

DISCOVER A TREATMENT FOR YOUR
CHRONIC HIVES
WITH NO KNOWN TRIGGER



DISCOVER **ONCE-MONTHLY XOLAIR** ➡

Model is for illustrative purposes. Individual results may vary.

What is XOLAIR?

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat 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 is not used to treat other forms of hives.

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.

Continue reading symptoms of anaphylaxis on pages 2, 4, and 26.

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

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg • 300 mg



Model is for illustrative purposes. Individual results may vary.

FACTS ABOUT CSU

The majority of chronic hives have no known trigger

The cause of chronic hives is often not identifiable by allergists or dermatologists. Chances are it may be a condition called **chronic spontaneous urticaria (CSU)**, also known as chronic hives with no known trigger. For more than half of patients with chronic hives, H1 antihistamines are not enough. Although frustrating, there is something you and your doctor can do about it.

Understanding CSU, or chronic hives with no known trigger

The symptoms of chronic hives are similar to other types of hives:

- Hives can be red, white, or flesh-colored **bumps that itch**
- Hives can often **occur on the chest, back, arms, or legs** but can appear anywhere on the body
- The location where **hives appear may move around**. They may show up on your hand, disappear, and then show up later on your shoulder
- A **red hive will turn pale** when pressed in the center

How are chronic hives diagnosed?

Chronic hives are diagnosed by ruling out other conditions. A doctor will start by reviewing your complete medical history, followed by a comprehensive physical examination. Additional testing may also be requested by your healthcare provider.

IMPORTANT SAFETY INFORMATION (continued)

Severe allergic reaction. (continued)

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

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

Chronic—Lasting 6 weeks or more

Spontaneous—No known trigger

Urticaria—The medical term for hives

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

CSU ON DIFFERENT SKIN TONES

Chronic hives with no known trigger may affect people of any ethnicity

Hives may look different on different people. See below for a few images of how CSU can look on various skin tones.

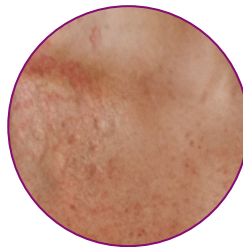
Pale white skin



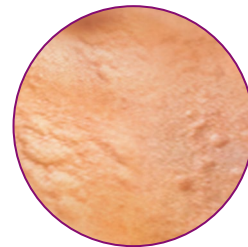
White skin



Darker white skin



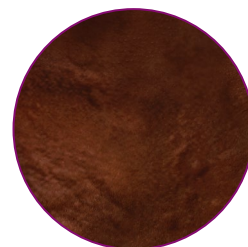
Light brown skin



Brown skin



Dark brown or black skin



**Talk to your allergist to see if
once-monthly XOLAIR is right for you.**

Images are for illustrative purposes. This is not intended to give medical advice and is not inclusive of all skin tones.

IMPORTANT SAFETY INFORMATION (continued)

Severe allergic reaction. (continued)

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.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

CONSIDER XOLAIR FOR CSU

If you suffer from chronic hives with no known trigger, it's time to fight back with XOLAIR

- ✓ The first **FDA-approved biologic treatment for chronic hives** with no known trigger
- ✓ **Proven to reduce itch and hives**
- ✓ **A once-monthly injection**
- ✓ **Works differently than H1 antihistamines**
- ✓ Since 2014, **over 380,000 patients** in the US with CSU have been prescribed XOLAIR*
- ✓ **XOLAIR targets one of the key drivers of inflammation in CSU.[†]** XOLAIR targets IgE, which attaches to mast cells. Mast cells play an important role in CSU by releasing inflammatory substances, and inflammation is thought to play a role in CSU
- ✓ Appropriate patients **may self-inject at home**. Your doctor will work with you to decide if you are eligible and create a plan that is right for you

*Data on file (December 2024). Genentech USA, Inc. South San Francisco, CA.

[†]The mechanism of how the effects of XOLAIR result in an improvement of CSU symptoms is not known.

IMPORTANT SAFETY INFORMATION (continued)

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 food allergy or seasonal allergies). The needle cap on the XOLAIR prefilled syringe contains a type of natural rubber latex
- have ever had a severe allergic reaction called anaphylaxis
- have or have had a parasitic infection
- have or have had cancer

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



Model is for illustrative purposes. Individual results may vary.

