

# Make the connection and ask your doctor about allergic asthma and XOLAIR

#### What is XOLAIR?

XOLAIR is an injectable prescription medicine used to treat moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens. It is not known if XOLAIR is safe and effective in people with asthma under 6 years of age.

XOLAIR is not used to treat other allergic conditions or sudden breathing problems.

#### **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 page 4, with additional information about anaphylaxis on page 22.



### Is there more to your asthma?

If you've ever thought that your asthma and allergies are connected, you may be right. Asthma that is caused by certain allergens, like dust and pets, is called allergic asthma, a condition of its own. If your asthma is allergic asthma, you're not alone. It's the most common type of asthma, affecting over 15 million Americans.

### **TRIGGERS**

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# What's triggering your asthma?

People with allergic asthma are sensitive to triggers from airborne allergens, like pet dander, dust mites, and cockroaches. When your body overreacts to them, it can cause an attack.

Allergens trigger the body to make a number of proteins, including one called IgE, which can cause asthma symptoms and an attack. There will be more on this a bit later.

Identifying your triggers can help you to get a diagnosis, know what triggers to avoid, explore treatment options, and better manage your symptoms.



# Is your allergic asthma under control?

If you're not treating allergic asthma for what it is, you may not be getting the relief you're seeking. Allergic asthma that is uncontrolled with inhaled corticosteroids can take its toll—day and night. Ask yourself how you are really doing and if you've noticed any of these signs:

Are your symptoms getting worse and occurring more often than they used to?

Are you wheezing and coughing, or having chest tightness?

Do you wake up during the night because of your asthma?



Are you not getting enough relief from your inhaled corticosteroid treatment?



Do you reach for your rescue inhaler more than 2 days a week?

Have you been concerned that your asthma symptoms are not controlled with your current treatment plan?



# If your doctor says you have allergic asthma, **XOLAIR** can help

XOLAIR is an injectable prescription medicine used to treat moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids.

XOLAIR is not inhaled, not a steroid, and is not something you take daily. It's an FDA-approved biologic medicine that targets an underlying cause of allergic asthma. Biologic treatments are targeted therapies that are made from living organisms.

XOLAIR is the only biologic drug designed to target IgE\* and help reduce asthma attacks in moderate to severe allergic asthma patients.

\*Learn more about IgE on page 6.

# IMPORTANT SAFETY INFORMATION (cont'd) Severe allergic reaction. (cont'd)

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



Models are for illustrative purposes only. Individual results may vary.

More than **305,000** patients 6 years of age and older have been treated with XOLAIR.<sup>†</sup>

XOLAIR is the #1 prescribed asthma biologic<sup>†</sup>

†Data on file (July 2020). Genentech USA, Inc. South San Francisco, CA.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

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.



# **XOLAIR** is designed to target IgE, an underlying cause of allergic asthma in your body

In allergic asthma, the immune system overreacts to an allergen (trigger) by making too much of a protein called immunoglobulin E, or IgE. An increase in IgE may lead to asthma symptoms and an attack.



#### **IMPORTANT SAFETY INFORMATION (cont'd)**

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

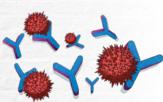
# Before receiving XOLAIR, tell your healthcare provider about all of your medical conditions, including if you:

 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. Unlike other medications you may have heard of, **XOLAIR** is the only approved targeted biologic treatment designed to block IgE in your body.

XOLAIR is not used to treat other allergic conditions.

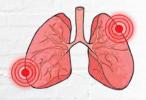


The IgE attaches to the allergen and to the inflammatory cells. This releases substances that may cause inflammation\* in the airways.





This inflammation can cause asthma symptoms that can lead to an attack.



\*Swelling and narrowing in the airways.



