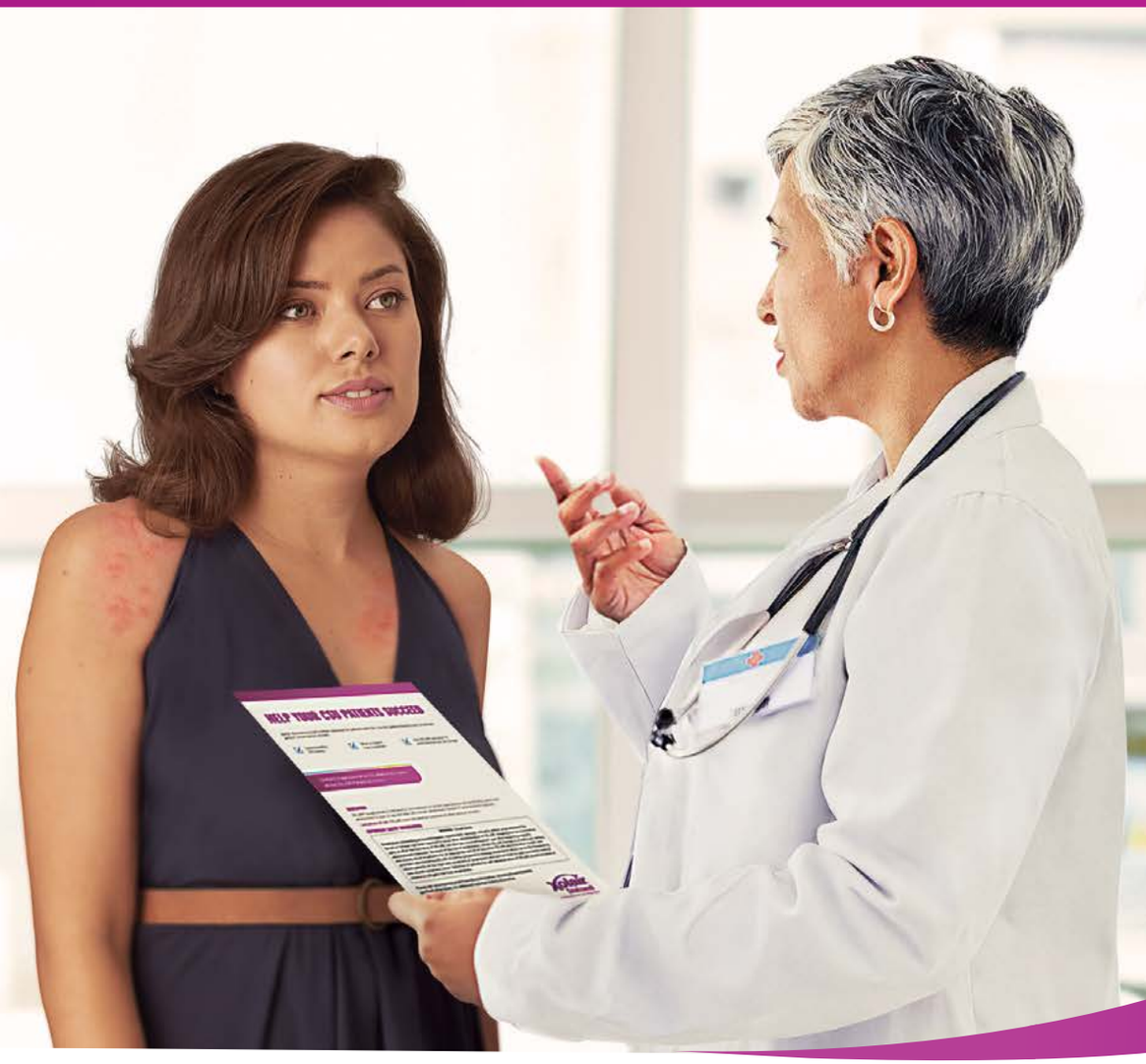
FOR USE DURING DISCUSSIONS WITH YOUR PATIENTS WITH CSU

NAVIGATING THE CSU JOURNEY TOGETHER

This tool is designed to **support your conversations** with patients.

It offers information and answers about CSU—from diagnosis to disease management—and discusses why **XOLAIR can be considered first** when H1 antihistamines aren't enough.[1]



Models are for illustrative purposes. Individual results may vary.
CSU=chronic spontaneous urticaria.