For more information, such as the results of the clinical studies and how they were conducted, see **pages 10-11**.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg • 300 mg

WHAT PATIENTS ARE SAYING



Jamika is an actual patient. She received compensation to share her story. Individual results may vary.



Everyone's different, but XOLAIR worked for me when nothing else would.

Jamika, an actual XOLAIR patient

Don't settle. Help interrupt the cycle of itch and hives with XOLAIR.

If you're interested in sharing your own story, email us at MyCSUStory@vml.com.

If selected, your story may appear in promotional materials. Selected participants will be compensated for their time.

Hear more from the XOLAIR community

Scan the QR code to watch real patients like you share their experiences living with chronic hives with no known trigger or visit XOLAIR.com/CSUpatientstories.



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



Things finally changed when I went to see an allergist. He recommended I try XOLAIR because it works differently than H1 antihistamines.

Carol, an actual XOLAIR patient



Carol is an actual patient. She received compensation to share her story. Individual results may vary.

Follow us on social media for more XOLAIR content.



[@xolair_omalizumab](#)

IMPORTANT SAFETY INFORMATION (continued)

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

- 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.



CLINICAL STUDY RESULTS

Itch severity* reduction at 12 weeks†

The 12-week itch data was the key study objective of the CSU trial.

300 mg, n=81

67%
REDUCTION

150 mg, n=80

48%
REDUCTION

Placebo,‡ n=80

26%
REDUCTION

Relief observed as early as 2 weeks

A post hoc analysis is a review of clinical trial data that was not planned before data collection was started, and it is not designed to prove cause and effect. Therefore, conclusions should not be drawn based on this information.

300 mg, n=81

54%
reduction

150 mg, n=80

36%
reduction

Placebo,‡ n=80

22%
reduction

*To measure itch severity, patients were asked to write down how itchy they felt every morning and night on a scale of 0-3. The average daily score was then added together over 7 days for the weekly itch severity score.

†Based on results from CSU study 1, a 24-week clinical study. A total of 319 patients with CSU who were already taking an antihistamine participated in the study. They were given different doses of XOLAIR or a placebo.

‡A placebo does not contain any active medicine.

A medically recognized international guideline for physicians includes the use of **XOLAIR** for patients 12 years or older whose chronic hives are uncontrolled by H1 antihistamines.

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

IMPORTANT SAFETY INFORMATION (continued)

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.
- 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.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

COMPLETE RELIEF IS POSSIBLE

CLINICAL STUDY RESULTS WERE OBSERVED AFTER 12 WEEKS

XOLAIR significantly reduced chronic hives with no known trigger

300 mg

patients' weekly hive count score*
was reduced by **67%**

150 mg

patients' weekly hive count score*
was reduced by **50%**

Placebo†

patients' weekly hive count score*
was reduced by 25%

BEFORE

AFTER



Typical chronic hives symptoms
before treatment with XOLAIR

Shows how a 67% reduction
of the weekly hive count score*
can look after 12 weeks on
XOLAIR (300 mg)

XOLAIR delivered relief that patients can see and feel

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- 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 4 weeks.

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

Itch and hives resolved completely in more
than **1 in 3** patients on **300 mg**

300 mg, n=81



More than 1 in 3
patients (36%) were
completely itch- and hive-free.

150 mg, n=80



Nearly 1 in 6
patients (15%) were
completely itch- and hive-free.

Placebo,† n=80



Around 1 in 10
patients (~10%) were
completely itch- and hive-free.

*To measure the hive score, patients were asked to count the number of hives on their bodies twice daily (0=no hives, 1=1 to 6 hives, 2=7 to 12 hives, and 3=more than 12 hives). The average daily hive score was then added together over 7 days for the weekly hive count score.

†A placebo does not contain any active medicine.

When you talk with your doctor, please refer to more information,
such as the results of the clinical studies and how they were
conducted, on **pages 10-11**.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

QUESTIONS? ASK A SPECIALIST



Models are for illustrative purposes. Individual results may vary.