**XOLAIR** binds to IgE, preventing it from binding to the inflammatory cell.

#### IMPORTANT SAFETY INFORMATION (cont'd)

- have sudden breathing problems (bronchospasm)
- have ever had a severe allergic reaction called anaphylaxis
- have or have had a parasitic infection



#### Results for patients 12 and older

# **XOLAIR** significantly reduced asthma attacks and symptoms

In two 28-week clinical studies\* with 1071 patients whose moderate to severe persistent allergic asthma was not controlled on inhaled corticosteroids:



- Up to 86% of patients taking XOLAIR had no asthma attacks
- Fewer patients taking XOLAIR had 1 or more asthma attacks than patients not taking XOLAIR

#### Results for Study 1, first 16 weeks\*:

	Zero (0) asthma attacks	One (1) asthma attack	Two (2) or more asthma attacks
XOLAIR† (n=268)	86%	12%	<b>2</b> %
Control† (n=257)	<b>77</b> %	17%	<b>7</b> %

#### Results for Study 1, next 12 weeks\*:

	Zero (0) asthma attacks	One (1) asthma attack	Two (2) or more asthma attacks
XOLAIR† (n=268)	<b>79</b> %	19%	<b>2</b> %
Control† (n=257)	68%	28%	4%

# Results of the second study were similar to those of Study 1 shown above. Individual results may vary.

\*In the 28-week studies, in the first 16 weeks, patients continued their prescribed dose of inhaled corticosteroids. For the following 12 weeks, patients' inhaled corticosteroid use was slowly reduced.

In the XOLAIR group, patients were given XOLAIR in addition to their regular inhaled corticosteroid treatment. In the Control group, patients were given a placebo in addition to their regular inhaled corticosteroid treatment. A placebo is a look-alike treatment with no active medicine that can affect an illness.

In one 32-week study with 341 severe allergic asthma patients, there was no difference in the number of asthma attacks between patients who took XOLAIR and patients who did not.

 Patients may have also received oral corticosteroids in addition to inhaled corticosteroids

Results for Study 3, after 32 weeks:
Patients completed the corticosteroid reduction phase

Percentage of patients with asthma attacks



To ask questions or to obtain more information about these XOLAIR study results, please consult your doctor.

### IMPORTANT SAFETY INFORMATION (cont'd)

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

- have or have had cancer
- are pregnant or plan to become pregnant. It is not known if XOLAIR may harm your unborn baby.





#### **IMPORTANT SAFETY INFORMATION (cont'd)**

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

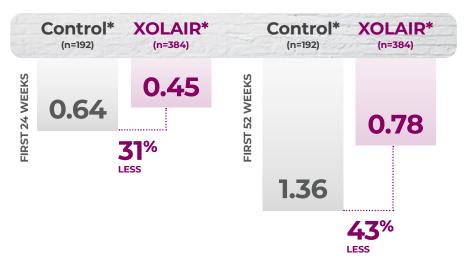
are breastfeeding or plan to breastfeed. It is not known
if XOLAIR passes into your breast milk. Talk with your
healthcare provider about the best way to feed your baby
while you receive and use XOLAIR.

#### Results for patients aged 6 to 11

### **XOLAIR** significantly reduced asthma attacks

In a 52-week study in children whose moderate to severe persistent allergic asthma was not controlled on inhaled corticosteroids:

#### Rate of asthma attacks:



**31**% relative decrease in the rate of asthma attacks for patients taking XOLAIR

**43**% relative decrease in the rate of asthma attacks for patients taking XOLAIR

 There was no difference in asthma symptom reduction between patients who took XOLAIR and patients who did not

Individual results may vary.

\*In the XOLAIR group, patients were given XOLAIR. In the Control group, patients were given a placebo. During the first 24 weeks of the study, the children in both groups took their prescribed dose of inhaled corticosteroid treatment. Over the next 28 weeks, adjustment of their inhaled corticosteroid dose was allowed. Throughout this study, patients were allowed to take other controller medications. (n) represents the number of patients included in that study group.

