# Most school-age kids with **asthma** have allergic asthma.

Does yours?

Learn about this distinct condition

### Enroll in our support program

for tools, information on financial resources, and more at **GetSupportForYou.com** or call 1-866-496-5247 As a parent of a child with asthma, you may already know a lot about the condition. But you may not know that **at least** 8 out of 10 school-age children with asthma have

**allergic asthma.** This brochure will tell you about allergic asthma and a treatment option called XOLAIR. You'll also learn:

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## What is XOLAIR?

XOLAIR<sup>®</sup> (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat patients 6 years of age and older with moderate to severe persistent asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens.

XOLAIR is not used to treat other allergic conditions, acute bronchospasm or status asthmaticus.

## 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
- Iow blood pressure, dizziness, fainting, rapid or weak heartbeat, anxiety, or feeling of "impending doom"
- Ilushing, 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.



## Could your child have allergic asthma?

When your child is having an asthma attack, you know it. Maybe there's wheezing, chest tightness, or trouble breathing. But did you know that things your child is allergic to may actually be *causing* those asthma attacks?

#### Allergic asthma is the most common type of asthma

Asthma is a long-term condition with inflammation and narrowing of the airways, as well as tightening of the muscles around the airways.

About 6.2 million people younger than 18 years old in the US have asthma. For most of them (and maybe for your child), their asthma symptoms are caused by breathing in an allergen like pet dander, dust mites, or cockroach debris. This is a distinct condition called **allergic asthma**.

In school-age children with asthma, **8** out of **10** have **allergic asthma** 



#### What is an **allergen**?

An allergen is a substance, such as pet dander or dust mites, that can cause an allergic reaction. Allergens are commonly called "**allergic triggers.**"



## Symptoms of asthma and allergic asthma that can lead to an attack are the same

#### These symptoms include:

- wheezing
- shortness of breath
- rapid breathing
- chest tightness
- coughing

## Certain triggers make allergic asthma distinct from other types of asthma

Triggers of allergic asthma include:



#### **Dust Mites**

Critters that are too small to be seen. They live in household dust.



#### Pet Dander

Tiny flakes that shed from skin and fur —similar to human dandruff but harder to see.



#### Cockroaches

These pests live all over the world. Their debris is a major trigger of allergic asthma.

#### Identifying your child's triggers can help you to:



get a diagnosis

know what triggers to avoid

explore treatment options

better manage your child's symptoms

## Diagnosing allergic asthma

If you think your child may have allergic asthma, seeking diagnosis and treatment from an asthma specialist could be an important step. It may lead to a needed change in your child's treatment plan. It may also lead to a decrease of his or her asthma attacks.

There are two types of asthma specialists:





A pulmonologist specializes in diseases of the lungs and breathing, including asthma.



There are a few things an asthma specialist will look at when diagnosing allergic asthma:





Results of your child's allergen test— 3 a blood or skin test that can show whether specific airborne allergens may be causing your child's asthma symptoms

> Ask your child's asthma specialist for an allergen test.

FOR PATIENTS 6 YEARS OF AGE AND OLDER WITH MODERATE TO SEVERE, PERSISTENT ALLERGIC ASTHMA UNCONTROLLED ON INHALED CORTICOSTEROIDS

## XOLAIR offers the possibility of fewer asthma attacks

If your child has moderate to severe, persistent, uncontrolled allergic asthma, inhaled corticosteroids may not be enough. **XOLAIR is the** *only* **FDA-approved biologic drug** designed to treat allergic asthma. A biologic drug, such as XOLAIR, is a medicine that is made from living organisms.

#### Adding XOLAIR has been shown to:

- Help reduce attacks and symptoms in appropriate allergic asthma patients 12 years and older.
- Help reduce attacks in appropriate patients 6 to less than 12 years old.
  - In a study of patients 6 to less than 12 years old, there was no difference in symptom reduction between those taking XOLAIR and those not taking XOLAIR.

#### Here's more you should know:

- XOLAIR is not an inhaled medication.
- XOLAIR is a prescription medicine that is injected under the skin (subcutaneous) by a doctor or nurse who is prepared to manage anaphylaxis that can be life-threatening.
- XOLAIR is not a corticosteroid.
- It is given every 2 or 4 weeks.
- XOLAIR is not used to treat other allergic conditions, acute bronchospasm (an asthma attack) or status asthmaticus (a severe asthma attack requiring immediate medical attention).



## Important Safety Information (continued)

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

- have any other allergies (such as food allergy or seasonal allergies)
- 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 XOLAIR.