INDICATION

XOLAIR® (omalizumab) is indicated for the treatment of chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

IMPORTANT SAFETY INFORMATION

WARNING: Anaphylaxis

Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of XOLAIR. Anaphylaxis has occurred as early as after the first dose of XOLAIR, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, initiate XOLAIR therapy in a healthcare setting and closely observe patients for an appropriate period of time after XOLAIR administration. Health care providers administering XOLAIR should be prepared to manage anaphylaxis which can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Selection of patients for self-administration of XOLAIR should be based on criteria to mitigate risk from anaphylaxis.

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Xolair® Omalizumab
FOR SUBCUTANEOUS USE 150 mg • 300 mg

HELPING PATIENTS UNDERSTAND CSU

This guide can help you in CSU discussions with patients during appointments.

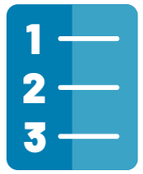
This guide can:

Aid discussions about CSU during the appointment

The information in this guide can help patients have a better understanding of CSU. Once they are familiar with their condition, they can more fully engage in their treatment journey.

Help bring early awareness to available treatment options

Discuss with patients that if H1 antihistamines don't provide adequate relief, there are other treatment options, like XOLAIR.[2]



Help you guide your patients from their initial visit

The patient section of this guide includes comprehensive CSU information that can help you guide your patients through their CSU journey.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

XOLAIR is contraindicated in patients with a severe hypersensitivity reaction to XOLAIR or to any ingredient of XOLAIR.

WARNINGS AND PRECAUTIONS

Anaphylaxis

Anaphylaxis has been reported to occur after administration of XOLAIR in premarketing clinical trials and in postmarketing spontaneous reports. In premarketing clinical trials in patients for a different indication, anaphylaxis was reported in 3 of 3507 (0.1%) patients. Anaphylaxis occurred with the first dose of XOLAIR in two patients and with the fourth dose in one patient. The time to onset of anaphylaxis was 90 minutes after administration in two patients and 2 hours after administration in one patient.

A case-control study in asthma patients showed that, among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

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MONITORING CSU AT EACH APPOINTMENT

Discuss H1 antihistamines and other treatments at the initial visit, including options like XOLAIR, if H1 antihistamines fail to provide symptom relief[2]

Among patients taking H1 antihistamines,* ~60% still experience CSU symptoms[3]

*At FDA-approved doses of standard, second-generation H1 antihistamines.[3]

†Reductions from baseline in mean weekly itch severity score (Study 1: XOLAIR 150 mg, -6.66; XOLAIR 300 mg, -9.40) and mean weekly hive count score (Study 1: XOLAIR 150 mg, -7.78; XOLAIR 300 mg, -11.35) were observed in 2 placebo-controlled, multiple-dose efficacy and safety studies at Week 12 (Study 1: 24 weeks, N=319; Study 2: 12 weeks, N=322).[1]

‡Based on the FDA approval in 2014 of XOLAIR for chronic spontaneous urticaria in patients aged ≥12 years.[5]

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Anaphylaxis (cont'd)

A case-control study in asthma patients showed that, among XOLAIR users, patients with a history of anaphylaxis to foods, medications, or other causes were at increased risk of anaphylaxis associated with XOLAIR, compared to those with no prior history of anaphylaxis.

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HELP TREAT CHRONIC HIVES

WITH NO KNOWN TRIGGER

Use the following pages to help guide conversations about CSU with your patients

Model is for illustrative purposes.
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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.

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.

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Xolair® Omalizumab
FOR SUBCUTANEOUS USE 150 mg • 300 mg

UNDERSTANDING THE BASICS OF CSU

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

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

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.

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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.

In **7 out of 10 people** with chronic hives, doctors **cannot find a cause for the hives.**

Some common CSU terms you may hear

- **Antihistamines:** Medications that work in the body to interrupt the effects of histamine, a chemical released by the immune system that can cause reactions like hives or swelling. For ~60% of people with chronic hives, antihistamines alone are not enough
- **Histamine:** A chemical released by the immune system that can cause reactions like hives or swelling, typically associated with allergic reactions
- **Hives:** Red or skin-colored raised, itchy bumps that appear on the outer layer of the skin and can vary in size, shape, and color
- **Inflammation:** The body's defense against injury and infection. It is the process by which the immune system recognizes and removes harmful and foreign substances, and begins the healing process
- **Pruritus:** The clinical term for itch
- **Second-line therapy:** Treatment that is given when initial treatment (first-line therapy) doesn't work or stops working
- **Wheals:** Another term for hives

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.

