

# ***GET HELP TREATING CHRONIC HIVES WITH NO KNOWN CAUSE***

Learn more inside >>

Actor portrayal. Results may vary.



Actor portrayal. Results may vary.

## The majority of chronic hives have no known cause.

If the cause for your chronic hives can't be identified by an allergist, chances are it may be a condition called CSU. Although frustrating, just because the cause is not known does not mean that there is nothing you and an allergist can do.

**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 and [Instructions for Use](#).

# FACTS ABOUT CSU

## Understanding Chronic Spontaneous Urticaria (CSU)

The symptoms of chronic hives with no known cause 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 spontaneous hives diagnosed?

Chronic hives are diagnosed by ruling out other potential causes. A doctor will start by reviewing your complete medical history, followed by a comprehensive physical examination. Additional tests may be ordered based on the results.

## 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.



# CONSIDER XOLAIR FOR CSU

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

- ✓ XOLAIR is **proven to reduce itch and hives**.
- ✓ XOLAIR is a **monthly injection**.
- ✓ It's the only **FDA-approved biologic** treatment for chronic hives with no known cause.
- ✓ It **works differently than H1 antihistamines**.
- ✓ Since 2014, **over 180,000 patients** in the US with CSU have been prescribed XOLAIR.\*
- ✓ For appropriate patients, **XOLAIR may be self-injected 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 about the results of the clinical studies and how they were conducted, see pages 6-7.

\*Data on file (December 2020). Genentech USA, Inc. South San Francisco, CA.

## 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

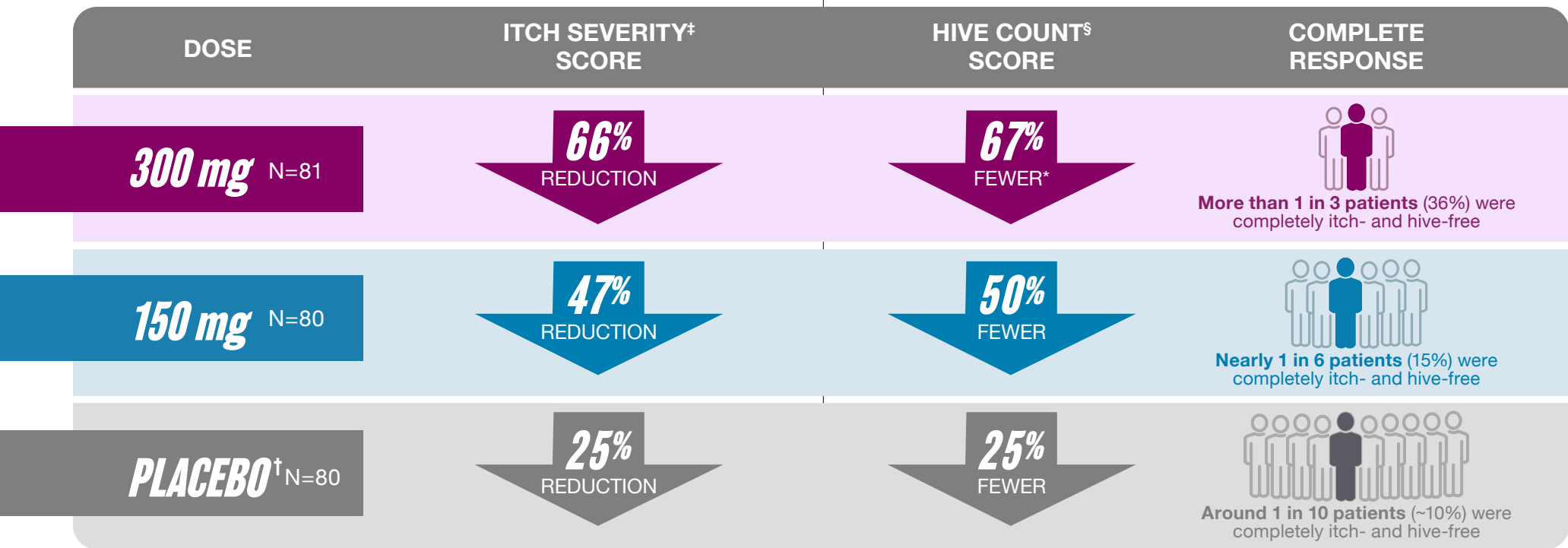
Please see full **Prescribing Information**, including **Medication Guide** for additional Important Safety Information and **Instructions for Use**.

**Xolair**  
Omalizumab  
FOR SUBCUTANEOUS USE 150 mg

Actor portrayal. Results may vary.