## Children with severe asthma who've had a recent\* asthma attack are 3 times more likely to have a future attack in the next 6 months.

It's important to find out if your child's asthma is controlled. The Asthma Control Test<sup>™</sup> (ACT<sup>™</sup>) is a good place to start:

■ If your child is 12 to 17 years old, he or she can take the ACT<sup>™</sup> test for people 12 years and older at xolair.com/ACTfor12plus.

Be sure to share the results with an asthma specialist. He or she may decide that adding XOLAIR is an appropriate treatment option for your child.



\*Recent was defined as within the prior 3 months.

Please see accompanying full Prescribing Information, including Medication Guide, as well as additional Important Safety Information throughout and on pages 34-37.

### 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.

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 2 or 4 weeks.
- In asthma patients, a blood test for a substance called IgE must be performed prior to 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.



## See how XOLAIR was studied in patients 12 years of age and older

XOLAIR was studied in two 28-week clinical studies (Studies 1 and 2) to see if it could help appropriate allergic asthma patients decrease their asthma attacks and symptoms.

#### How the studies were done:

- The studies looked at 1071 patients 12 to 76 years old with moderate to severe, persistent allergic asthma uncontrolled on inhaled corticosteroids.
- In addition to their regular inhaled corticosteroid treatment, patients were given either XOLAIR (the "**XOLAIR group**") or a placebo (the "Control group").
- In **Study 1**, 268 patients were in the XOLAIR group and 257 patients were in the Control group.
- In **Study 2**, 274 patients were in the XOLAIR group and 272 patients were in the Control group.
- During the first **16 weeks** of each study, both groups of patients took their prescribed dose of inhaled steroid treatment
- Then, over the next **12 weeks**, their inhaled corticosteroid dose was slowly reduced.

#### What is the Control group?

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In this group, patients received inhaled corticosteroid treatment and a placebo. A placebo is a look-alike treatment with no active medicine that can affect an illness.

#### How did we define "asthma attack" in these studies?

"Asthma attack" meant that asthma symptoms got so bad, patients needed twice their inhaled corticosteroid dose and/or treatment with an oral corticosteroid.

In Studies 1 and 2, more patients taking XOLAIR had

## fewer asthma attacks—

even when their corticosteroid dose was reduced

- With patients taking XOLAIR, more had zero asthma attacks than patients not taking XOLAIR
- Fewer patients taking XOLAIR had 1 or more asthma attacks than patients not taking XOLAIR
- In Studies 1 and 2, patients taking XOLAIR had a significantly lower mean number of attacks than patients not taking XOLAIR

### Important Safety Information (continued)

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.
- **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. 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.

#### Here are the results from Study 1 for patients 12 years of age and older

Percentage of patients who had			
Zero (0) asthma attacks		Two (2) or more asthma attacks	
astrima attacks	азтпта аттаск	astrima attacks	

First 16 weeks: While maintaining inhaled corticosteroid dose

XOLAIR group (n=268)	<b>85.8</b> %	<b>11.9</b> %	<b>2.2</b> %
Control group (n=257)	<b>76.7</b> %	<b>16.7</b> %	<b>6.6</b> <sup>%</sup>
Next 12 weeks: While <i>lowering</i> inhaled corticosteroid d			ticosteroid dose
XOLAIR group (n=268)	<b>78.7</b> %	<b>19.0</b> %	<b>2.2</b> <sup>%</sup>
Control group (n=257)	<b>67.7</b> %	<b>28.4</b> %	<b>3.9</b> %

XOLAIR

Contro

XOLAIR

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#### Here are the results from Study 2 for patients 12 years of age and older

	Percentage of patients who had				
	Zero (0) asthma attacks	One (1) asthma attack	Two (2) or more asthma attacks		
	orticosteroid dose				
group n=274)	87.6%	11.3%	1.1%		
group n=272)	<b>69.9</b> %	<b>25.0</b> %	<b>5.1</b> <sup>%</sup>		
	Next 12 weeks: Wi	hile <i>lowering</i> inhaled co	rticosteroid dose		
group n=274)	<b>83.9</b> %	<b>14.2</b> %	<b>1.8</b> %		
group n=272)	<b>70.2</b> %	<b>26.1</b> %	<b>3.7</b> %		

## XOLAIR helped to significantly reduce asthma symptoms

for patients 12 years of age and older. In Studies 1 and 2, asthma symptoms were defined as:



## Important Safety Information (continued)

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

#### 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.
- **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.



## XOLAIR was studied in patients 12 years of age and older with *severe* allergic asthma

XOLAIR was studied in a **32-week** clinical study (**Study 3**) to see if it could help appropriate patients with severe allergic asthma decrease their asthma attacks and symptoms.

