

The U.S. Food and Drug Administration (FDA) has approved Xolair® (omalizumab) for the reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with immunoglobulin E (IgE)-mediated food allergy. People taking Xolair for food allergies should continue to avoid all foods they are allergic to (commonly referred to as “food allergen avoidance”).

Xolair should not be used for the emergency treatment of any allergic reactions, including anaphylaxis.

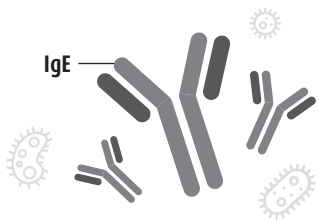


NOTE: Products not shown to scale.

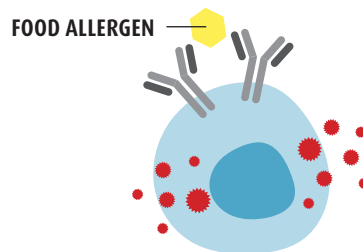
Xolair is the first and only FDA-approved medicine to reduce allergic reactions, including anaphylaxis, from accidental exposure to one or more foods.

HOW XOLAIR IS DESIGNED TO WORK FOR FOOD ALLERGIES

Xolair is the only FDA-approved medicine designed to target and block immunoglobulin E (IgE) — an underlying driver of food allergy reactions.¹



If you have a food allergy, your immune system overreacts by producing antibodies called IgE.



These antibodies bind to cells that release chemicals, like histamine, that cause the symptoms of an allergic reaction.¹



By targeting and blocking IgE, Xolair helps limit the chain reaction that may lead to allergic reactions.²

IgE-mediated food allergies are the most common type and are typically characterized by the rapid onset of symptoms following exposure to certain food allergens.¹ In the body of a person with an IgE-mediated peanut allergy, for example, the presence of peanut protein causes the release of peanut-specific IgE antibodies, which sets off the release of chemicals into the bloodstream.¹

IMPORTANT INFORMATION TO KNOW ABOUT XOLAIR

A severe allergic reaction called anaphylaxis can happen when you receive Xolair. The reaction can occur after the first dose, or after many doses. It may also occur right after a Xolair injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of the symptoms of a severe allergic reaction. See additional safety information on last page.

Please see full [Prescribing Information](#), including [Medication Guide](#) for additional [Important Safety Information](#) and [Instructions for Use](#).

ABOUT FOOD ALLERGIES

Food allergy is defined as the immune system overreacting to certain foods.³ **The 9 most common food allergens are:**^{3,4}



PEANUTS



MILK



EGGS



WHEAT



TREE NUTS



FISH



CRUSTACEAN SHELLFISH



SOYBEANS



SESAME



An allergic reaction to an ingested food allergen generally begins to appear within minutes or up to two hours after eating.¹ These symptoms could indicate a medical emergency and may include but are not limited to:¹

- Coughing, wheezing, runny nose, or trouble breathing
- Diarrhea
- Severe nausea or vomiting
- Stomach cramps or stomach pain
- Red, itchy rash (hives)
- Swelling of the face
- Itching or swelling of the lips, tongue, or mouth
- Itching or tightness in the throat
- Dizziness, with lowered blood pressure
- Feeling something bad is about to happen, anxiety, confusion
- Anaphylaxis



Anaphylaxis is a potentially life-threatening reaction. Symptoms can include shortness of breath or inability to breathe; a rapid, weak pulse; a skin rash; and nausea and vomiting.¹

About

17 MILLION 

children and adults in the U.S. have been diagnosed with IgE-mediated food allergies, based on estimates for 2024.^{5,6}

More than

40% 

of children and more than half of adults with food allergies have experienced a severe reaction at least once.^{5,6}

It is estimated that food-related anaphylaxis results in

30,000 

MEDICAL EVENTS

treated in emergency rooms in the U.S. each year.³

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XOLAIR (OMALIZUMAB) EFFICACY AND SAFETY²