# CLINICAL STUDY RESULTS

Results after 12 weeks.  
XOLAIR reduced the feeling of itch  
and appearance of hives.\*



\*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.

†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.

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

Individual results may vary.

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

**IMPORTANT SAFETY INFORMATION (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.

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





# XOLAIR BEFORE & AFTER

For patients 12 years or older  
whose CSU is uncontrolled by  
H1 antihistamines

**XOLAIR significantly reduced hives.**

**at 300 mg**

patients' weekly hive count score\*  
was reduced by **over two-thirds (67%)**

**at 150 mg**

patients' weekly hive count score\*  
was reduced by **one-half (50%)**

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

**at 300 mg**

more than **1 in 3 patients (36%)** were  
completely itch- and hive-free\*

**at 150 mg**

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

**Before XOLAIR**



Typical CSU symptom before  
treatment with XOLAIR

Actor portrayal. Results may vary.

Before/after results for illustrative purposes only.

**After XOLAIR (300mg)**



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

**Before XOLAIR**



Typical CSU symptom before  
treatment with XOLAIR

Actor portrayal. Results may vary.

Before/after results for illustrative purposes only.

**After XOLAIR**



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

## 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

\*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.

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

Please see full **Prescribing Information**,  
including **Medication Guide** for additional  
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**Instructions for Use.**

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# QUESTIONS TO ASK AN ALLERGIST



Actor portrayal. Results may vary.

## IMPORTANT SAFETY INFORMATION (continued)

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

- 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 and **Instructions for Use**.



**Talk to an allergist about XOLAIR.** You may have a lot of questions and you may not know where to begin. Here are some questions you may want to ask an allergist:

- Is XOLAIR an **appropriate treatment** option for my type of hives? Can it help me?
- Can you **explain how XOLAIR works?**
- **Will I still need my other medications** for CSU?
- **Can I take XOLAIR with the other medications** I'm currently taking?
- How long does it take for XOLAIR to **start working?**
- How often would I need to get a **XOLAIR injection?**
- Would I **receive my injections** at the allergist's office, or could I take them at home? If at the office, how long does each injection visit take?
- Can you explain the **potential side effects** of XOLAIR?
- How can I find out whether XOLAIR is covered by **my insurance?**

For more information, download our **Doctor Discussion Guide** at **XOLAIR.COM/DISCUSSIONGUIDE** or scan this QR code.



“

Because of XOLAIR, I know I'm not alone in dealing with chronic hives and my symptoms.

Dina, actual XOLAIR patient\*

\*Results may vary. Patient compensated for her time.

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# GETTING STARTED AFTER YOU'VE BEEN PRESCRIBED XOLAIR



Actor portrayal. Results may vary.

## IMPORTANT SAFETY INFORMATION (continued)

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



### 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 14 and 15 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 the practice 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** and **Instructions for Use**.

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# GET HELP PAYING FOR XOLAIR

## Committed to helping eligible patients find financial assistance options for XOLAIR

There may be options to help you afford your XOLAIR, no matter what type of health insurance you have.



### XOLAIR CO-PAY PROGRAM\*

#### Support for Your Drug Out-of-Pocket Costs

Eligible commercially insured patients pay **as little as \$5 per XOLAIR drug out-of-pocket cost**. The program covers the rest up to \$10,000 for each 12-month period.

#### Support for Your Administration Out-of-Pocket Costs

Eligible commercially insured patients pay **as little as \$5 per administration out-of-pocket cost**. The program covers the rest up to \$1,000 for each 12-month period.

## 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 injections, you should receive training on the right way to prepare and inject XOLAIR.
- Do not try to inject your XOLAIR prefilled syringe until you have been shown the right way to give XOLAIR injections by a healthcare provider. Use XOLAIR exactly as prescribed by your healthcare provider. For children 12 years of age and older, XOLAIR prefilled syringe may be self-injected under adult supervision.

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

## Other financial assistance referrals

### ACCESS SOLUTIONS®



#### Referrals to Independent Co-pay Assistance Foundations†

If you need help with your co-pay for XOLAIR, XOLAIR **Access Solutions** can refer you to an independent co-pay assistance foundation.



#### Referrals to the Genentech Patient Foundation‡

The Genentech Patient Foundation gives eligible patients XOLAIR free of charge. Eligible patients who do not have health insurance, who have health insurance that does not cover XOLAIR, or cannot afford their out-of-pocket costs may get free medicine.

**Learn more** at [XOLAIR.COM/CSUFINANCIALSUPPORT](https://www.xolair.com/csufinancialsupport), or call 866-4XOLAIR (866-496-5247) Monday through Friday, 9 am to 8 pm ET to find out which assistance option might be right for you.

