XOLAIR® is an injectable prescription medicine used to treat adults and children 12 years of age and older with chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H1 antihistamine treatment. XOLAIR is not used to treat other forms of urticaria.

IMPORTANT SAFETY INFORMATION

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

Severe allergic reaction.

A severe allergic reaction called anaphylaxis can happen when you receive XOLAIR. The reaction can occur after the first dose, or after many doses. It may also occur right after a XOLAIR injection or days later. Anaphylaxis is a life-threatening condition and can lead to death. Go to the nearest emergency room right away if you have any of these symptoms of an allergic reaction:

- Continue reading symptoms of anaphylaxis inside this brochure.

Chronic hives with no known cause?

Antihistamines not helping enough?

TALK TO YOUR ALLERGIST OR DERMATOLOGIST ABOUT XOLAIR.

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XOL/121718/0232 (1) 09/19  Printed in the USA.

YOU CAN

TAKE CHARGE

LEARN MORE INSIDE...
XOLAIR MAY HELP

If antihistamines are not enough to relieve your chronic hives with no known cause, it’s time to talk to your doctor about XOLAIR.

XOLAIR has been shown to reduce the itch and hives associated with CIU.

For more information about the results of the clinical studies and how they were conducted see page 8.

Individual results may vary.

What is XOLAIR?
XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat adults and children 12 years of age and older with chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H1 antihistamine treatment. XOLAIR is not used to treat other forms of urticaria.

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

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Chronic hives may have no known cause
If your doctor cannot identify a cause for your chronic hives, chances are it’s a condition called Chronic Idiopathic Urticaria or CIU. Although frustrating, just because the cause is not known does not mean that there is nothing you and your doctor can do.

CHRONIC—Lasting 6 weeks or more
IDIOPATHIC—No known cause
URTICARIA—The medical term for “hives”

DID YOU KNOW?

• 7 out of 10 people with chronic hives are diagnosed with CIU.
• Women are twice as likely to have CIU as men.
• For most people with CIU, flares come and go for 1 to 5 years. Some patients have symptoms that last even longer.
• CIU is unpredictable. Symptoms can appear at any time without triggers.
• You cannot catch CIU by touching or being touched by someone with hives.

IMPORTANT SAFETY INFORMATION (cont’d)
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 your injection.
Individual results may vary. The road to finding the right doctor and getting the right diagnosis for CIU can take time and feel endless. Although sometimes hard to accept, even after a diagnosis, a specific underlying cause of CIU cannot be determined. But there are things you can do to manage your CIU:

• Talk to your allergist or dermatologist about your treatment options.
• Consider sharing this brochure with your family and friends to help them understand CIU and what you’re going through.

How are chronic hives diagnosed?

Chronic hives with no known cause are diagnosed by ruling out other potential causes. Your doctor will start by reviewing your complete medical history, followed by a comprehensive physical examination. Additional tests may be ordered based on the results.

If a cause still isn’t found and if your symptoms have lasted 6 weeks or more, your doctor may diagnose you with CIU.

IMPORTANT SAFETY INFORMATION (cont’d)

Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction after leaving the healthcare provider’s office or treatment center.

Do not receive XOLAIR® (omalizumab) if you are allergic to omalizumab or any of the ingredients in XOLAIR.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.
Consider XOLAIR
Some patients taking antihistamines prescribed by their doctor still experience CIU symptoms. If that is your case, consider XOLAIR.

XOLAIR is a monthly injection that is proven to reduce itch and hives.

It’s the only FDA-approved biologic treatment for chronic hives with no known cause.

IMPORTANT SAFETY INFORMATION (cont’d)
Before receiving XOLAIR, tell your healthcare provider about all of your medical conditions, including if you:

• have a latex allergy. The needle cap on the XOLAIR prefilled syringe may contain latex.
• have ever had a severe allergic reaction called anaphylaxis
• have or have had a parasitic infection
• have or have had cancer

Individual results may vary.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.
Results After 12 Weeks
XOLAIR reduced the feeling of itch and appearance of hives.*

<table>
<thead>
<tr>
<th>DOSE</th>
<th>ITCH SEVERITY‡</th>
<th>HIVE COUNT§</th>
<th>COMPLETE RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg</td>
<td>66% REDUCTION</td>
<td>67% FEWER</td>
<td>MORE THAN 1 IN 3 PATIENTS (36%) WERE COMPLETELY ITCH- AND HIVE-FREE</td>
</tr>
<tr>
<td>150 mg</td>
<td>47% REDUCTION</td>
<td>50% FEWER</td>
<td>NEARLY 1 IN 6 PATIENTS (15%) WERE COMPLETELY ITCH- AND HIVE-FREE</td>
</tr>
<tr>
<td>PLACEBO†</td>
<td>25% REDUCTION</td>
<td>25% FEWER</td>
<td>AROUND 1 IN 10 PATIENTS (-10%) WERE COMPLETELY ITCH- AND HIVE-FREE</td>
</tr>
</tbody>
</table>

*Based on results from CIU study 1, a 24-week clinical study. A total of 319 patients with CIU 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.
‡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.

IMPORTANT SAFETY INFORMATION (cont’d)
Before receiving XOLAIR, tell your healthcare provider about all of your medical conditions, including if you:
• are pregnant or plan to become pregnant. It is not known if XOLAIR may harm your unborn baby.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.

IMPORTANT SAFETY INFORMATION (cont’d)
• 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 XOLAIR.
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%)

Before XOLAIR

![Typical CIU flare before treatment with XOLAIR](image1)

After XOLAIR (300 mg)

![Shows how a 67% reduction of the weekly hive count score can look after 12 weeks on XOLAIR (300 mg)](image2)

*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.

