

Rx ADALIMUMAB

(Adalimumab is an injectable protein that blocks the inflammatory effects)



100% EXPORT QUALITY MEDICINE



GENERIC NAME: adalimumab

DRUG CLASS AND MECHANISM

Adalimumab is an injectable protein that blocks the inflammatory effects of tumor necrosis factor alpha (TNF alpha) in rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease of the intestine. Inflammation is the body's reaction to injury and is a necessary process for the repair of injury. TNF is a protein that the body produces when there is inflammation. The TNF promotes inflammation and the signs of inflammation, which, in the case of arthritis, include fever as well as pain, tenderness, and swelling of joints. In the case of Crohn's disease, the signs of inflammation include fever, abdominal pain, and diarrhea. The unchecked inflammation of rheumatoid arthritis eventually leads to destruction of the joints. The inflammation in Crohn's disease can lead to strictures (narrowing) of the intestine or intestinal perforation. Adalimumab is a synthetic (man-made) protein, similar to human protein, that binds to TNF in the body and thereby blocks the effects of TNF. As a result, inflammation and its consequences in the joints and intestine are reduced. In arthritis, the progressive destruction of the joints is slowed or prevented. Adalimumab was approved by the FDA in December, 2002.

PRESCRIPTION: Yes

GENERIC AVAILABLE: No

PREPARATIONS: Prefilled glass syringe: 40 mg (0.8 ml); glass vial : 40 mg (0.8 ml)

PRESCRIBED FOR

Adalimumab is used for reducing the signs and symptoms of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease. It also slows the progression (destruction of the joints) and improves physical function (in adults) in moderate to severe rheumatoid arthritis. It is used after one or more other drugs that slow the destruction of the joints (referred to as disease modifying, anti-rheumatic drugs or DMARDs) have failed. In arthritis, adalimumab can be used alone or in combination with methotrexate or other DMARDs. Adalimumab is used similarly (alone or in combination with DMARDs) for the treatment of ankylosing spondylitis, psoriatic arthritis, and Crohn's disease.

DOSING

Adalimumab is injected under the skin. The recommended dose for adults is 40 mg every other week, but some patients may need weekly administration.

DRUG INTERACTIONS

This drug should not be used with the following medications because very serious interactions may occur: live vaccines, other TNF-blockers (e.g., etanercept, infliximab). If you are currently using any of these medications, tell your doctor or pharmacist before starting adalimumab. Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription products you may use, especially of: other arthritis drugs (e.g., methotrexate, prednisone, leflunomide, anakinra), drugs that suppress the immune system (e.g., cyclosporine). Do not start or stop any medicine without doctor or pharmacist approval.

USES

This medication is used to reduce pain and swelling due to rheumatoid arthritis. It works by blocking a protein (tumor necrosis factor or TNF) found in the body's immune system that causes joint swelling and damage. Early treatment of rheumatoid arthritis with more aggressive therapy, including this type of medication (TNF blockers), helps to reduce further joint damage and preserve joint function.

HOW TO USE

Use this medication exactly as prescribed. This drug is given under the skin (subcutaneously or SC) every other week, or weekly in some cases, or as directed by your doctor. Learn all preparation and usage instructions in the product package. Do not shake. Read the Patient Information Leaflet carefully. If any of the information is unclear, consult your doctor, nurse or pharmacist. Rotate injection sites. New injections should be given at least one inch from an old site. Do not inject into any areas of the skin that are sore, bruised, red or hard. 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.

SIDE EFFECTS

Redness, itching, pain, or swelling at the injection site may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: fast/irregular/pounding heartbeat, stomach pain, blood in the stools, mental/mood changes, severe headache, easy bruising or bleeding, dark urine, yellowing eyes and skin, leg pain or swelling. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: numbness or tingling of the hands or feet, unsteadiness, unexplained muscle

weakness, seizures, vision changes, extreme fatigue, chest pain, joint pain, butterfly-shaped rash on the nose and cheeks. Though unlikely, you may have a slightly increased risk of developing a certain type of cancer (lymphoma) due to this medication or due to rheumatoid arthritis. Tell your doctor immediately if you develop symptoms such as: unusual lumps/growths, swollen glands. Tell your doctor immediately if you develop signs of infection while using this drug, such as: fever, chills, persistent sore throat, trouble breathing, painful or frequent urination, unusual vaginal discharge, white patches in the mouth (oral thrush). Tell your doctor immediately if you develop signs of tuberculosis infection such as: mild fever, persistent dry cough, unexplained weight loss, night sweats. 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, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

See also Warnings section. This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: an active infection, TB infection, certain fungal infection (histoplasmosis), lupus, latex allergy (to the rubber needle cover on the medication syringe). Before using this medication, tell your doctor or pharmacist your medical history, especially of: recurrent infections, decreased bone marrow function, seizures, certain brain/spinal cord disorders (demyelinating disorders such as multiple sclerosis), history of cancer (e.g., lymphoma), scheduled surgery, any allergies. Do not have immunizations/vaccinations without the consent of your doctor and avoid contact with people who have recently received oral polio vaccine. Consult your doctor about the risks of exposure to chickenpox and other infections. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects of the drug. 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. Because of the potential risk to the infant, breastfeeding while using this drug is not recommended.

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.

MISSED DOSE

If you miss a dose, contact your doctor or pharmacist to establish a new dosing schedule.

STORAGE

Store in the refrigerator between 36-46 degrees F (2-8 degrees C) away from light and moisture. Do not freeze. Keep all medicines away from children and pets.

WARNING: This medication can decrease your immune system's ability to fight infections. Though unlikely, this drug may slightly increase your risk of developing serious, possibly fatal, infections. This risk is higher if you are also taking other drugs to suppress the immune system such as cyclosporine. Before starting this drug, you should take a tuberculosis (TB) skin test to check for a type of tuberculosis that may not be causing any symptoms (latent TB). If you are diagnosed with TB, you must first be treated for it before you start adalimumab to prevent a serious TB infection.

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.



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Revised November 2010