XOLAIR is FDA approved for patients 6 years old and up



# Talk to your asthma specialist about treatment with XOLAIR

Adding another medicine to your allergic asthma treatment plan can feel like a lot. But in clinical studies, adding XOLAIR helped reduce asthma attacks in patients who were not getting enough relief from their steroid inhalers. Your doctor will decide if XOLAIR could be the right choice for you.

# How long does **XOLAIR** take to work?



Sometimes it is hard to know if you are making progress, but over time you may start to notice your asthma is getting under control. It's important to allow some time before you see improvements. Talk to your doctor about what is a reasonable amount of time for you.

If your asthma symptoms do not improve or they get worse, call your healthcare provider.

Go to **XOLAIR.com/track** to get your own Progress Tracker and start measuring how XOLAIR is helping you take on your allergic asthma.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

**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.
- 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.

### Connecting you to the resources you need

Once you and your doctor have made the decision that XOLAIR is the right treatment for your allergic asthma, there are resources available to help you get started.

# Get help paying for XOLAIR

# ACCESS >> SOLUTIONS

 There may be options to help you afford your XOLAIR, no matter what type of health insurance you have.
 Scan here to learn more about how we can help:



 You may also call XOLAIR Access Solutions at 1-800-704-6610 if you have questions or to see if you qualify for assistance

### IMPORTANT SAFETY INFORMATION (cont'd)

 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. For children 6 to 11 years of age, XOLAIR prefilled syringe should be injected by a caregiver.



#### **GETTING STARTED**

### Simple steps to getting your XOLAIR

You don't have to go to your local pharmacy. We work with your doctor's office and **Specialty Pharmacies** to deliver XOLAIR to your doctor's office or your home (if you are doing the injection yourself). There's more on self-injection on page 18.

These steps may vary for some patients and/or doctors' offices.



Sign and date the Patient Consent Form in your doctor's office. This form lets us discuss your health information with your doctor and your health insurance plan.



XOLAIR Access Solutions will let you know your coverage, out-of-pocket cost, and financial assistance options.



Your Specialty Pharmacy may call you to confirm insurance and shipment details for XOLAIR. Be sure to return all calls from the Specialty Pharmacy. This helps them send your XOLAIR on time.

# IMPORTANT SAFETY INFORMATION (cont'd) How should I receive and use XOLAIR? (cont'd)

- 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 asthma, a blood test for a substance called IgE must be performed before starting XOLAIR to determine the appropriate dose and dosing frequency.
- Do not decrease or stop taking any of your other asthma medicine unless your healthcare providers tell you to.

#### Scan here to learn more.



You can review the full process of starting your XOLAIR treatment here.

### What is a Specialty Pharmacy?

A Specialty Pharmacy supplies certain medicines for patients. Some plans require you to use a certain Specialty Pharmacy to receive your medicine. They may also offer other services, such as suggesting programs that can help you afford your medicine.

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

- You may not see improvement in your symptoms right away after XOLAIR treatment. If your asthma symptoms do not improve or get worse, call your healthcare provider.
- If you inject more XOLAIR than prescribed, call your healthcare provider right away.



#### Connect to support



From diagnosis to treatment, every patient's experience is unique. If you've been prescribed XOLAIR, **the Support**For You Program is designed with YOU in mind. This free program provides relevant and timely support and resources, including periodic emails, to help ensure you have a positive experience while taking XOLAIR.



You can also sign up by calling 1-866-4XOLAIR (1-866-496-5247) Monday through Friday, 9 AM to 8 PM ET.

# IMPORTANT SAFETY INFORMATION (cont'd) 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.
- Inflammation of your blood vessels. Rarely, this can happen in people with asthma who receive XOLAIR. This usually, but not always, happens in people who also take a steroid medicine by mouth that is being stopped or the dose is being lowered. It is not known whether this is caused by XOLAIR.

# It's time to get started

A skin or blood test is needed to see if you are allergic to year-round allergens.



Your doctor will customize the dose of XOLAIR for you, and will determine if injections will be needed every 2 or 4 weeks.

