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Xolair

Generic name: [omalizumab](#) [OH-ma-LIZ-oo-mab]

Dosage forms: 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), ... [show all 3 dosage forms](#)

Drug class: [Selective immunosuppressants](#)

Medically reviewed by [Melisa Puckey, BPharm](#). Last updated on Mar 31, 2025.

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What is Xolair?

Xolair (omalizumab) injection is a medication used to treat types of allergic [asthma](#), [nasal polyps](#), [chronic hives](#) (chronic spontaneous urticaria), and to reduce the risk of severe food allergy reactions ([anaphylaxis](#)). Xolair works by reducing the release of inflammatory substances that cause allergy symptoms, thereby decreasing allergic responses in the body. Xolair is an anti-IgE antibody that blocks a protein from your immune system called IgE, which helps to reduce allergy symptoms.

Xolair can be self-injected under the skin using a Xolair pen (autoinjector) or a prefilled syringe, every 2 or 4 weeks, to maintain its therapeutic effects.

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

- [Omlyclo](#) is an interchangeable biosimilar to Xolair approved on March 7, 2025.

How does Xolair work?

If you have allergies, your overactive immune system produces antibodies called Immunoglobulin E (IgE) which bind to receptors on cells, triggering the release of chemicals like histamine that cause allergy symptoms.

When you are exposed to the allergen (food, dust, grass), the allergen binds to IgE on the cells, triggering the release of chemicals like histamine, which causes the allergic reaction.

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

What is Xolair used for?

Xolair is FDA-approved to treat:

- **Food allergies to reduce allergic reactions including anaphylaxis** after accidentally eating food you are allergic to. Xolair can be used for IgE-mediated food allergy in adults and children aged 1 year and older. May be given regularly 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.
- **Chronic Rhinosinusitis with nasal polyps** in people 18 years of age and older as an add-on medicine if medicines called nasal corticosteroids have not worked well

Xolair Food Allergies

In February 2024, the FDA approved **Xolair to help reduce allergic reactions—including anaphylaxis—after accidental exposure to multiple foods**. It is not a cure for food allergies and doesn't replace the need to avoid allergenic foods, but it may offer protection for people with multiple severe food allergies.

Xolair is approved for patients aged 1 year and older with confirmed IgE-mediated food allergies to peanuts, milk, eggs, wheat, tree nuts, or other foods. Patients must continue to carry an epinephrine auto-injector.

Clinical trial Xolair for Food Allergy

A multi-center, double-blind, placebo-controlled trial [NCT03881696](#) studied 168 patients (ages 1 and older) with confirmed allergies to peanuts and at least two additional foods (milk, egg, wheat, cashew, hazelnut, or walnut). Participants were treated for 16–20 weeks with either Xolair or placebo.

Peanut allergy:

- **68% of Xolair-treated patients** (75 of 110) tolerated 600+ mg of peanut protein (about 2.5 peanuts) without moderate to severe symptoms.
- Only 6% of placebo patients (3 of 55) reached this level.
- However, 17% of Xolair-treated patients saw no significant improvement and could not tolerate even 100 mg.

Cashew, Milk, and Egg allergy

Tolerances: At 1,000+ mg protein challenge:

- **Cashew: 42% (Xolair)** vs. 3% (placebo)
- **Milk: 66% (Xolair)** vs. 11% (placebo)
- **Egg: 67% (Xolair)** vs. 0% (placebo)

Learn more from the official FDA announcement here: [FDA Approves Xolair as First and Only Medicine for Children and Adults With One or More Food Allergies](#)

Xolair side effects

Common Xolair side effects

Common Xolair side effects include:

- [Pain](#) 7%
- [Tiredness](#), fatigue 3%
- [Joint pain](#) 8%
- Bone fracture 2%
- Leg pain 4%
- Arm pain 2%
- [Dizziness](#) 3%
- Itchy skin 2%
- Dermatitis 2%
- [Earache](#) 2%.

Injection site reactions with symptoms of bruising, redness, warmth, burning, stinging, itching, hive formation, pain, indurations, mass, and inflammation occurred in 45% of Xolair patients and 43% of placebo patients. Severe injection site reactions affected 12% of the xolair treated and 9% of the placebo group.

