

## Patient Education

### Omalizumab

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*You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information*

### Pronunciation

(oh mah lye ZOO mab)

### Brand Names: US

Xolair

### Brand Names: Canada

Omlyclo; Xolair

### Warning

- Allergic reactions have happened after this drug was given. Sometimes, this has been life-threatening. Allergic reactions have happened as early as after the first dose. They have also happened after a year of treatment. This drug will be started in a health care setting where you will be watched closely after getting it. Tell your doctor right away about any anxiety, chest or throat tightness, cough, dizziness, fast or weak heartbeat, feeling warm, flushing, hives, hoarse voice, itching, passing out, rash, shortness of breath, swelling of the throat or tongue, trouble breathing or swallowing, wheezing, or any other bad effects.

### What is this drug used for?

- It is used to treat hives.
- It is used to treat certain nose and sinus problems with nasal polyps.
- It is used to treat asthma.

- It is used to lower the chance of severe allergic reaction that may happen from accidentally eating a food to which a person is allergic.

### **For asthma:**

- Do not use this drug to treat an asthma attack. Use a rescue inhaler. Talk with your doctor.

### **For allergic reasons:**

- Do not use this drug to treat an allergic reaction. Talk with the doctor about what drug to use to treat an allergic reaction.

## **What do I need to tell my doctor BEFORE I take this drug?**

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

## **What are some things I need to know or do while I take this drug?**

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- If you have a latex allergy, talk with your doctor. Some products have latex.
- It may take a few months to see the full effect.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.

- Cases of cancer have happened in some people taking this drug. If you have questions, talk with the doctor.
- Some people at high risk for parasite infections have gotten a parasite infection after taking this drug. Your doctor may test your stool to see if you have a parasite infection. Talk with your doctor.
- If you are switching to this drug from a steroid, do not stop taking the steroid all of a sudden. The dose of the steroid may need to be slowly lowered to avoid side effects. Talk with the doctor.
- Some forms of this drug may not be for use in all ages of children. If you have questions, talk with the doctor.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

### **For allergic reasons:**

- This drug is not a cure for allergies. Continue to avoid foods that cause an allergic reaction. If you are taking other drugs for your allergy, do not stop taking them unless your doctor tells you otherwise.

### **For asthma:**

- Call your doctor right away if your breathing problems get worse, if your rescue inhaler does not work as well, or if you need to use your rescue inhaler more often.

## **What are some side effects that I need to call my doctor about right away?**

**WARNING/CAUTION:** Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Rarely, some allergic reactions have been deadly.
- A burning, numbness, or tingling feeling that is not normal.
- Bone pain.
- Trouble breathing that is new or worse.
- Some people using this drug get fever; joint pain, stiffness, or swelling; muscle pain; swollen glands; or rash. This has happened within 1 to 5 days after getting this drug. Call your doctor right away if you have any of these signs.
- Some people taking this drug have had chest pain, heart attacks, transient ischemic attacks (TIAs), or blood clots. It is not known if this drug caused these problems. Call your doctor if you have chest, jaw, or arm pain or pressure; passing out; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or coughing up blood. Call your doctor if you have a change in strength on 1 side is greater than the other, trouble speaking or thinking, change in balance, or blurred eyesight.

## What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

### For all patients taking this drug:

- Headache.
- Upset stomach.
- Stomach pain.
- Irritation where the shot is given.
- Bruising, itching, pain, or redness where the shot was given.

- Feeling tired or weak.
- Nose or throat irritation.
- Signs of a common cold.
- Pain in arms or legs.
- Ear pain.

### **Children:**

- Nosebleed.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

## **How is this drug best taken?**

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

### **Prefilled syringes and auto-injectors:**

- It is given as a shot into the fatty part of the skin on the top of the thigh or the belly area.
- This drug may be given into the outer area of the upper arm if given by someone else.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Wash your hands before and after use.
- Before using this drug, take it out of the refrigerator. Allow it to reach room temperature. Some products will take 15 to 30 minutes. Some products will take 30 to 45 minutes. Be sure you know how long to let your product sit out. Do not heat this drug.
- Some products must not be shaken. Be sure you know whether your product must not be shaken.
- Do not use if the solution is cloudy, leaking, or has particles.
- Do not use this drug if it has been dropped or if it is broken.

- This drug is colorless to slightly yellow or slightly brown. Do not use if the solution changes color.
- Do not give into a mole, scar, or skin that is irritated, tender, bruised, red, hard, or broken.
- Do not inject through clothes.
- Inject at least 1 inch away from where the last dose was given. If your dose has more than 1 injection, give the injections into 2 different places at least 1 inch apart.
- Do not give into skin within 2 inches (5 cm) of the belly button.
- If you see a small air bubble in the device, do not get rid of it.
- Do not rub the site where you give the shot.
- Each auto-injector and prefilled syringe is for one use only.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

### **Vials:**

- It is given as a shot into the fatty part of the skin on the top of the thigh, belly area, or upper arm.

## **What do I do if I miss a dose?**

- Call your doctor to find out what to do.

## **How do I store and/or throw out this drug?**

### **Prefilled syringes and auto-injectors:**

- Store in a refrigerator. Do not freeze.
- Do not use if it has been frozen.
- Store in the original container to protect from light.

### **Xolair prefilled syringes and auto-injectors:**

- This drug can be taken out of the refrigerator and put back in if needed. The total amount of time out of the refrigerator must not be more than 2 days.

- Protect from heat. Do not use if the syringe has been at temperatures above 77°F (25°C).

### **Omlyclo prefilled syringes:**

- This drug can be taken out of the refrigerator and put back in if needed. The total amount of time out of the refrigerator must not be more than 7 days.
- Protect from heat. Do not use if the syringe has been at temperatures above 77°F (25°C).

### **Vials:**

- If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

### **All products:**

- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

## **General drug facts**

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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