You will need to start XOLAIR treatment in a healthcare setting. A nurse or doctor will inject XOLAIR under the skin.

After treatment has been established at your doctor's office, your doctor may determine that self-injection with the prefilled syringe is right for you. For appropriate patients, XOLAIR may provide flexibility on where it can be injected—at home or while traveling.

During and after the injection, your healthcare provider will monitor you closely for signs of anaphylaxis. If determined appropriate for self-injection, your healthcare provider will help you recognize the signs and symptoms of a severe allergic reaction and what to do if this occurs. 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.



Not actual size.



### Preparing for injection day

Read the Medication Guide and Instructions for Use before every injection.

Before your visit, ask your healthcare provider where the injection will be applied so what you wear gives them 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.







**GAME** 

**BOOK** 

**MOVIE** 

### Self-injection with XOLAIR prefilled syringe

After you've established your XOLAIR treatment in a doctor's office or infusion center, your doctor may determine that self-injection is right for you. Here is what you need to know:

If your doctor 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 your doctor.

- For children 12 years of age and older, XOLAIR prefilled syringe may be self-injected under adult supervision
- For children 6 to 11 years of age, XOLAIR prefilled syringe should be injected by a caregiver

Your doctor may ask you about your confidence with self-injection and about your at-home support team, if you require injection assistance.

See the detailed Instructions for Use that comes with XOLAIR for information on the right way to prepare and inject XOLAIR.

#### TREATMENT SCHEDULE

_ weeks between doses	My XOLAIR dosage is _
Date:	
Date	
Date:	
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# IMPORTANT SAFETY INFORMATION (cont'd) XOLAIR may cause serious side effects, including (cont'd):

Tell your healthcare provider right away if you have rash; chest pain; shortness of breath; or a feeling of pins and needles or numbness of your arms or legs.

• 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.



# Have more questions about self-injection with **XOLAIR** prefilled syringe after your training?

#### You're not alone! You can:

- Schedule a virtual session with certified personnel at 1-866-878-0493 or learn more at XOLAIR.com
- Call 1-866-4XOLAIR (1-866-496-5247) if you have any questions



 Scan here to watch a supplemental step-by-step video of how to inject with the prefilled syringe at XOLAIR.com

#### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### XOLAIR may cause serious side effects, including (cont'd):

- 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 adults and children 12 years of age and older with asthma: joint pain especially in your arms and legs, dizziness, feeling tired, itching, skin rash, bone fractures, and pain or discomfort of your ears.
- In children 6 to less than 12 years of age with asthma: swelling of the inside of your nose, throat, or sinuses, headache, fever, throat infection, ear infection, abdominal pain, stomach infection, and nose bleeds.

These are not all the possible side effects of XOLAIR. Call your doctor for medical advice about side effects.



# IMPORTANT SAFETY INFORMATION (cont'd)

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.



#### **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
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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 sudden breathing problems (bronchospasm)
- 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?

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#### **IMPORTANT SAFETY INFORMATION (cont'd)**

- XOLAIR is given in 1 or more injections under the skin (subcutaneous), 1 time every 2 or 4 weeks.
- In people with asthma, a blood test for a substance called IgE must be performed before starting XOLAIR to determine the appropriate dose and dosing frequency.
- Do not decrease or stop taking any of your other asthma medicine unless your healthcare providers tell you to.
- You may not see improvement in your symptoms right away after XOLAIR treatment. If your asthma symptoms do not improve or get worse, call your healthcare provider.
- 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.
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- 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.

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# Ask your doctor about XOLAIR

- For 17 years, asthma specialists and allergists have prescribed XOLAIR to help their patients 12 years of age and older with allergic asthma
- XOLAIR has been approved for children 6 years and older since 2016

XOLAIR is an injectable prescription medicine used to treat moderate to severe persistent asthma in people 6 years of age and older whose asthma symptoms are not well controlled with asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens. It is not known if XOLAIR is safe and effective in people with asthma under 6 years of age.

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