Individual results may vary.
Simulation for illustrative purposes only.
For more information about the results of the clinical studies and how they were conducted, see page 8.

**IMPORTANT SAFETY INFORMATION (cont’d)**

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

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.

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**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 CIU flare before treatment with XOLAIR](image3)

After XOLAIR

![Possible complete response after 12 weeks on XOLAIR](image4)

Individual results may vary.
Simulation for illustrative purposes only.
For more information about the results of the clinical studies and how they were conducted, see page 8.

**IMPORTANT SAFETY INFORMATION (cont’d)**

**How should I receive XOLAIR?**

- XOLAIR should be given by your healthcare provider, in a healthcare setting.
- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 4 weeks.
Here’s **HOW XOLAIR MAY WORK** in helping to reduce itch severity and amount of hives:

1. **Histamine release is mediated by IgE**
   - Attached on the surface of mast cells through IgE receptors.
   - Mast cells are found in almost all tissues and play an important role in CIU by releasing certain inflammatory substances.

2. **Histamines cause inflammation**, leading to itching and hives.

3. **XOLAIR** was designed to bind to IgE to limit its ability to attach to mast cells, which reduces the release of inflammatory substances and IgE receptors on the surface of mast cells. How this specifically improves CIU symptoms is not clear.

**IMPORTANT SAFETY INFORMATION (cont’d)**
- In patients with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.

**IMPORTANT SAFETY INFORMATION (cont’d)**
- 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.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.
Talk to your allergist or dermatologist about XOLAIR® (omalizumab)

You may have a lot of questions and you may not know where to begin.

CONVERSATION STARTERS:

- Are my chronic hives really CIU?
- I’m taking an H1 antihistamine treatment, but my CIU symptoms are still uncontrolled. What more can I do?
- Can XOLAIR help me?
- How long does it take for XOLAIR to start working?
- What important safety information should I know about XOLAIR?
- Where would I get my XOLAIR injections?
- Will my insurance cover XOLAIR?
- What else can I do to manage my symptoms?

IMPORTANT SAFETY INFORMATION (cont’d)

What are the possible side effects of XOLAIR?

XOLAIR may cause serious side effects, including:

- See, “What is the most important information I should know about XOLAIR” regarding the risk of anaphylaxis.
- Cancer. Cases of cancer were observed in some people who received XOLAIR.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.

It’s important to keep an open dialogue with your allergist or dermatologist about your journey to treat chronic hives. Be sure to tell him or her about how your CIU has impacted you.

Individual results may vary.
Steps to getting started after your doctor prescribes XOLAIR:

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

2. **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. Remember to answer the phone. A voicemail left for you requesting a call-back may not mention XOLAIR by name. This is to protect your privacy.

3. **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 20 and 21 of this brochure.

4. **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.

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

**IMPORTANT SAFETY INFORMATION (cont’d)**

XOLAIR may cause serious side effects, including:

- **Fever, muscle aches, and rash.** Some people who take XOLAIR get these symptoms 1 to 5 days after receiving a XOLAIR injection. If you have any of these symptoms, tell your healthcare provider.

Individual results may vary.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.
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.

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

Fear of needles? Not to worry. 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 (cont’d)

XOLAIR may cause serious side effects, including:
- 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 accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.

IMPORTANT SAFETY INFORMATION (cont’d)

- 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 this is caused by XOLAIR.
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. 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/financial-support, or call 1-866-4XOLAIR (1-866-496-5247) Monday through Friday, 9 am to 8 pm ET.

† 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.

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IMPORTANT SAFETY INFORMATION (cont’d)
These are not all the possible side effects of XOLAIR. Call your doctor for medical advice about side effects.
You Have Resources

**XOLAIR® (omalizumab) “Support For You” program**
Receive useful resources to help you stay motivated and aware of what to expect on your XOLAIR treatment journey by completing the marketing consent section on the Patient Consent Form at your doctor’s office.

**Hear from patients like you**
Visit XOLAIR.COM to watch videos of patients like you with chronic hives open up to share their journey and experiences.

**Have questions?**
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 health or treatment, please contact your healthcare provider.

**IMPORTANT SAFETY INFORMATION (cont’d)**
You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full prescribing information, including Medication Guide in back inside pocket, as well as additional Important Safety Information on pages 26-28.

Individual results may vary.
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 by your allergist or dermatologist. Only they can tell you how long you’ll need to take XOLAIR and if you need any treatment changes.

Also, keep a treatment diary that includes your CIU medicines and pictures to share with your doctor so they can see what is working and what is not.

KEEP IN MIND:

While XOLAIR may help reduce your symptoms, it is not a cure.

Do not change or stop taking XOLAIR or any of your other hive medicines unless your doctor tells you to.

IMPORTANT SAFETY INFORMATION (cont’d)

You may also report side effects to Genentech at (888) 835-2555 or Novartis Pharmaceuticals Corporation at 888-669-6682.
What is XOLAIR?

XOLAIR® (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat adults and children 12 years of age and older with chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H1 antihistamine treatment. XOLAIR is not used to treat other forms of urticaria.

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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

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 your injection. Your healthcare provider should talk to you about getting medical treatment if you have symptoms of an allergic reaction after leaving the healthcare provider’s office or treatment center.

Do not receive 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. The needle cap on the XOLAIR prefilled syringe may contain 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 XOLAIR.

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

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• In patients with chronic hives, a blood test is not necessary to determine the dose or dosing frequency.
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• You may not see improvement in your symptoms right away after XOLAIR treatment.

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

• Fever, muscle aches, and rash. Some people who take XOLAIR 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 this is caused by XOLAIR.

The most common side effects of XOLAIR:

• In people with chronic idiopathic 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.
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XOL/121718/0232 (1) 09/19 Printed in the USA.