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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CSU TREATMENT CONSIDERATIONS

CSU diagnosis

H1 antihistamine treatment

If H1 antihistamines are not enough, that's when **XOLAIR** may be an appropriate choice

For ~60% of patients with chronic hives, H1 antihistamines may not be enough.

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Consider XOLAIR for CSU when H1 antihistamines are not enough

- The **#1 prescribed FDA-approved** treatment for CSU after H1 antihistamine failure*
- **A once-monthly injection**
- XOLAIR can help when **H1 antihistamines aren't providing adequate relief**
- Since 2014, **over 475,000 patients** in the US with CSU have been treated with XOLAIR†
- **XOLAIR targets one of the key drivers of inflammation in CSU.‡** XOLAIR targets immunoglobulin E (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

*Through December 2025.
†Data on file (January 2026). 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)

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.

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XOLAIR DELIVERED SIGNIFICANT ITCH RELIEF

Itch severity* reduction at 12 weeks†

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

300 mg, n=81	150 mg, n=80	Placebo,‡ n=80
67% REDUCTION	**48%** REDUCTION	**26%** REDUCTION

Post hoc analysis

Relief by Week 12, observed as fast as 1 week after the first dose.

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	150 mg, n=80	Placebo,‡ n=80
38% reduction	**23%** reduction	**14%** 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.

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.

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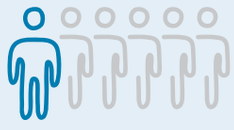
COMPLETE RELIEF IS POSSIBLE AT 12 WEEKS

XOLAIR demonstrated **zero itch and zero hives** at Week 12 (300 mg)

XOLAIR 300 mg, n=81

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

XOLAIR 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.

*A placebo does not contain any active medicine.

XOLAIR delivers relief that patients can SEE AND FEEL

Typical chronic hives symptoms before treatment with XOLAIR.

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

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.

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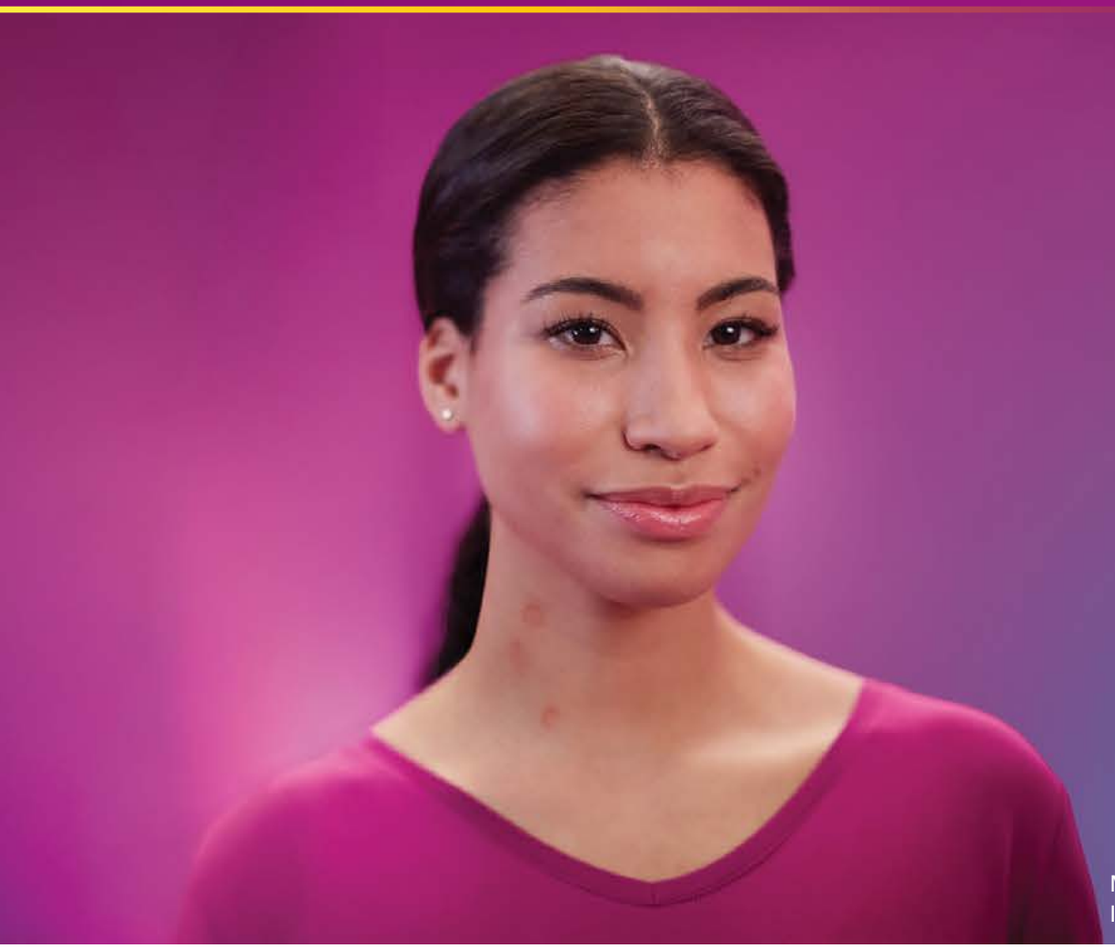
FOR SUBCUTANEOUS USE 150 mg • 300 mg

