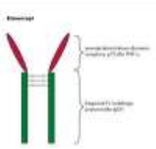
Rx ETANERCEPT

(Etanercept is an injectable drug that blocks tumor necrosis factor alpha)



GENERIC NAME: etanercept

DRUG CLASS AND MECHANISM
Etanercept is an injectable drug that blocks tumor necrosis factor alpha (TNF alpha) and is used for treating rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis. TNF alpha is a protein that the body produces during the inflammatory response, the body's reaction to injury. TNF alpha promotes the inflammation and its associated fever and signs (pain, tenderness, and swelling) in several inflammatory conditions including rheumatoid arthritis and ankylosing spondylitis. Etanercept is a synthetic (man-made) protein that binds to TNF alpha. It thereby acts like a sponge to remove most of the TNF alpha molecules from the joints and blood. This prevents TNF alpha from promoting inflammation and the fever, pain, tenderness and swelling of joints in patients with rheumatoid or psoriatic arthritis and ankylosing spondylitis. Etanercept reduces the signs and symptoms of rheumatoid arthritis, the arthritis of psoriasis, and ankylosing spondylitis. It prevents the progressive destruction of the joints in patients with rheumatoid arthritis and the arthritis of psoriasis.

GENERIC AVAILABLE: No

PRESCRIPTION: Yes

PREPARATIONS
White preservative-free powder in 25 mg vials. Before injection, etanercept is mixed with 1 milliliter of sterile water to form a clear colorless solution. 50 mg/mL prefilled syringe containing 1 mL.

PRESCRIBED FOR
Etanercept is used as primary treatment to reduce the pain, swelling and tenderness of joints resulting from moderate to severe rheumatoid arthritis in adults. It also may be used when rheumatoid arthritis has not adequately responded to other drugs (called disease-modifying medicines for rheumatoid arthritis). Etanercept can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.

Etanercept also is used to reduce the signs and symptoms of moderately to severely active, polyarticular-course, juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying medicines.

Etanercept is approved for the treatment of ankylosing spondylitis and the arthritis of psoriasis. It can prevent the progressive destruction of the joints in patients with psoriatic arthritis. Etanercept can improve physical function in patients with psoriatic arthritis. It also is reported to be of benefit in psoriasis, and uveitis.

Etanercept is not recommended for persons with preexisting disease of the central nervous system (brain and/or spinal cord) or for those with multiple sclerosis, myelitis, or optic neuritis.

DOSING
Etanercept is injected under the skin. Adults usually inject 25mg twice weekly. Children 4 to 17 years old should receive 0.4mg/kg (maximum 25mg) twice weekly. Etanercept has not been studied in children younger than 4 years.

DRUG INTERACTIONS
Drug interaction studies have not been conducted. Because etanercept may reduce the response of the immune system, etanercept should not be administered with live vaccines.

USES
This medication is used to treat certain types of arthritis (e.g., rheumatoid, psoriatic, and ankylosing spondylitis). It is also used to treat certain skin conditions (psoriasis).

HOW TO USE
Use this medication exactly as prescribed. This drug is given under the skin (SC) twice weekly or as directed. Learn all the preparation and administration instructions in the product package and ask your doctor or pharmacist if you are unclear on any information. Rotate injection sites. New injections should be given at least one inch from an old site. Do not inject into areas of the skin that are sore, bruised, red or hard. Do not use if the liquid contains particles or is discolored. Make sure needles and any medical supplies are stored safely and disposed of properly.

SIDE EFFECTS
Redness, itching, pain, or swelling at the injection site; colds; cough; headache; or nausea may occur. If these effects persist or worsen, notify your doctor promptly. Tell your doctor immediately if any of these unlikely but serious side effects occur: chest pain, stomach pain, trouble breathing, mental/mood changes, severe headache, signs of infections (e.g., persistent sore throat, fever), butterfly rash (i.e., rash on nose and cheeks), extreme fatigue. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: tingling of the hands or feet, unsteadiness, unexplained muscle weakness, seizures, vision changes, unusual bruising or bleeding. Though very unlikely, you may have a slight increased risk of developing cancer (e.g., lymphoma) to this medication. Tell your doctor immediately if you develop symptoms such as: unusual lumps/growths, swollen glands, night sweats, unexplained weight loss. 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
Tell your doctor your medical history, including: decreased bone marrow function, history of cancer (e.g., lymphoma), seizures, active or reoccurring infections, diabetes, certain brain/spinal cord disorders (demyelinating disorders such as multiple sclerosis), blood disorders, heart disease (e.g., heart failure), 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 risks of exposure to chickenpox and other infections. Tell your doctor if you are pregnant before using this medication. It is not known whether this drug is excreted into breast milk. Because of the potential risk to the infant, breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

DRUG INTERACTIONS
Tell your doctor of all nonprescription and prescription medication you may use, especially of: other arthritis drugs (e.g., methotrexate, prednisone, leflunomide, anakinra), immune suppressors such as cyclosporine. Do not start or stop any medicine without doctor or pharmacist approval.

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 unopened vials in a refrigerator between 36 and 46 degrees F (2 and 8 degrees C) away from light and moisture. Do not freeze. Once mixed, this drug must be used within 6 hours and should be stored in the refrigerator at 36-46 degrees F (2-8 degrees C).

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

Taj Group of Companies INDIA

Taj Pharmaceuticals Ltd.

Phone : *General EPA BX* : 91 - (0)22 - 26374592/92 91, (0)22 - 26374592/93 91 - (0)22 - 30601000,
Fax : 91-(0)22-26341274

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