While allergists primarily diagnose and treat chronic hives, dermatologists and other specialists can also prescribe XOLAIR for CSU.

Here are some questions you may want to ask your doctor:

- Would XOLAIR be an **appropriate treatment** to help with my CSU?
- How does **XOLAIR work differently** than what I am currently taking?
- Should I **keep taking my other CSU medications** in addition to XOLAIR?
- When can I **expect to see results** after starting XOLAIR?
- How often would I need to get a **XOLAIR injection**?
- Would I **receive my injections** at the doctor's office, or could I take them at home? If at the office, how long does each injection visit take?
- What are the **potential side effects** of XOLAIR?
- How can I find out whether XOLAIR is **covered by my insurance**?

“

It wasn't until my doctor told me about XOLAIR that I learned what's possible for my CSU.

Rachel, an actual XOLAIR patient*

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- 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 hive medicine unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after XOLAIR treatment.
- 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.

For more information, scan the QR code to access the **XOLAIR Journey Guide** or go to XOLAIR.com/journeyguide.



*Rachel is an actual patient. She received compensation to share her story. Individual results may vary.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

GETTING STARTED AFTER YOU'VE BEEN PRESCRIBED XOLAIR

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 with health insurance, you may still have cost concerns.

YOU can find more information about financial assistance options on pages 24-25 of this brochure.

SCHEDULE your XOLAIR appointment

XOLAIR Access Solutions works with your doctor's office and specialty pharmacy to 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 available.

*XOLAIR Access Solutions is a patient assistance program from Genentech that helps people who are taking XOLAIR.

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



Model is for illustrative purposes. Individual results may vary.

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.
- **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.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

PREPARE FOR INJECTION DAY

Simple things you can do to prepare for injection day



Read the **Medication Guide** before every injection.

Before your doctor's visit, ask where the injection will be applied so what you wear **gives the staff easy access** to the injection site.

Fear of needles? If receiving your injection in-office or by a caregiver, **focus your attention elsewhere** with something like a game, book, or movie while you get your injection.

Model is for illustrative purposes. Individual results may vary.

What to expect with the XOLAIR injection

- **XOLAIR is a once-monthly injection**
- XOLAIR is given by injection just under the skin every 4 weeks by a nurse or doctor
- During and after the injection, the doctor will watch for signs of anaphylaxis, a severe, life-threatening allergic reaction
- In patients with asthma, 0.1% experience severe allergic reaction with XOLAIR. Patients with a history of anaphylaxis to foods, medications, or other causes can be at an increased risk of anaphylaxis associated with XOLAIR, compared with those with no prior history of anaphylaxis
- For appropriate patients, XOLAIR may be approved by your doctor for self-injection with the XOLAIR prefilled syringe or autoinjector. See more information about self-injection on page 20

Please see full **Prescribing Information**, including **Medication Guide**, for additional **Important Safety Information**.

Your improvements may not happen right away when you start XOLAIR

- Remember that results may vary
- Be sure to let your allergist or dermatologist know what you are experiencing
- Only your allergist or dermatologist can tell you how long you will need to take XOLAIR

IMPORTANT SAFETY INFORMATION (continued)

What are the possible side effects of XOLAIR? (continued)

XOLAIR may cause serious side effects, including: (continued)

- **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.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

STAYING ON XOLAIR

You may have less itching and fewer hives when your XOLAIR treatment starts working. It's important to stick with your treatment as prescribed. Only your doctor can tell you how long you'll need to take XOLAIR and if you need any treatment changes.

Scan the QR code to access the XOLAIR Journey Guide, where you will find tips to help prepare for a conversation with your doctor about your journey with hives. You can also access the tracker by going to [XOLAIR.com/journeyguide](https://xolair.com/journeyguide).