BETTER INFORMED PATIENTS CAN MAKE BETTER DECISIONS



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Share the Patient Brochure with your patients with CSU.

View the patient brochure online or contact a representative for additional copies

Find help for your CSU Journey

Watch real patients share their experiences living with chronic hives with no known cause by visiting XOLAIR.com/CSUpatientstories

To learn more about CSU and how XOLAIR could help, visit XOLAIR.com/journeyguide

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INDICATION

XOLAIR® (omalizumab) is indicated for the treatment of chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: XOLAIR is not indicated for treatment of other forms of urticaria.

Genentech
A Member of the Roche Group

NOVARTIS

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In postmarketing spontaneous reports, the frequency of anaphylaxis attributed to XOLAIR use was estimated to be at least 0.2% of patients based on an estimated exposure of about 57,300 patients from June 2003 through December 2006. Approximately 60% to 70% of anaphylaxis cases have been reported to occur within the first three doses of XOLAIR, with additional cases occurring sporadically beyond the third dose.

Initiate XOLAIR only in a healthcare setting equipped to manage anaphylaxis which can be life-threatening. Observe patients closely for an appropriate period of time after administration of XOLAIR, taking into account the time to onset of anaphylaxis seen in premarketing clinical trials and postmarketing spontaneous reports. Inform patients of the signs and symptoms of anaphylaxis, and instruct them to seek immediate medical care should signs or symptoms occur.

Once XOLAIR therapy has been established, administration of XOLAIR prefilled syringe or autoinjector outside of a healthcare setting by a patient or a caregiver may be appropriate for selected patients. Patient selection, determined by the healthcare provider in consultation with the patient, should take into account the pattern of anaphylaxis events seen in premarketing clinical trials and postmarketing spontaneous reports, as well as individual patient risk factors (e.g. prior history of anaphylaxis), ability to recognize signs and symptoms of anaphylaxis, and ability to perform subcutaneous injections with XOLAIR prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use.

Discontinue XOLAIR in patients who experience a severe hypersensitivity reaction.

Malignancy

Malignant neoplasms were observed in 20 of 4127 (0.5%) XOLAIR-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents (≥12 years of age) for a different indication and other allergic disorders. The observed malignancies in XOLAIR-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to XOLAIR or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known.

A subsequent 5-year observational study of 5007 XOLAIR-treated and 2829 non-XOLAIR-treated adolescent and adult patients for a different indication found that the incidence rates of primary malignancies (per 1000 patient years) were similar in both groups (12.3 vs 13.0, respectively). Study limitations which include the observational study design, the bias introduced by allowing enrollment of patients previously exposed to XOLAIR (88%), enrollment of patients (56%) while a history of cancer or a premalignant condition were study exclusion criteria, and the high study discontinuation rate (44%) preclude definitively ruling out a malignancy risk with XOLAIR.

Corticosteroid Reduction

In CSU patients, the use of XOLAIR in combination with corticosteroids has not been evaluated.

Fever, Arthralgia, and Rash

In post-approval use, some patients have experienced a constellation of signs and symptoms, including arthritis/arthralgia, rash, fever, and lymphadenopathy with an onset 1 to 5 days after the first or subsequent injections of XOLAIR. These signs and symptoms have recurred after additional doses in some patients. Physicians should stop XOLAIR if a patient develops this constellation of signs and symptoms.