#### How the study was done:

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- The study looked at **341** patients 12 to 76 years old with severe, persistent allergic asthma uncontrolled on inhaled corticosteroids.
- The patients were divided into two groups—176 who were given XOLAIR (the "XOLAIR group") and 165 who were given a placebo (the "Control group"). Long-acting beta agonists (LABA) were also allowed.
- Each group was then divided into two smaller groups. Both were given inhaled corticosteroids. However, the second group was also given oral corticosteroids.
- For the first 16 weeks, patients continued their prescribed dose of inhaled corticosteroids. For the second 16 weeks, their inhaled corticosteroid dose was slowly reduced.

*Please see page 13 for definitions of "Control group" and "asthma attack" in this study.* 

The number of asthma attacks in the XOLAIR group was similar to the number of asthma attacks in the Control group. The possible reason why these results differ from Studies 1 and 2 may be related to the smaller number of patients studied, the types of patients studied, or other factors.

#### Here are the results from Study 3

	Percentage of patients who had one or more asthma attacks				
	+ Inhaled Corticosteroids Only	+ Oral and Inhaled Corticosteroids			
	First 16 weeks: While maintaining inhaled corticosteroid dose				
XOLAIR group	<b>15.9</b> <sup>%</sup> (n=126)	<b>32.0</b> <sup>%</sup> (n=50)			
Control group	<b>15.0</b> % (n=120)	<b>22.2</b> <sup>%</sup> (n=45)			
	Next 16 weeks: While lowering inhaled corticosteroid dose				
XOLAIR group	<b>22.2</b> <sup>%</sup> (n=126)	<b>42.0</b> <sup>%</sup> (n=50)			
Control group	<b>26.7</b> <sup>%</sup> (n=120)	<b>42.2</b> <sup>%</sup> (n=45)			

### Important Safety Information (continued)

The most common side effects of XOLAIR:

- In adults and children 12 years of age and older with asthma: pain especially in your arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of your ears.
- In children 6 to less than 12 years of age with asthma: common cold symptoms, headache, fever, sore throat, pain or discomfort of your ear, abdominal pain, nausea, vomiting and nose bleeds.

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.



## See how XOLAIR was studied in children 6 to less than 12 years of age

XOLAIR was studied in a **52-week** clinical study to see if adding it to inhaled corticosteroid treatment could help children with moderate to severe allergic asthma decrease their attacks.

#### How the study was done:

- The study lasted 52 weeks and looked at 628 children from 6 to less than 12 years of age with moderate to severe, persistent allergic asthma uncontrolled on inhaled corticosteroids.
- **421** of the children were given XOLAIR (the "**XOLAIR group**").
- **207** of the children were given a placebo (the "**Control group**").
- 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.

## 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
- Iow 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.

#### What is the Control group?

In this group, patients received inhaled corticosteroid treatment and a placebo. A placebo is a look-alike treatment with no active medicine that can affect an illness.

#### How did we define "asthma attack" in this study?

"Asthma attack" meant that asthma symptoms got so bad, patients needed twice their inhaled corticosteroid dose and/or treatment with an oral corticosteroid for at least 3 days.



## See how XOLAIR was studied in children 6 to less than 12 years of age

XOLAIR was studied in a **52-week** clinical study to see if adding it to inhaled corticosteroid treatment could help children with moderate to severe allergic asthma decrease their attacks.

#### How the study was done:

- The study lasted 52 weeks and looked at 628 children from 6 to less than 12 years of age with moderate to severe, persistent allergic asthma uncontrolled on inhaled corticosteroids.
- **421** of the children were given XOLAIR (the "**XOLAIR group**").
- **207** of the children were given a placebo (the "Control group").
- 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.



In this group, patients received inhaled corticosteroid treatment and a placebo. A placebo is a look-alike treatment with no active medicine that can affect an illness.

#### How did we define "asthma attack" in this study?

"Asthma attack" meant that asthma symptoms got so bad, patients needed twice their inhaled corticosteroid dose and/or treatment with an oral corticosteroid for at least 3 days.

## Children 6 to less than 12 years old who received XOLAIR had a lower rate of asthma attacks



In this study, although patients on XOLAIR showed a decrease in asthma attacks, there was no difference in asthma symptom reduction between those in the XOLAIR group and those in the Control group.



