

HELP TREAT YOUR **CHRONIC HIVES** WITH NO KNOWN CAUSE

LEARN MORE INSIDE 

Model is for illustrative purposes only. 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 3-4, with additional information about anaphylaxis on page 22.

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

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

FACTS ABOUT CSU



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The majority of chronic hives have no known cause

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 cause. 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.

Chronic—Lasting 6 weeks or more

Spontaneous—No known trigger

Urticaria—The medical term for “hives”

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

Understanding CSU, or chronic hives with no known cause

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, 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

CONSIDER XOLAIR FOR CSU

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

- ✓ The first and only **FDA-approved biologic treatment for chronic hives** with no known cause
- ✓ **Proven to reduce itch and hives**
- ✓ **A once-monthly injection**
- ✓ **Works differently than H1 antihistamines**
- ✓ Since 2014, **over 350,000 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

For more information, such as the results of the clinical studies and how they were conducted, **see pages 6-7.**

*Data on file (January 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)

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.

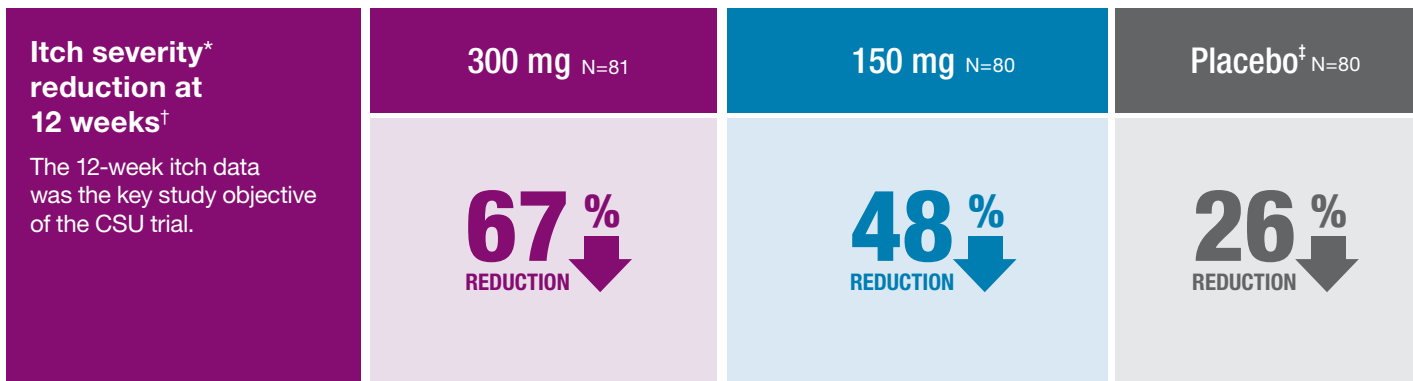


Model is for illustrative purposes only. Individual results may vary.

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

Xolair
Omalizumab
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CLINICAL STUDY RESULTS



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

IMPORTANT SAFETY INFORMATION (continued)

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.

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

*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.

Individual results may vary.

COMPLETE RELIEF IS POSSIBLE

Clinical study results were observed after 12 weeks.

XOLAIR significantly reduced chronic hives with no known cause

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%

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

300 mg

1 in 3 patients (36%) experienced complete relief of itch and hives*

150 mg

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

Placebo†

around 1 in 10 patients were completely itch- and hive-free*

Before XOLAIR

After XOLAIR



Typical chronic hives symptom before treatment with XOLAIR

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

Images are for illustrative purposes only.

Before XOLAIR

After XOLAIR



Typical chronic hives symptom before treatment with XOLAIR

Possible complete response after 12 weeks on XOLAIR (300 mg)

Individual results may vary.

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 6-7.

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.

*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.

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.

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QUESTIONS TO ASK A SPECIALIST



Models are for illustrative purposes only.

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**?

IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

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



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

Rachel, an actual XOLAIR patient*

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

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

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GETTING STARTED AFTER YOU'VE BEEN PRESCRIBED XOLAIR



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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.



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 20-21 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 available.

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

PREPARE FOR INJECTION DAY

What to expect with the XOLAIR injection

- XOLAIR is a once-monthly injection
- XOLAIR is injected under the skin by a nurse or doctor
- During and after the injection, the doctor will watch for signs of anaphylaxis, a severe, life-threatening allergic reaction
- 0.1% of patients 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 prefilled syringe or autoinjector. See more information about self-injection on page 16

Simple things you can do to prepare for injection day.



Read the **Medication Guide** before every injection, found in the back pocket of this brochure.



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, **try focusing your attention elsewhere** with something like a game, book, or movie while you get your injection.



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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.

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.

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 the XOLAIR prefilled syringe or autoinjector