Parasitic (Helminth) Infection

Monitor patients at high risk of geohelminth infection while on XOLAIR therapy. Insufficient data are available to determine the length of monitoring required for geohelminth infections after stopping XOLAIR treatment.

Laboratory Tests

Due to formation of XOLAIR:IgE complexes, serum total IgE levels increase following administration of XOLAIR and may remain elevated for up to 1 year following discontinuation of XOLAIR.

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IMPORTANT SAFETY INFORMATION (cont'd)
WARNINGS AND PRECAUTIONS (cont'd)

Potential Medication Error Related to Emergency Treatment of Anaphylaxis

XOLAIR should not be used for the emergency treatment of allergic reactions, including anaphylaxis. In studies to simulate use, some patients and caregivers did not understand that XOLAIR is not intended for the emergency treatment of allergic reactions, including anaphylaxis. The safety and effectiveness of XOLAIR for emergency treatment of allergic reactions, including anaphylaxis, have not been established. Instruct patients that XOLAIR is for maintenance use to reduce allergic reactions, including anaphylaxis, while avoiding food allergens.

ADVERSE REACTIONS

Chronic Spontaneous Urticaria

The most common adverse reactions (≥2% incidence in XOLAIR-treated patients and more frequent than in placebo) for XOLAIR 150 mg and 300 mg, respectively, included: headache (12%, 6%), nasopharyngitis (9%, 7%), arthralgia (3%, 3%), viral upper respiratory infection (2%, 1%), nausea (1%, 3%), sinusitis (1%, 5%), upper respiratory tract infection (1%, 3%), and cough (1%, 2%).

Injection Site Reactions

Injection site reactions of any severity occurred in more XOLAIR-treated patients (11 patients [2.7%] at 300 mg, 1 patient [0.6%] at 150 mg) compared with 2 placebo-treated patients (0.8%). The types of injection site reactions included: swelling, erythema, pain, bruising, itching, bleeding, and urticaria. None of the events resulted in study discontinuation or treatment interruption.

Injection Site Reactions in Healthy Adults

In an open label trial in healthy adults, in which the 300 mg/2 mL autoinjector was compared to the 300 mg/2 mL prefilled syringe, injection site reactions (e.g., induration, pain, erythema, hemorrhage, swelling, discomfort, bruising, hypoesthesia, edema, pruritus) were observed in 24% (16/66) of subjects treated with the autoinjector compared with 14% (9/64) of subjects treated with the prefilled syringe.

Cardiovascular and Cerebrovascular Events from Clinical Studies in Patients for a Different Indication

A 5-year observational study was conducted in 5007 XOLAIR-treated and 2829 non-XOLAIR-treated patients ≥12 years of age for a different indication to evaluate the long term safety of XOLAIR, including the risk of malignancy. The results suggest a potential increased risk of serious cardiovascular and cerebrovascular events in patients treated with XOLAIR, however the observational study design, the inclusion of patients previously exposed to XOLAIR (88% for a mean of 8 months), baseline imbalances in cardiovascular risk factors between the treatment groups, an inability to adjust for unmeasured risk factors, and the high study discontinuation rate (44%) limit the ability to quantify the magnitude of the risk.

Pregnancy

Data with XOLAIR use in pregnant women are insufficient to inform on drug associated risk.

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.

References: 1. XOLAIR. Prescribing information. Genentech USA, Inc. and Novartis Pharmaceuticals Corporation. **2.** Zuberbier T, Abdul Hameed Ansari Z, Abdul Latiff AH, et al. The international guideline for the definition, classification, diagnosis and management of urticaria. *Allergy*. Published online February 6, 2026. doi:10.1111/all.70210 **3.** Guillén-Aguinaga S, Jáuregui Presa I, Aguinaga-Ontoso E, Guillén-Grima F, Ferrer M. Updosing nonsedating antihistamines in patients with chronic spontaneous urticaria: a systematic review and meta-analysis. *Br J Dermatol*. 2016;175(6):1153–1165. **4.** Maurer M, Rosén K, Hsieh H-J, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013;368(10):924-935. **5.** Data on file. Genentech USA, Inc. South San Francisco, CA.

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- 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 Boxed WARNING and Medication Guide, for additional Important Safety Information.