## Important Safety Information (continued)

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

- have any other allergies (such as food allergy or seasonal allergies)
- 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 XOLAIR.



## What happens in an allergic asthma attack?

laE

A person with allergic asthma breathes in an allergen like pet dander, dust mites, or cockroach debris.

Moderate

Blood

vessels

When the allergen is breathed in again, IgE attaches to the allergen *and* to the surface of inflammatory cells.

This releases substances that may

cause inflammation (swelling and

narrowing) in the airways.

narrowing of airway



In response, the body makes a substance called

Allergen

**Severely narrowed** 

airway in the lung

IgE (immunoglobulin E).

Inflammatory cell

Inflammatory

substances

This inflammation can cause asthma symptoms that can

lead to an attack.

### How XOLAIR is thought to work

XOLAIR is **designed to capture** most of the IgE in your body. It blocks IgE's role in the steps leading up to **the allergic asthma response**.

XOLAIR is not used to treat other allergic conditions.



### 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.



## Please see accompanying full Prescribing Information, including Medication Guide, as well as additional Important Safety Information throughout and on pages 34-37.



### Going for your child's XOLAIR treatment Here is what will happen when you go for XOLAIR treatment:

- Before your child receives his or her prescribed dose of XOLAIR from a doctor or nurse, be sure to read the XOLAIR Medication Guide in the back pocket of this brochure. (Do this before every injection.)
- During your child's injection, and for a time after the injection, the doctor will watch for signs and symptoms of anaphylaxis. Anaphylaxis is a severe, life-threatening allergic reaction.
- While you wait, your child can draw, listen to music, color, read, do homework, etc.
- Before you and your child leave the injection center, the doctor will remind you to continue to look for signs of severe side effects and anaphylaxis in your child.

#### What does a XOLAIR injection mean for your child?

Because XOLAIR is an injection given by a doctor or nurse:

- You know that your child is getting the full dose of the medicine.
- There is predictability with scheduled appointments once or twice a month.
- Appropriate dosing is specific to your child and determined by your child's age, weight, and IgE levels.

## What is XOLAIR ?

XOLAIR<sup>®</sup> (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat patients 6 years of age and older with moderate to severe persistent asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens.

XOLAIR is not used to treat other allergic conditions, acute bronchospasm or status asthmaticus.

## Important Safety Information (continued)

#### 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 2 or 4 weeks.
- In asthma patients, a blood test for a substance called IgE must be performed prior to 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.



## Preparing your child for injection day

As a parent or caregiver, helping to prepare your child for his or her first XOLAIR injection may be a good idea. Especially if he or she has a fear of needles. Here are some things you might try:

- Educate your child about why the XOLAIR injection is important and how it may help his or her allergic asthma.
- Look for role models together—or peers—who also get injections.
- Create a coping card. Have your child write out brave statements on an index card ahead of injection day. For example, "Other children like me with allergic asthma have gotten a needle. I can do it." During the injection, hold up the cards for your child to read.
- Tell your child that he or she will get a reward after the XOLAIR injection. A small toy or a homemade coupon for his or her favorite dessert may do nicely.



## About the XOLAIR injection

When preparing your child for his or her XOLAIR injection, it can be helpful to know about:

#### **XOLAIR dose and frequency**

Your asthma specialist will look at your child's age, IgE levels and body weight to determine the specific dose of XOLAIR. And if your child will get an injection every 2 weeks or every 4 weeks. Depending on the dose, your child may receive 1, 2, or 3 injections at each visit.

#### Subcutaneous (under the skin) injection

XOLAIR is a clear, slightly viscous fluid (like syrup). The injection is given under the skin.

## Important Safety Information (continued)

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.
- 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. 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 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.



## Financial assistance and support with XOLAIR XOLAIR Access Solutions

Once your child has a prescription, XOLAIR Access Solutions can help your doctor's office find out if he or she is covered by insurance. This can take about 2 weeks.

You can go to **genentech-access.com/patient** or call XOLAIR Access Solutions at **1-800-704-6610** with questions.

If it turns out your child is not covered by insurance and/or you need help with your co-pay, several **financial assistance options** may be available to you:

#### The XOLAIR Co-pay Assistance Program (1-855-965-2472)\*

Eligible patients pay \$5 per drug co-pay until a maximum of \$10,000 of co-pay assistance per 12-month period is reached

#### **Co-pay Foundations<sup>+</sup>**

Call XOLAIR Access Solutions for a referral

#### **Genentech® Access to Care Foundation<sup>‡</sup>**

May help you get your child's medicine for free

Learn more at xolair.com/financial-support-options or call **1-866-4XOLAIR (1-866-496-5247)** Monday through Friday, 9 AM to 9 PM ET.