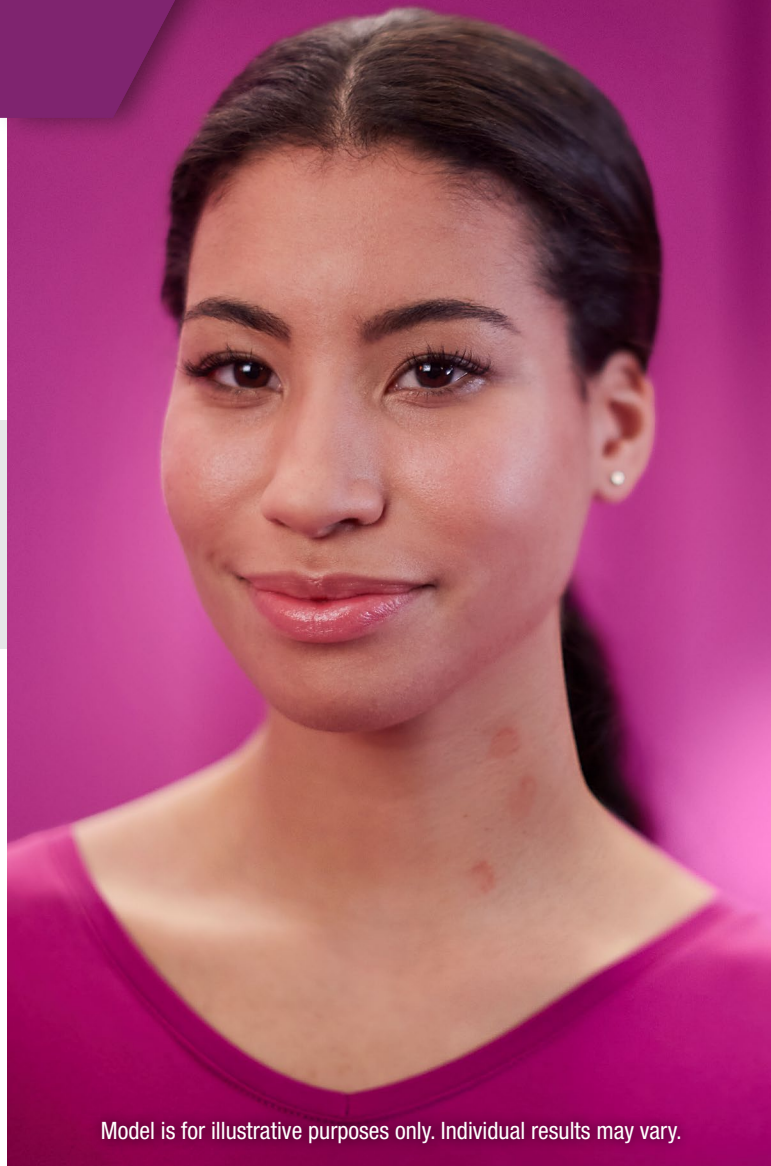
After you've established treatment in a doctor's office, your doctor will determine if you or your caregiver may inject XOLAIR. If your doctor decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe or autoinjector injections, you should receive training on the right way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

DO NOT try to inject XOLAIR until you have been shown the right way 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.



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IMPORTANT SAFETY INFORMATION (continued)

How should I receive and use XOLAIR? (continued)

- 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.

SUPPORT FOR YOU PROGRAM




Starting XOLAIR? You've got a partner

From diagnosis to treatment, your journey with chronic hives with no known cause 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
-  **Virtual education session** with a Clinical Education Manager* trained to provide information on XOLAIR, as well as the support services available to you. To schedule, call **1-866-878-0493**

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

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



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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.

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

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** 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 eligible patients to appropriate financial assistance options:

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



XOLAIR Access Solutions: **1-800-704-6610** or visit **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 the rest up to **\$15,000** for each 12-month 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 the rest up to **\$1,500** for each 12-month calendar year benefit period.



XOLAIR Co-pay Program: **1-855-965-2472** or visit **XOLAIRcopay.com**

*The Product and Administration Co-pay Programs ("Programs") are 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. Patients using Medicare, Medicaid or any other federal or state government program (collectively, "Government Programs") to pay for their Genentech medicine and/or administration services are not eligible.

Under the Programs, the patient may be required to pay a co-pay for drug costs and a co-pay for administration costs. The final amount owed by a patient may be as little as \$0 for the Genentech medicine or administration of the Genentech medicine (see Program specific details available at the Program website). The total patient out-of-pocket cost is dependent on the patient's health insurance plan. The Programs assist with the cost of the Genentech medicine and the Genentech medicine administration only. It does not assist with the cost of other administrations, medicines, procedures or office visit fees. After reaching the maximum Programs' benefit amounts, the patient will be responsible for all remaining out-of-pocket expenses. The amount of the Programs' benefits cannot exceed the patient's out-of-pocket expenses for the cost of the Genentech medicine or administration fees for the Genentech medicine.

All participants are responsible for reporting the receipt of all Programs' benefits as required by any insurer or by law. The Programs are only valid in the United States and U.S. Territories and are void where prohibited by law. The Drug Co-pay Program shall follow state restrictions in relation to AB-rated 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 Programs. The value of the Programs is intended exclusively for the benefit of the patient. The funds made available through the Programs may only be used to reduce the out-of-pocket costs for the patient enrolled in the Programs. The Programs are not intended for the benefit of third parties, including without limitation third party payers, pharmacy benefit managers, or their agents. If Genentech determines that a third party has implemented programs that adjust patient

cost-sharing obligations based on the availability of support under the Programs and/or excludes the assistance provided under the Programs from counting towards the patient's deductible or out-of-pocket cost limitations. Genentech may impose a per fill cap on the cost-sharing assistance available under the Programs. Submission of true and accurate information is a requirement for eligibility and Genentech reserves the right to disqualify patients who do not comply from Genentech programs. Genentech reserves the right to rescind, revoke or amend the Programs without notice at any time.

Additional terms and conditions apply. Please visit the co-pay Program website for the full list of Terms and Conditions.

[†]The final amount you owe may be as little as \$0 but may vary depending on your health insurance plan.

IMPORTANT SAFETY INFORMATION (continued)

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

- **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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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.

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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

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- 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.
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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.





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

Hear from others like you

Scan the QR code to watch real patients like you share their experiences living with chronic hives with no known cause or visit [XOLAIR.com/CSUpatientstories](https://www.xolair.com/CSUpatientstories)



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)

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Genentech
A Member of the Roche Group

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