



Xolair[®]
Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg

XOLAIR FOR FOOD ALLERGIES

Models are for illustrative purposes. Individual results may vary.

What is XOLAIR?

XOLAIR[®] (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat 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. XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis.

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.

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

ABOUT FOOD ALLERGIES



4 in 10 people with a food allergy are allergic to multiple foods.



51% of children with 2 or more food allergies have been treated at an emergency department.



Each year, roughly 30,000 individuals who practice food avoidance still **require emergency room treatment due to accidental exposure** of food allergens.



1 in 3 children with food allergies also have asthma.

People who have both asthma and food allergy have more severe allergic reactions to food.

No matter how much we prepare, accidental food exposures can still happen.

WHAT IS IgE?

Models are for illustrative purposes. Individual results may vary.



What is IgE?

IgE stands for immunoglobulin E, which is an underlying cause of food allergy reactions. When an allergen in food is eaten by patients with IgE-mediated food allergies, the body responds by making a protein called IgE. IgE causes inflammation that leads to food allergy symptoms.

More than 160 foods cause IgE-mediated food allergies.



Models are for illustrative purposes. Individual results may vary.

THINGS TO KNOW ABOUT XOLAIR

Things to know about XOLAIR:

- ✓ XOLAIR significantly reduced allergic reactions, including anaphylaxis, following accidental exposure to one or more foods.
- ✓ XOLAIR is the first and only available* FDA-approved treatment for adults and children 1 year of age and older who are allergic to one or more foods.
- ✓ XOLAIR can be used to treat food allergies caused by IgE. While on XOLAIR, continue to avoid eating any foods you may be allergic to.
- ✓ At the end of 16 to 20 weeks, 68% of people treated with XOLAIR could consume 6x more peanut than before treatment compared with 5% treated with the placebo without moderate to severe allergic symptoms.
 - This means they did not have moderate to severe allergic symptoms; no more than mild skin, respiratory, or gastrointestinal symptoms occurred.
 - 17% of people were still not able to eat more than half of a peanut (100 mg) without moderate to severe allergic symptoms.
- ✓ XOLAIR is a once- or twice-monthly injection. XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis.
- ✓ The most common side effects of XOLAIR in people with food allergy are injection site reactions and fever.
- ✓ XOLAIR has been approved since 2003 for allergic asthma.†

*Available refers to commercial availability in the US.
†In patients 12 years and older.

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.
- 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.

XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis. XOLAIR should also not be used to treat sudden breathing problems.



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XOLAIR CLINICAL STUDY OVERVIEW

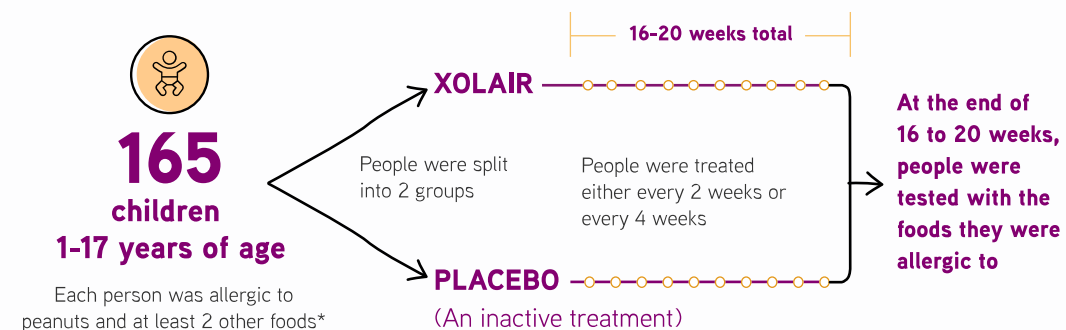


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XOLAIR has a well-studied safety profile and is effective in reducing allergic reactions, including anaphylaxis.

How XOLAIR was studied

XOLAIR was studied in a clinical trial for 16 to 20 weeks to measure how much of an allergy-causing food people could consume without moderate to severe allergic symptoms; no more than mild skin, respiratory, or gastrointestinal symptoms occurred.



*The other foods were milk, eggs, wheat, cashews, hazelnuts, and walnuts.

†Equates to 600 mg of peanuts.

‡This means they did not have moderate to severe allergic symptoms; no more than mild skin, respiratory, or gastrointestinal symptoms occurred.