\*Limitations apply and you must meet certain conditions. To learn more and for complete terms and conditions, visit www.xolair.com/copay.

<sup>†</sup>We cannot guarantee you will get help from a co-pay assistance foundation. The co-pay assistance foundations each have their own rules, including financial rules. Neither Genentech USA, Inc. nor Novartis Pharmaceuticals Corporation influence or control these co-pay assistance foundations. But XOLAIR Access Solutions can help you. We can refer you to an appropriate co-pay assistance foundation.

\*Visit www.xolair.com/GATCF to learn more.

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### Support for You

With Support For You, you can get tools and resources to help stay motivated and in-the-know about what to expect next on your child's treatment journey.

Signing up is free. Once you do, you'll get a Care Pack that includes:

- Step-By-Step: The roadmap to getting started on XOLAIR
- Here to Help: Financial Resource Support Guide
- More information that may be helpful

Ready to sign up? To get started, either: call us toll-free at 1-866-4XOLAIR (1-866-496-5247) Monday through Friday, 9 AM to 9 PM ET. or go to **xolair.com/supportforyou**.

#### The most common side effects of XOLAIR:

- In adults and children 12 years of age and older with asthma: pain especially in your arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of your ears.
- In children 6 to less than 12 years of age with asthma: common cold symptoms, headache, fever, sore throat, pain or discomfort of your ear, abdominal pain, nausea, vomiting and nose bleeds.



Please see accompanying full Prescribing Information, including Medication Guide, as well as additional Important Safety Information throughout and on pages 34-37.

## More than **200,000** patients 12 years of age and older have been **treated with XOLAIR**\*

- This number refers to appropriate allergic asthma patients 12 years of age and older treated from June 2003 until July 2016.
- As of July 2016, XOLAIR has also been approved to treat appropriate allergic asthma patients 6 to less than 12 years old.

### Important Safety Information (continued)

The most common side effects of XOLAIR:

- In adults and children 12 years of age and older with asthma: pain especially in your arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of your ears.
- In children 6 to less than 12 years of age with asthma: common cold symptoms, headache, fever, sore throat, pain or discomfort of your ear, abdominal pain, nausea, vomiting and nose bleeds.

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.

## Do you think your child may have moderate to severe, persistent allergic asthma?

If it's uncontrolled on inhaled corticosteroids—and if he or she is 6 years of age or older—remember:

- Certain triggers make allergic asthma **distinct** from other types of asthma.
- XOLAIR is the only FDA-approved biologic drug designed to treat allergic asthma.
- XOLAIR offers the **possibility** of:
  - fewer asthma attacks and symptoms if your child is 12 years or older.
  - fewer asthma attacks if your child is 6 to less than 12 years old.
- The **XOLAIR Co-pay Assistance Program** may help you pay for XOLAIR:
  - Eligible patients pay \$5 per drug co-pay until a maximum of \$10,000 of co-pay assistance per 12-month period is reached. To learn more and for complete terms and conditions, visit XOLAIRcopay.com.

Ask an asthma specialist if adding XOLAIR may be right for your child.



\*Based on US data.

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## What is XOLAIR?

XOLAIR<sup>®</sup> (omalizumab) for subcutaneous use is an injectable prescription medicine used to treat patients 6 years of age and older with moderate to severe persistent asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergens.

XOLAIR is not used to treat other allergic conditions, acute bronchospasm or status asthmaticus.

## **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
- Iow 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.

## Important Safety Information (continued)

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

- have any other allergies (such as food allergy or seasonal allergies)
- 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 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 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 2 or 4 weeks.
- In asthma patients, a blood test for a substance called IgE must be performed prior to 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.



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### Important Safety Information (continued)

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.
- 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. 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 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.

## Important Safety Information (continued)

The most common side effects of XOLAIR:

- In adults and children 12 years of age and older with asthma: pain especially in your arms and legs, dizziness, feeling tired, skin rash, bone fractures, and pain or discomfort of your ears.
- In children 6 to less than 12 years of age with asthma: common cold symptoms, headache, fever, sore throat, pain or discomfort of your ear, abdominal pain, nausea, vomiting and nose bleeds.

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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