Self-injection with XOLAIR

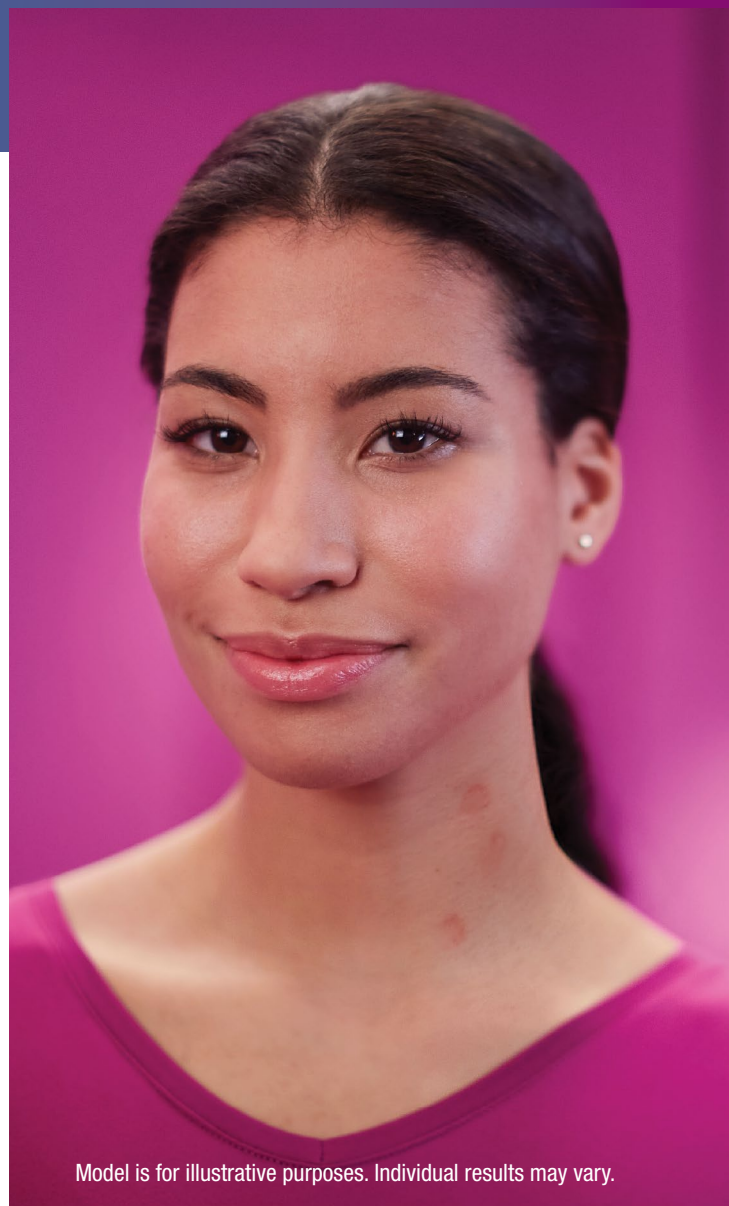
After you've established treatment in a doctor's office, your doctor will determine if you or your caregiver may inject XOLAIR. If your doctor decides that you or a caregiver may be able to give you your XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way to prepare and inject XOLAIR.

DO NOT try to inject XOLAIR until you have been shown the right way by your doctor. For appropriate patients, XOLAIR may provide flexibility on where it can be injected—at home or while traveling.

To watch a step-by-step video on self-injection, scan the QR code or visit [XOLAIR.com/selfinjection](https://xolair.com/selfinjection).



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



Model is for illustrative purposes. Individual results may vary.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of XOLAIR 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.

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.



SUPPORT FOR YOU PROGRAM

Starting XOLAIR? You've got a partner

From diagnosis to treatment, your journey with chronic hives with no known trigger is unique. The **Support For You** program is designed with YOU in mind. Take advantage of free support resources that can help you at every step of the way—from talking to a specialist to getting started to potentially saving on XOLAIR.

You'll get a support kit that includes:

- Information on getting started on XOLAIR
- Comprehensive treatment information
- A review of financial assistance options

As part of this program, you can also expect:



Email updates to help you stay on track with XOLAIR



Ongoing mailings to keep you informed on what to expect during treatment

A virtual education session with a Clinical Education Manager* trained to provide information on XOLAIR and support services is available to you. To schedule, call **1-866-878-0493**.

Model is for illustrative purposes. Individual results may vary.

What is XOLAIR?

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat 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 is not used to treat other forms of hives.

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

Scan the QR code to register for Support For You or visit XOLAIR.com/CSUsupport.