§Equates to 1000 mg of each respective food.

PRIMARY GOAL

The primary goal of the study was to see if people could eat at least 2.5 peanuts[†] without moderate to severe allergic symptoms.[‡]

SECONDARY GOAL

The secondary goals were to see if people could eat at least 1/4 of an egg, 2 tablespoons of 1% milk, or 3.5 cashews.[§] An additional goal was to see if people could eat at least 4.5 peanuts[§] without moderate to severe allergic symptoms.[‡]

IMPORTANT SAFETY INFORMATION

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

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- low blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of “impending doom”
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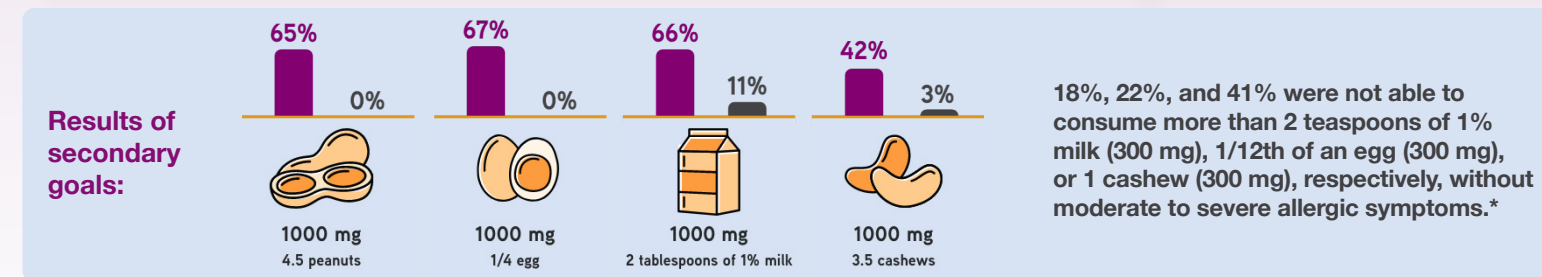
XOLAIR CLINICAL STUDY RESULTS

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XOLAIR significantly reduced allergic reactions, including anaphylaxis, after 16 to 20 weeks of treatment.

In a clinical study, a total of 168 people participated. Data below were based on the 165 pediatric individuals.

Percentage of people who were able to consume at least:



*This means they did not have moderate to severe allergic symptoms; no more than mild skin, respiratory, or gastrointestinal symptoms occurred.

IMPORTANT SAFETY INFORMATION (continued)

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

Severe allergic reaction. (continued)

- swelling of the throat or tongue, throat tightness, hoarse voice, or trouble swallowing

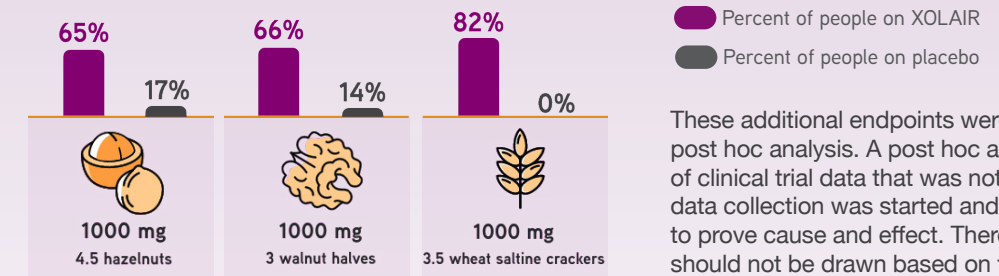
Your healthcare provider will monitor you closely for symptoms of an allergic reaction while you are receiving XOLAIR and for a period of time after treatment is initiated. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction.

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.

Results of additional secondary goals:



Open-label extension study

Of the children taking XOLAIR, 38 continued their treatment for an additional 24 to 28 weeks. The improvements seen at 16 to 20 weeks for all foods studied were maintained at 28 weeks.*

If you have any questions, talk to your doctor.

*Data is from an uncontrolled open-label study and does not establish efficacy.

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

- 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.

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Below are some of the most commonly asked questions about safety when taking XOLAIR for food allergies. If you have any further questions or concerns about safety, always talk to your doctor.