The FDA approval of Xolair for food allergies was based on data from the Phase III OUTMATCH study, which was conducted by the National Institutes of Health. The study evaluated people that were allergic to peanuts and at least two other food allergens, including milk, egg, wheat, cashew, hazelnut or walnut. The primary efficacy endpoint was the percentage of patients who were able to consume a single dose of at least 600 mg of peanut protein without moderate to severe allergic symptoms. Study results showed a statistically significant higher proportion of patients (68%) treated with Xolair tolerated at least 600 mg of peanut protein without moderate to severe allergic symptoms, compared to 5% of those treated with placebo ($p < 0.0001$). This amount is equivalent to approximately two and a half peanuts or half a teaspoon of regular peanut butter. The key secondary efficacy endpoints were the percentage of patients who were able to consume a single dose of at least 1000 mg of milk, egg or cashew protein without moderate to severe allergic symptoms. A statistically significant higher proportion of patients treated with Xolair compared to placebo tolerated at least 1,000 mg of protein from milk (66% vs. 11%; $p < 0.0001$), egg (67% vs. 0%; $p < 0.0001$) or cashew (42% vs. 3%; $p < 0.0001$) without moderate to severe allergic symptoms. This amount is equivalent to approximately two tablespoons of 1% milk, one-quarter of an egg or three and a half cashews. These efficacy data are based on 165 pediatric patients treated for 16 to 20 weeks.

Safety findings were consistent with the safety profile of Xolair for its approved indications and previous clinical trials. The most common adverse events ($\geq 3\%$ of patients) in Xolair-treated patients in the study were injection site reaction (15.5% vs. 10.9% with placebo) and fever (6.4% vs. 3.6% with placebo).

XOLAIR DOSING²

The recommended dosage for treatment of food allergy is Xolair 75 mg to 600 mg by injection under the skin (subcutaneous), once every 2 or 4 weeks. Xolair dose and dosing frequency is determined by total serum IgE level (IU/mL), measured before the start of treatment, and body weight (kg). Injections can be given by a healthcare provider, in a healthcare setting, or at home through self-injection. Healthcare providers will determine appropriate candidates for self-injection.

Xolair is now FDA-approved to treat four health conditions, including moderate to severe persistent allergic asthma, chronic spontaneous urticaria (CSU), chronic rhinosinusitis with nasal polyps (CRSwNP) and IgE-mediated food allergy.

In the U.S., Genentech and Novartis Pharmaceuticals Corporation work together to develop and co-promote Xolair.

WHAT IS XOLAIR?

Xolair[®] (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat:

- moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens. It is not known if XOLAIR is safe and effective in people with asthma under 6 years of age.
- chronic rhinosinusitis with nasal polyps (CRSwNP) in people 18 years of age and older when medicines to treat CRSwNP called nasal corticosteroids have not worked well enough. It is not known if XOLAIR is safe and effective in people with CRSwNP under 18 years of age.
- food allergy in people 1 year of age and older to reduce allergic reactions that may occur after accidentally eating one or more foods to which you are allergic. While taking XOLAIR you should continue to avoid all foods to which you are allergic. It is not known if XOLAIR is safe and effective in people with food allergy under 1 year of age.
- chronic spontaneous urticaria (CSU, previously referred to as chronic idiopathic urticaria (CIU), chronic hives without a known cause) in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment. It is not known if XOLAIR is safe and effective in people with CSU under 12 years of age.

XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis.

XOLAIR should also not be used to treat other forms of hives, or sudden breathing problems.

Please see full [Prescribing Information](#), including [Medication Guide](#) for additional Important Safety Information and [Instructions for Use](#).

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about XOLAIR?

Severe allergic reaction. A severe allergic reaction called anaphylaxis can happen when you receive XOLAIR. The reaction can occur after the first dose, or after many doses. It may also occur right after a XOLAIR injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- wheezing, shortness of breath, cough, chest tightness, or trouble breathing
- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
- flushing, itching, hives, or feeling warm
- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving XOLAIR and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

Do not receive and use XOLAIR if you are allergic to omalizumab or any of the ingredients in XOLAIR.

Before receiving XOLAIR, tell your healthcare provider about all of your medical conditions, including if you:

- have a latex allergy or any other allergies (such as seasonal allergies). The needle cap on the XOLAIR prefilled syringe contains a type of natural rubber latex.
- have sudden breathing problems (bronchospasm)
- have ever had a severe allergic reaction called anaphylaxis have or have had a parasitic infection
- have or have had cancer
- are pregnant or plan to become pregnant. It is not known if XOLAIR may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XOLAIR passes into your breast milk.
Talk with your healthcare provider about the best way to feed your baby while you receive and use XOLAIR.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I receive and use XOLAIR?

