalizumab's mechanism of action?



Can Xolair be self-administered at home?



Omalizumab and Covid-19 vaccine, what should I know?



What is Xolair approved for?



More FAQ

- [What are the most common skin conditions? \(with photos\)](#)

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References

1. [Food and Drug Administration \(FDA\) Xolair Product Label](#)
2. [Omalizumab: Clinical Use for the Management of Asthma](#)

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- [Asthma](#)
- [Asthma, Maintenance](#)
- [Chronic Rhinosinusitis With Nasal Polyps](#)
- [Nasal Polyps](#)

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal


circumstances.

[Medical Disclaimer](#)


DRUG STATUS

- Availability

Rx Prescription only
- [Pregnancy & Lactation](#)

 Risk data available
- CSA Schedule*

N/A Not a controlled drug
- Approval History

 Drug history at FDA



User Reviews & Ratings

7.6 / 10

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