1. What were the most common side effects of XOLAIR in the food allergy trial?

In people with food allergies, the most common side effects of XOLAIR are injection site reactions and fever. These are not all the possible side effects of XOLAIR. Call your doctor for medical advice about side effects.

2. Why is anaphylaxis listed as a side effect?

In the food allergy clinical trial, **no** patient experienced anaphylaxis due to XOLAIR and there were no discontinuations due to adverse reactions. In premarketing clinical trials where XOLAIR was used to treat allergic asthma, anaphylaxis was reported in 3 of 3507 (0.1%) patients.

In postmarketing reports, the frequency of anaphylaxis attributed to XOLAIR was estimated to be at least 0.2% of patients. This means that after XOLAIR approval, patients or healthcare professionals reached out to the company to make a report.

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.

3. Why is cancer listed as a side effect?

In the food allergy clinical trial, **no** cases of cancer were observed and there were no discontinuations due to adverse reactions. When XOLAIR was first studied for allergic asthma, cancer was observed in 0.5% (20 of 4127) of XOLAIR-treated patients, compared with 0.2% (5 of 2236) of non-XOLAIR-treated patients.

Following that trial, 5007 XOLAIR-treated patients and 2829 non-XOLAIR-treated patients were observed for 5 years, and no difference was found between the number of XOLAIR-treated patients who experienced cancer (12.3 people) versus the number of non-XOLAIR-treated patients who experienced cancer (13.0 people). However, because of the way the study was designed, this does not definitively rule out the potential risk of cancer.

These are not all the possible side effects of XOLAIR. If you have any questions, talk to your doctor.



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IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR?

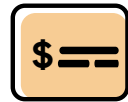
- When starting treatment, XOLAIR should be given by your healthcare provider in a healthcare setting.
- If your healthcare provider decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way to prepare 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.

How should I receive and use XOLAIR? (continued)

- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.
- In people with asthma 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.
- Do not decrease or stop taking any of your other asthma 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.

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





XOLAIR Co-pay Program*

If you have commercial health insurance and meet other eligibility criteria, the XOLAIR Co-pay Program may be able to help you pay for your medicine and in-office injection.

Call **1-855-965-2472** or visit [XOLAIRcopay.com](https://www.xolaircopay.com)



If you've been prescribed XOLAIR, you can sign up for the Support For You program, which provides information and resources to help along the way. Sign up at:

[XOLAIR.com/food-allergies/resources/patient-support-program](https://www.xolair.com/food-allergies/resources/patient-support-program)



1-on-1 session with a Clinical Education Manager (CEM)†

Once you sign up for Support For You, you can talk to a Clinical Education Manager who is trained to provide information on XOLAIR and help you learn about support services available. You might also receive a call from us about our 1-on-1 session. A XOLAIR prescription is required for patients with food allergies.



For additional resources and support, scan this QR code or visit [XOLAIR.com/FAsupport](https://www.xolair.com/FAsupport)

Get help paying for XOLAIR



A Member of the Roche Group

Access Solutions

There are different financial programs and services that may be available to help you pay for

XOLAIR. Find the one that works for you at [XOLAIR.com](https://www.xolair.com) or talk to a XOLAIR Access Solutions Case Manager. **XOLAIR Access Solutions** can refer you to appropriate assistance options:

- The XOLAIR Co-pay Program
- Independent co-pay assistance foundations
- A review of financial support options
- The Genentech Patient Foundation

Call **1-800-704-6610** or visit [XOLAIR.com/FAsupport](https://www.xolair.com/FAsupport)

More support for food allergies

For additional support and resources, here's a list of advocacy groups*:

- Food Allergy Research and Education (FARE) [foodallergy.org](https://www.foodallergy.org)
- Kids with Food Allergy (KFA) [kidswithfoodallergies.org](https://www.kidswithfoodallergies.org)
- Asthma and Allergy Foundation of America (AAFA) [aafa.org](https://www.aafa.org)
- Allergy Asthma Network (AAN) [allergyasthmanetwork.org](https://www.allergyasthmanetwork.org)
- Food Allergy & Anaphylaxis Connection Team (FAACT) [foodallergyawareness.org](https://www.foodallergyawareness.org)

*Eligibility criteria and benefit limits apply. Not valid for patients whose prescriptions are reimbursed under any federal or state government programs to pay for their Genentech medicine. Patients must be taking the Genentech medicine for an FDA-approved indication. Please visit the Co-pay Program website for the full list of Terms and Conditions.

