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Omalizumab Injection

pronounced as (oh mah lye zoo' mab)

IMPORTANT WARNING:

Omalizumab injection may cause serious or life-threatening allergic reactions. You may experience an allergic reaction immediately after receiving a dose of omalizumab injection or up to 4 days later. Also, an allergic reaction can occur after you receive the first dose of medication or at any time during your treatment with omalizumab. Tell your doctor if you are allergic to omalizumab injection, and if you have or have ever had food or seasonal allergies, a serious or life-threatening allergic reaction to any medication, or sudden breathing problems.

You will receive your first dose of omalizumab in a doctor's office or medical facility and additional doses until your doctor feels that you are safe to receive omalizumab at home. You will stay in the office for some time after you receive the medication so your doctor can watch you closely for any signs of an allergic reaction. Tell your doctor if you experience any of the following symptoms: wheezing or difficulty breathing, shortness of breath, cough, chest tightness, dizziness, fainting, fast or weak heartbeat, anxiety, feeling that something bad is about to happen, flushing, itching, hives, feeling warm, swelling of the throat or tongue, throat tightness, hoarse voice, or difficulty swallowing. Call your doctor immediately or get immediate emergency medical attention if you experience any of these symptoms after you leave your doctor's office or medical facility.

Your doctor will give you the manufacturer's patient information sheet (Medication Guide) each time you receive an injection of omalizumab. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of receiving omalizumab injection.

Why is this medication prescribed?

Omalizumab injection is used to decrease the number of asthma attacks (sudden episodes of wheezing, shortness of breath, and trouble breathing) in adults and children 6 years of age and older with allergic

asthma (asthma caused by inhaling substances such as dander, pollen, and dust mites) whose symptoms are not controlled with inhaled steroids. It is also used to treat nasal polyps (swelling of the lining of the nose) in adults whose symptoms are not controlled with inhaled steroids. Omalizumab is also used to treat chronic hives without a known cause that cannot successfully be treated with antihistamine medications such as diphenhydramine (Benadryl), cetirizine (Zyrtec), hydroxyzine (Vistaril), and loratadine (Claritin) in adults and children 12 years of age and older. Omalizumab is not used to treat other forms of hives or allergic conditions. Omalizumab injection is in a class of medications called monoclonal antibodies. It works by blocking the action of a certain natural substance in the body that causes the symptoms of allergic asthma, nasal polyps, and hives.

How should this medicine be used?

Omalizumab injection comes as a prefilled syringe and as a powder to be mixed with water to be injected subcutaneously (under the skin). When omalizumab is used to treat allergic asthma or nasal polyps, it is usually injected once every 2 or 4 weeks. You may receive one or more injections, depending on your weight and medical condition. When omalizumab is used to treat chronic hives, it is usually given once every 4 weeks. Your doctor will determine the length of your treatment based on your condition and how well you respond to the medication.

If you will be injecting omalizumab injection by yourself at home or having a friend or relative inject the medication for you, your doctor will show you or the person who will be injecting the medication how to inject it. You and the person who will be injecting the medication should also read the written instructions for use that come with the medication.

Check the prefilled syringe to be sure that the expiration date printed on the package has not passed. Holding the syringe with the covered needle pointing down, look closely at the liquid in the syringe. The liquid should be clear and colorless to pale brownish yellow and should not be cloudy or discolored or contain lumps or particles. Call your pharmacist if there are any problems with the package or the syringe and do not inject the medication.

Allow the syringe to warm to room temperature for 15 to 30 minutes away from direct sunlight before you inject the medication. Do not try to warm the medication by heating it in a microwave, placing it in hot water, or through any other method. Inject omalizumab within 4 hours after taking it out of the refrigerator. Dispose of used syringe in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

Do not remove the cap from the prefilled syringe until you are ready to inject omalizumab. Do not replace the cap after you remove it. Do not use the syringe if you drop it on the floor.

You may inject omalizumab injection on the front of the thighs or anywhere on your stomach except your navel (belly button) and the area 2 inches around it. If another person is injecting your medication, the outer area of the upper arms also may be used. Do not inject the medication into skin that is tender, bruised, red, hard, or not intact, or that has scars, moles, or bruises. Choose a different spot each time you inject the medication, at least 1 inch away from a spot that you have used before. If the full dose is not injected, call your doctor or pharmacist.

It may take some time before you feel the full benefit of omalizumab injection. Do not decrease your dose of any other asthma, nasal polyps, or hives medication or stop taking any other medication that has been prescribed by your doctor unless your doctor tells you to do so. Your doctor may want to decrease the doses of your other medications gradually.

Omalizumab injection is not used to treat a sudden attack of asthma symptoms. Your doctor will prescribe a short-acting inhaler to use during attacks. Talk to your doctor about how to treat symptoms of a sudden asthma attack. If your asthma symptoms get worse or if you have asthma attacks more often, be sure to talk to your doctor.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving omalizumab injection,

- tell your doctor and pharmacist if you are allergic to omalizumab, any other medications, or to any of the ingredients in omalizumab injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients. If you will be using the prefilled syringe, tell your doctor if you or the person who will be injecting the medication for you are allergic to rubber or latex.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: allergy shots (a series of injections given regularly to prevent the body from developing allergic reactions to specific substances) and medications that suppress your immune system. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had cancer.
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while using omalizumab injection, call your doctor.
- talk to your doctor about whether there is a risk that you will develop a hookworm, roundworm, whipworm, or threadworm infection (infection with worms that live inside the body). Tell your doctor if you have or have ever had any type infection caused by worms. If you are at high risk of developing this type of infection, using omalizumab injection may increase the chance that you will actually become infected. Your doctor will monitor you carefully during and after your treatment.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss a dose of omalizumab injection, call your doctor as soon as possible.

What side effects can this medication cause?

Omalizumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- pain, redness, swelling, warmth, burning, bruising, hardness, or itching in the place omalizumab was injected
- pain, especially in the joints, arms, or legs
- tiredness
- ear pain
- headache
- nausea
- swelling inside of the nose, throat, or sinuses
- stomach pain
- nose bleeds

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section or the SPECIAL PRECAUTIONS section, call your doctor immediately or get emergency medical treatment:

- fever, muscle aches, rash, and swollen glands within 1 to 5 days after receiving a dose of omalizumab injection
- shortness of breath
- coughing up blood
- skin sores
- severe pain, numbness, and tingling in your hands and feet

Some people who received omalizumab injection have had chest pain, heart attacks, blood clots in the lungs or legs, temporary symptoms of weakness on one side of the body, slurred speech, and changes in vision. There is not enough information to determine whether these symptoms are caused by omalizumab injection.

Omalizumab injection may increase the risk of developing certain types of cancer. There is not enough information to determine whether these cancers are caused by omalizumab injection.

Talk to your doctor about the risks of using this medication.

Omalizumab injection may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the package it came in, away from light, tightly closed, and out of reach of children. Store omalizumab injection in the refrigerator, but do not freeze it. Discard any medication that is outdated or no longer needed. Talk to your pharmacist about the proper disposal of your medication.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to check your body's response to omalizumab injection.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are receiving omalizumab injection or if you have received omalizumab injection within the past year.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Xolair[®]

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