These common side effects occurred in 1% or more of patients 12 years or older in [Four Placebo-controlled Asthma Trials](#).

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

Serious Xolair side effects

Some people using Xolair 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 Xolair:

- 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, difficulty breathing;
- fast or weak heartbeats; or
- swelling of your face, lips, tongue, or throat.

Other serious side effects may occur, 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.

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

Related/similar drugs

Dupixent

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

Reviews & ratings

7.2 / 10

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Promethazine

Promethazine is a phenothiazine and antihistamine used to treat allergies, motion sickness, nausea ...

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Loratadine

Loratadine is a non-drowsy antihistamine used to relieve allergy symptoms like sneezing, runny ...

Reviews & ratings

4.7 / 10

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Cetirizine

Cetirizine treats cold or allergy symptoms such as sneezing, itching, watery eyes, or runny nose ...

Reviews & ratings

5.8 / 10

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Hydroxyzine

Hydroxyzine is an antihistamine used to treat itching, hives, and anxiety. It also acts as a ...

Reviews & ratings

5.9 / 10

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Albuterol

Albuterol is a bronchodilator that relaxes muscles in the airways and increases air flow to the ...

Reviews & ratings

3.2 / 10

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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 Xolair: 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 Xolair. 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.

Xolair 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 Xolair 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 below for a full list of ingredients ingredients.

To make sure Xolair 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 Xolair on the baby.

Breastfeeding

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

 [Xolair pregnancy and breastfeeding warnings](#) (more detail)

Xolair copay card

You may pay as little as \$0 for out-of-pocket if you qualify for the Xolair copay card, but it may vary depending on the health insurance plan. The Xolair Copay Card helps you save money on prescriptions if you have commercial or private insurance and fit the criteria.

If you do not have insurance then the Genentech Patient Foundation may help funding this medicine if you meet the criteria.

See the [Xolair Prices, Coupons, Copay Cards & Patient Assistance](#) page for more information on cost, pricing, and Genentech Patient Foundation.

See" [Xolair copay card: Do I qualify and how much can I save?](#)" for more information on the Xolair copay card.

How should I use Xolair?

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.

Xolair 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 Xolair 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.

Xolair 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.

Xolair 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, click on this link: [Xolair Instructions For Use](#).

 [Xolair patient tips](#) (more detail)

Xolair dosing information

Usual Xolair 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: Xolair 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. Click on the link below "Detailed Xolair dosage information" for dose details.

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 Xolair 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 Xolair?

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 [Xolair drug interactions](#) (more detail)

Does Xolair interact with my other drugs?

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

Xolair

+

Enter a drug name

Add

Xolair Package Insert

HCPs and patients often use the [Xolair Package Insert](#) (PI) for more detailed information about this medicine. The Xolair Package Insert (prescribing information) contains more comprehensive information on Indications and Usage, Dosage and Administration, Clinical Pharmacology, Clinical Studies, Drug Interaction, and more. Discuss any medical questions you have with your HCP (health care professional). This is not all the information you need to know about this medicine for safe and effective use, and it does not take the place of talking to your doctor about your treatment.

The Package Insert is sometimes called Prescribing Information (PI) or FDA label.

Xolair J code

Xolair J code is J2357 (5 mg, injection)

J codes are used for medicines that are not taken orally and include injections, inhalations, and chemotherapies. J codes are important for accurate and consistent coding for billing and reimbursement purposes.

Your physician will need the Xolair J code when filling out forms for your treatment.

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.

Xolair 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 Xolair.

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

Popular FAQ

What are monoclonal antibodies?



Is Xolair an immunosuppressant?



How long before Xolair starts working?



Does Xolair cause hair loss?



Does Xolair cause cancer?



How does Xolair work?



How long can Xolair stay out of the fridge?



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



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. [Immunoglobulin E, what is it good for?](#)
3. [Omalizumab: Clinical Use for the Management of Asthma](#)
4. [Xolair Financial Support](#)

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

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

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 Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2003



User Reviews & Ratings

7.5 / 10

[229 Reviews](#)

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[FDA Approves Omyclo \(omalizumab-igec\), an Interchangeable Biosimilar to Xolair](#)

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Xolair 150 mg/mL prefilled syringe



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