\*The XOLAIR Co-pay Program is available only for commercially insured patients. Patients using Medicare, Medicaid or any other government-funded program to pay for their medications are not eligible. It requires a valid, on-label prescription and cannot be combined with any other rebate/coupon, free trial or similar offer for the specified prescription. It is available only for a patient (or their guardian) who is 18 years or older. It is not valid for medications the patient receives for free or that are eligible to be reimbursed by private insurance plans or other health care or pharmaceutical assistance programs that reimburse the patient in whole or in part for the medication. It is only valid for Genentech products and only valid in the U.S. and U.S. Territories.

The XOLAIR Co-pay Program is not health insurance or a benefit plan.

Please see full terms and conditions at [XOLAIRcopy.com](https://www.xolair.com/copy).

†Independent co-pay assistance foundations have their own rules for eligibility. We cannot guarantee a foundation will help you. We only can refer you to a foundation that supports your disease state. We do not endorse or show financial preference for any particular foundation. The foundations we refer you to are not the only ones that might be able to help you.

‡If you have health insurance coverage for your medicine, you must have already tried other types of patient assistance to qualify for free XOLAIR from the Genentech Patient Foundation. This includes the XOLAIR Co-pay Program and support from independent co-pay assistance foundations. You must also meet financial criteria. If you do not have insurance or your insurance does not cover your medicine, you must meet different financial criteria.






# SUPPORT FOR YOU PROGRAM


## Starting XOLAIR? You've got a partner

From diagnosis to treatment, your journey with chronic hives 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—be it talking to an allergist, to getting started and potential savings on XOLAIR.

## Stay informed, motivated and committed with:

 **Email updates** designed to help you stay on track with your treatment

 **Step-by-step guide** to getting started on XOLAIR

 **Relevant information** a patient needs to know about treatment with XOLAIR

 **Review of Financial Assistance Options** and XOLAIR Co-pay Program

**1:1 Schedule a 1:1 Virtual Education Session** with a clinical education manager trained to provide information on XOLAIR as well as the support services available to you. You may also receive a call or a text message from us about your 1:1 session. Call 1-866-878-0493 to schedule a session today.

Visit **XOLAIR.COM/CSUSUPPORT** or scan the QR code to register for Support For You today.



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



Actor portrayal. Results may vary.

## IMPORTANT SAFETY INFORMATION (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 2 or 4 weeks.
- In people with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
- If you inject more XOLAIR than prescribed, call your healthcare provider right away.

# PREPARE FOR INJECTION DAY



Actor portrayal. Results may vary.

## 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.
- Anaphylaxis is a severe, life-threatening allergic reaction. 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 pre-filled syringes. See more information about self-injection on page 21.

## 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, **focus your attention elsewhere** with a game, book, or movie while you get your injection.

## 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?

#### XOLAIR may cause serious side effects, including:

- **Cancer.** Cases of cancer were observed in some people who received XOLAIR.

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

**Xolair**  
Omalizumab  
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# 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.

It may take some time for your symptoms to improve after starting XOLAIR. Go to [XOLAIR.COM/SYMPTOMTRACKER](https://xolair.com/symptomtracker) or scan the QR code to the right to download our progress tracker to keep track of your results to share with your doctor.



## Self-injection with the XOLAIR pre-filled syringe

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 pre-filled syringe 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 learn more or watch a step-by-step video guide, please visit [XOLAIR.COM/SELFINJECTION](https://xolair.com/selfinjection) or scan the QR code to the right.



## IMPORTANT SAFETY INFORMATION (continued)

- **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.

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



Actor portrayal. 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. 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, or herbal supplements.

### How should I receive and use XOLAIR?

- When starting treatment XOLAIR should be given by your healthcare provider in a healthcare setting.

- If your healthcare provider decides that you or a caregiver may be able to give your own XOLAIR prefilled syringe injections, you should receive training on the right way to prepare and inject XOLAIR.
- Do not try to inject your XOLAIR prefilled syringe until you have been shown the right way to give XOLAIR injections by a healthcare provider. Use XOLAIR exactly as prescribed by your healthcare provider. For children 12 years of age and older, XOLAIR prefilled syringe 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 2 or 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](http://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** and **Instructions for Use**.





Actor portrayal. Results may vary.

## You are not alone in living with CSU.

Visit [XOLAIR.COM/PATIENTSTORIES](https://XOLAIR.COM/PATIENTSTORIES) or scan the QR code to the right to hear the real stories of patients like you as they share their concerns, struggles and how they are living with their chronic hives with no known cause.



### Have questions? We have answers.

A knowledgeable 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)

### XOLAIR may cause serious side effects, including:

- **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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