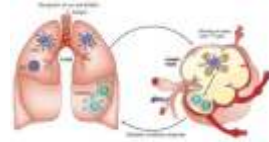


# Rx OMALIZUMAB

(Omalizumab is an injectable drug that is used for treating asthma)



**GENERIC NAME:** omalizumab

#### DRUG CLASS AND MECHANISM

Omalizumab is an injectable drug that is used for treating asthma. Omalizumab is a protein that resembles one type of human antibody. Antibodies are proteins produced by the body that recognize foreign substances such as bacteria (that cause infection) and pollens (that cause allergies). Once they recognize a foreign substance, the antibodies attach to receptors on two types of cells in tissues and blood, mast cells and basophils. These cells then release chemicals that cause an allergic reaction that leads to inflammation. Omalizumab blocks the receptors on the surfaces of the mast cells and basophils to which antibodies attach, thereby preventing antibodies from attaching to the cells. As a result, the cells do not release their chemicals, and the allergic reaction and inflammation are prevented. In asthmatic individuals, allergic reactions often cause attacks of asthma. Omalizumab reduces the attacks of asthma by preventing the allergic reactions caused by foreign substances. Omalizumab was approved by the FDA in June, 2003.

**PRESCRIPTION:** Yes

**GENERIC AVAILABLE:** No

**PREPARATIONS:** Sterile powder: 5 ml vial (150 mg)

#### DRUG INTERACTIONS

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription products you may use, especially of: other medications for asthma. Do not start or stop any medicine without doctor or pharmacist approval.

#### PRESCRIBED FOR

Omalizumab is used for treating adolescents and adults 12 years and older who have allergy sensitive, moderate to severe persistent asthma, that is not adequately controlled with inhaled steroids.

#### USES

This medication is used to treat moderate to severe asthma in adults and children over 12 years of age. It works by blocking your immune system's natural response to allergic triggers that can lead to an acute asthma attack. This action on your immune system (specifically immunoglobulin E-IgE), helps keep your air passages open and, over time, it keeps your asthma in better control. This medication does not work immediately and should not be used for the quick relief of an acute asthma attack.

#### HOW TO USE

Inject this medication under the skin (subcutaneously-SC), usually every 2 or 4 weeks as directed by your doctor. Learn how to prepare and inject the drug. Review all the product package instructions and consult your doctor or pharmacist if any of the information is unclear. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Learn how to store and discard needles and medical supplies safely. Consult your pharmacist. Use this medication regularly in order to get the most benefit from it. To help you remember, use it on the same day of the week according to your schedule. It may take up to several months of continued use to see improvement in your condition. The dosage is based on your body weight and blood level of IgE antibody, as well as your medical condition and response to therapy. Contact your doctor if you have a significant change in body weight during treatment. Your dose may need to be adjusted. Do not stop any of your asthma medications without consulting your doctor. Your condition may become worse if your asthma drugs are abruptly stopped. Any decrease of your medications (e.g., corticosteroids) should be done gradually, under the supervision of your doctor.

#### SIDE EFFECTS

Injection site itching, redness, stinging, or pain may occur. Leg, arm or ear pain may also occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: unusual lumps/growths/moles. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction

include: rash, itching, swelling (especially of the tongue or throat), dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

#### DOSING

Omalizumab is injected under the skin. The recommended dose is 150-375 mg every 2 to 4 weeks. The dose and frequency is based on body weight and levels of serum IgE, a type of antibody. Doses greater than 150 mg should be divided and administered at different sites so that no more than 150 mg is administered at each injection site.

#### OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly.

#### PRECAUTIONS

Before using this medication, tell your doctor or pharmacist your medical history, especially of: any allergies. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

#### MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

#### STORAGE

Store unopened vials in the refrigerator between 36 and 46 degrees F (2-8 degrees C). Once a vial is mixed, use the solution within 8 hours when stored in the refrigerator, or within 4 hours when stored at room temperature. Keep vials away from direct sunlight. Keep all medicines away from children and pets.

**Note :** This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

**Taj DRUG** WORLD

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Revised November 2010