- When starting treatment, XOLAIR should be given by your healthcare provider in a healthcare setting.
- If your healthcare provider decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way to prepare and inject XOLAIR.
- Do not try to inject XOLAIR until you have been shown the right way to give XOLAIR prefilled syringe or autoinjector injections by a healthcare provider. Use XOLAIR exactly as prescribed by your healthcare provider.
- The XOLAIR autoinjector (all doses) is intended for use only in adults and adolescents aged 12 years and older. For children 12 years of age and older, XOLAIR prefilled syringe or autoinjector may be self-injected under adult supervision. For children 1 to 11 years of age, XOLAIR prefilled syringe should be injected by a caregiver.
- See the detailed Instructions for Use that comes with XOLAIR for information on the right way to prepare and inject XOLAIR.
- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks. In people with asthma, CRSwNP, and food allergy, a blood test for a substance called IgE must be performed before starting XOLAIR to determine the appropriate dose and dosing frequency.
- In people with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- Do not decrease or stop taking any of your other asthma, CRSwNP, hive medicine, food allergy medicine or allergen immunotherapy, unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after XOLAIR treatment. If your symptoms do not improve or get worse, call your healthcare provider.
- If you inject more XOLAIR than prescribed, call your healthcare provider right away.

Important Safety Information continued on next page

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 **NOVARTIS**

IMPORTANT SAFETY INFORMATION (CONTINUED)

What are the possible side effects of XOLAIR?

XOLAIR may cause serious side effects, including:

- **Cancer.** Cases of cancer were observed in some people who received XOLAIR.
- **Inflammation of your blood vessels.** Rarely, this can happen in people with asthma who receive XOLAIR. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by XOLAIR. Tell your healthcare provider right away if you have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of your arms or legs.
- **Fever, muscle aches, and rash.** Some people get these symptoms 1 to 5 days after receiving a XOLAIR injection. If you have any of these symptoms, tell your healthcare provider.
- **Parasitic infection.** Some people who are at a high risk for parasite (worm) infections, get a parasite infection after receiving XOLAIR. Your healthcare provider can test your stool to check if you have a parasite infection.
- **Heart and circulation problems.** Some people who receive XOLAIR have had chest pain, heart attack, blood clots in the lungs or legs, or temporary symptoms of weakness on one side of the body, slurred speech, or altered vision. It is not known whether these are caused by XOLAIR.

The most common side effects of XOLAIR:

- **In adults and children 12 years of age and older with asthma:** joint pain especially in your arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of your ears.
- **In children 6 to less than 12 years of age with asthma:** swelling of the inside of your nose, throat, or sinuses, headache, fever, throat infection, ear infection, abdominal pain, stomach infection, and nose bleeds.
- **In adults with chronic rhinosinusitis with nasal polyps:** headache, injection site reactions, joint pain, upper abdominal pain, and dizziness.
- **In people with chronic spontaneous urticaria:** nausea, headaches, swelling of the inside of your nose, throat or sinuses, cough, joint pain, and upper respiratory tract infection.
- **In people with food allergy:** injection site reactions and fever.

These are not all the possible side effects of XOLAIR. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at (888) 669-6682.

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1 Anvari S, Miller J, Yeh CY, Davis CM. IgE-Mediated Food Allergy. *Clin Rev Allergy Immunol*. 2019 Oct;57(2):244-260. doi: 10.1007/s12016-018-8710-3. PMID: 30370459.

2 Xolair (omalizumab) Prescribing Information. Genentech, Inc. and Novartis Pharmaceuticals Corporation.

3 USDA Food Safety and Inspection Service. Food Allergies. <https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/food-allergies>. Accessed November 2023.

4 U.S. Food and Drug Administration. Food Allergies: What You Need to Know. <https://www.fda.gov/food/buy-store-serve-safe-food/food-allergies-what-you-need-know>. Accessed November 2023.

5 Gupta RS, Warren CM, Smith BM et al. The Public Health Impact of Parent-Reported Childhood Food Allergies in the United States. *Pediatrics*. 2018 Dec;142(6):e20181235. doi: 10.1542/peds.2018-1235.

6 Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630.

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