†Clinical Education Managers and Contract Nurses are representatives of Genentech and do not give medical advice. Please contact your doctor for medical advice.

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.

*Visiting any of these links will take you to a site that is not owned or controlled by Genentech or Novartis. Genentech and Novartis make no representation as to the accuracy of the information contained on sites we do not own or control. Genentech and Novartis do not recommend and do not endorse the content on any third-party websites. Your use of third-party websites is at your own risk and subject to the terms and conditions of use for such sites.

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 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.

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



QUESTIONS TO ASK YOUR OR YOUR CHILD'S DOCTOR ABOUT XOLAIR

You may want to have this list of questions on hand during your appointment.

- Do you recommend XOLAIR for my child's or my food allergies?
- What does XOLAIR do for people with food allergies?
- Will my child or I still need other medications for food allergies?
- Can my child or I take XOLAIR with other medications?
- How long does it take XOLAIR to begin working?
- How often will my child or I need to get a XOLAIR injection?
- Would my child or I receive XOLAIR injections at the doctor's office or at home?
- What are the potential side effects of XOLAIR?
- How can I find out if XOLAIR is covered by my insurance?

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.
- 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.

XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis. XOLAIR should also not be used to treat sudden breathing problems.



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Have questions about self-injection with the XOLAIR autoinjector or prefilled syringe? Visit [XOLAIR.com/injectiontraining](https://www.xolair.com/injectiontraining) or scan this QR code to

watch detailed training videos for the prefilled syringe and autoinjector. Your doctor will determine if self-injection is right for you.

AFTER YOU OR YOUR CHILD HAS BEEN PRESCRIBED XOLAIR

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COMPLETE the Patient Consent Form. **YOU** may need to complete the Patient Consent Form at your doctor's office to access financial and patient support.



CONFIRM your insurance coverage. Your doctor's office will work with XOLAIR Access Solutions or a specialty pharmacy to check your coverage and costs. **YOU** may receive a call from XOLAIR Access Solutions to talk about your insurance coverage. A voicemail left for you requesting a callback may not mention XOLAIR by name. This is to protect your privacy.



APPLY for financial assistance. Even if you have health insurance, you might feel concerned about the cost of your treatment. **YOU** can find more information about financial assistance options on pages 10-11 of this brochure.



SCHEDULE your XOLAIR appointment. XOLAIR Access Solutions works with your doctor's office and specialty pharmacy to help deliver XOLAIR to your injection location. **YOU** should return all calls from the specialty pharmacy. This helps them send XOLAIR on time. **YOU** should make an appointment to receive XOLAIR.

These steps may vary for some patients and/or medical offices. In some cases, patients can be referred directly to a specialty pharmacy or may be given the XOLAIR injection at their doctor's office right away if it's available.

Sign up for support. Once you or your child has been prescribed XOLAIR, **YOU** can sign up for the Support For You program offering 1-on-1 educational sessions with Clinical Education Managers. These support specialists are available to help you get started on XOLAIR. Learn more on page 10.

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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.

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How should I receive and use XOLAIR? (continued)

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- 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.

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.

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KEY THINGS TO KNOW ABOUT XOLAIR

- XOLAIR can significantly reduce allergic reactions, including anaphylaxis, due to accidental exposure to one or more foods
- XOLAIR can be used to treat food allergies caused by immunoglobulin E (IgE), an underlying cause of food allergy reactions
- XOLAIR is a once- or twice-monthly injection (depending on the person) that may be taken at home after initial treatments at a doctor's office with either prefilled syringes or autoinjectors
- The most common side effects of XOLAIR in people with food allergy are injection site reactions and fever

Models are for illustrative purposes. Individual results may vary.

Ask an allergist about XOLAIR for food allergies

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.
- 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.

XOLAIR should not be used for the emergency treatment of any allergic reactions, including anaphylaxis. XOLAIR should also not be used to treat sudden breathing problems.

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:

Continue reading symptoms of anaphylaxis on page 5, with additional information about anaphylaxis on pages 14-15.

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

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Xolair
Omalizumab
FOR SUBCUTANEOUS USE 75 mg • 150 mg • 300 mg