*Clinical Education Managers are Genentech employees and do not give medical advice. Please consult your doctor for medical advice.

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg + 300 mg

GET HELP PAYING FOR XOLAIR

ACCESS SOLUTIONS®

There are different financial programs and services 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:

Help you understand your health insurance coverage by finding out:

- If your health insurance covers XOLAIR
- How much your co-pay will be for XOLAIR

Refer you to appropriate financial assistance options:

- XOLAIR Co-pay Program
- Independent co-pay assistance foundations
- Genentech Patient Foundation



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



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.

\$0† Support for your drug out-of-pocket cost

Eligible commercially insured patients pay as little as **\$0 per XOLAIR drug out-of-pocket cost**. The program covers up to **\$1,500** per calendar year benefit period.

Support for your administration out-of-pocket cost

Eligible commercially insured patients pay as little as **\$0 per administration out-of-pocket cost**. The program covers up to **\$1,500** per calendar year benefit period.



XOLAIR Co-pay Program: **1-855-965-2472** or visit [XOLAIRcopay.com](https://www.xolair.com/XOLAIRcopay.com)

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

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

*The Co-pay Program (“Program”) is valid ONLY for patients with commercial (private or non-governmental) insurance who have a valid prescription for a Food and Drug Administration (FDA)-approved indication of a Genentech medicine. The Program is not available to patients whose prescriptions are reimbursed under any federal state, or government-funded insurance programs (included but not limited to Medicare, Medicare Advantage, Medigap, Medicaid, TRICARE, Department of Defense, or Veterans Affairs Programs) or where prohibited by law or by the patient’s health insurance provider. If at any time a patient begins receiving prescription drug coverage under any such federal, state or government-funded healthcare programs, the patient will no longer be eligible for the Program. To receive co-pay assistance for both drug cost and administration fees, patients must apply for and be enrolled in each type of program benefit (i.e., drug cost and administration fees).

Under the Programs, the patient may be required to pay a co-pay for drug costs and a co-pay for administration costs. After reaching the maximum annual Program benefit amount, the patient will be responsible for all remaining out-of-pocket expenses. The Program benefit amount cannot exceed the patient’s out-of-pocket expenses for the Genentech medicine.

All participants are responsible for reporting the receipt of all Program benefits as required by any insurer or law. The Programs are only valid in the United States and U.S. territories. These Programs are void where prohibited by law. The Drug Co-pay Program shall follow state restrictions in relation to AB-rate generic equivalents (e.g., MA, CA) where applicable. The Administration Co-pay Program is not valid for Massachusetts or Rhode Island residents. No party may seek reimbursement for all or any part of the benefit received through the Program. The value of the Program is intended exclusively for the benefit of the patient. Genentech reserves the right to rescind, revoke or amend the Program without notice at any time. Additional Terms and Conditions apply. Please visit [XOLAIRcopay.com](https://www.xolair.com/XOLAIRcopay.com) for the full list of Terms and Conditions.

†The final amount owed by a patient may be as little as \$0 for XOLAIR (see Program specific details available at [XOLAIRcopay.com](https://www.xolair.com/XOLAIRcopay.com)).

Xolair®
Omalizumab
FOR SUBCUTANEOUS USE 150 mg • 300 mg

What is XOLAIR?

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat 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 is not used to treat other forms of hives.

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 food allergy or seasonal allergies). The needle cap on the XOLAIR prefilled syringe contains a type of natural rubber latex
- 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.

- 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.
- 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 4 weeks.
- 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 hive medicine unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after XOLAIR treatment.
- 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.
- **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 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.

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.





Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg - 300 mg

Model is for illustrative purposes. Individual results may vary.

Have questions? We have answers.

Our team is available to answer your questions about XOLAIR at **1-866-4XOLAIR (1-866-496-5247)** Monday through Friday, 9 AM to 8 PM ET.

Hours of operation may vary during US holidays. If you have questions about your condition or treatment, please contact your healthcare provider.

IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of XOLAIR 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.

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.

Genentech
A Member of the Roche Group

 **NOVARTIS**

Xolair
Omalizumab
FOR SUBCUTANEOUS USE 150 mg - 300 mg