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Etanercept Injection

pronounced as (et a ner' set)

IMPORTANT WARNING:

Using etanercept injection may decrease your ability to fight infection and increase the risk that you will get a serious infection, including severe viral, bacterial, or fungal infections that spread throughout the body. These infections may need to be treated in a hospital and may cause death. Tell your doctor if you often get any type of infection or if you think you may have any type of infection now. This includes minor infections (such as open cuts or sores), infections that come and go (such as cold sores) and chronic infections that do not go away. Also tell your doctor if you have or have ever had diabetes, human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), or any other condition that affects your immune system. You should also tell your doctor if you live or have ever lived in areas such as the Ohio and Mississippi river valleys where severe fungal infections are more common. Ask your doctor if you do not know if these infections are common in your area. Also tell your doctor if you are taking medications that decrease the activity of the immune system such as the following: abatacept (Orencia); anakinra (Kineret); azathioprine (Imuran); steroids including dexamethasone, methylprednisolone (Medrol), prednisolone (Prelone) and prednisone; or methotrexate (Rheumatrex).

Your doctor will monitor you for signs of infection during and shortly after your treatment. If you have any of the following symptoms before you begin your treatment or if you experience any of the following symptoms during or shortly after your treatment, call your doctor immediately: weakness; sweating; difficulty breathing; sore throat; cough; coughing up bloody mucus; fever; weight loss; extreme tiredness; diarrhea; stomach pain; flu-like symptoms; warm, red, or painful skin; or other signs of infection.

You may be infected with tuberculosis (TB, a type of lung infection) or hepatitis B (a type of liver disease) but do not have any symptoms of the disease. In this case, etanercept injection may increase the risk that your infection will become more serious and you will develop symptoms. Your doctor will perform a skin test to see if you have an inactive TB infection and may order blood tests to see if you have an inactive hepatitis B infection. If necessary, your doctor will give you medicine to treat this infection before you begin using etanercept injection. Tell your doctor if you have or have ever had TB, if you have lived in a country where TB is common, or if you have been around someone who has TB. If you have any of the following symptoms of TB, or if you develop any of these symptoms during your treatment, call your doctor immediately: cough, weight loss, loss of

muscle tone, or fever. Also call your doctor immediately if you have any of these symptoms of hepatitis B or if you develop any of these symptoms during or after your treatment: excessive tiredness, yellowing of the skin or eyes, loss of appetite, nausea or vomiting, muscle aches, dark urine, clay-colored bowel movements, fever, chills, stomach pain, or rash.

Some children and teenagers who received etanercept injection and similar medications developed severe or life-threatening cancers including lymphoma (cancer that begins in the cells that fight infection). If your child develops any of these symptoms during his treatment, call his doctor immediately: unexplained weight loss; swollen glands in the neck, underarms, or groin; or easy bruising or bleeding. Talk to your child's doctor about the risks of giving etanercept injection to your child.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with etanercept injection and each time you refill your prescription. 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 using etanercept injection.

Why is this medication prescribed?

Etanercept is used alone or with other medications to relieve the symptoms of certain autoimmune disorders (conditions in which the immune system attacks healthy parts of the body and causes pain, swelling, and damage) including:

- rheumatoid arthritis (condition in which the body attacks its own joints, causing pain, swelling, and loss of function) in adults,
- psoriatic arthritis (condition that causes joint pain and swelling and scales on the skin) in adults,
- juvenile idiopathic arthritis (JIA; a condition that affects children in which the body attacks its own joints, causing pain, swelling, loss of function, and delays in growth and development) in children 2 years of age and older,
- ankylosing spondylitis (a condition in which the body attacks the joints of the spine and other areas causing pain and joint damage),
- chronic plaque psoriasis (a skin disease in which red, scaly patches form on some areas of the body) in adults and children 4 years of age and older whose psoriasis is too severe to be treated by topical medications alone.

Etanercept is in a class of medications called tumor-necrosis factor (TNF) inhibitors. It works by blocking the action of TNF, a substance in the body that causes inflammation

How should this medicine be used?

Etanercept injection comes as a solution (liquid) in a prefilled syringe and an automatic injection device, and as a powder to be mixed with a provided liquid. Etanercept is injected subcutaneously (under the skin). It is usually injected once a week. When etanercept injection is used to treat chronic plaque psoriasis, it may be injected twice a week during the first 3 months of treatment and then once a week after the first 3 months. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use etanercept exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

You will receive your first dose of etanercept injection in a doctor's office. After that, you can inject the medication yourself at home or have a friend or relative perform the injections. Ask your doctor or pharmacist to show you or the person who will be performing the injections how to inject etanercept. Read the written instructions that come with etanercept injection before you inject the medication.

Vials of etanercept injection may contain enough medication for more than one dose. If there is enough medication left in the vial for a complete dose, place the vial in the refrigerator as soon as possible, but no later than 4 hours after you mix it. You may store the vial of etanercept injection for up to 14 days after you mix it if there is enough medication remaining for a complete dose. However, you should not combine the contents of two or more vials of etanercept injection to make a complete dose. You also should not mix any other medications with etanercept injection.

If your medication comes in a prefilled syringe or automatic injection device, use each syringe or device only once and inject all the solution in the syringe or device. Even if there is still some solution left in the syringe or device, do not use it again. Dispose of used needles, syringes, and devices in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

If you are using a prefilled syringe, an automatic injection device, or a vial that has been refrigerated, place the syringe, device, or vial on a flat surface and allow it warm to room temperature for 15-30 minutes before you are ready to 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.

Do not shake a syringe, automatic injection device, or vial that contains etanercept. Be careful not to drop the device onto a hard surface because this may damage the device, syringe, or needle.

Always look at etanercept solution before injecting it. Check that the expiration date has not passed and that the liquid is clear and colorless. The liquid may contain small white particles, but should not contain large or colored particles. Do not use a syringe or dosing pen if it is cracked or broken, if it is expired, or if the liquid is cloudy or contains large or colored particles.

The best place to inject etanercept injection is the front of your middle thighs. You can also inject the medication in your lower stomach below your navel, except the area 2 inches (5 centimeters) around your navel. If someone else is giving you the injection, that person can also inject the medication into your upper arms. If etanercept is injected into the upper arms or stomach, the skin in the area must be stretched to create a firm surface for the injection. Choose a different site for each injection. Do not inject into an area where the skin is tender, bruised, red, hard, or where there are scars or stretch marks. If you have psoriasis, do not inject into skin that is red, thick, raised, or scaly.

Etanercept injection may help control your condition but will not cure it. Continue to use etanercept injection even if you feel well. Do not stop using etanercept without talking 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 using etanercept injection,

- tell your doctor and pharmacist if you are allergic to etanercept or any other medications. If you will be using the prefilled syringe or automatic injection device, 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 prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section, medications for diabetes, and cyclophosphamide (Cytoxan). 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 seizures; a disease that affects your nervous system, such as multiple sclerosis (MS; loss of coordination, weakness, and numbness due to nerve damage); transverse myelitis (inflammation of the spinal cord that may cause abnormal sensations, loss of sensation, or loss of ability to move the lower body); optic neuritis (inflammation of the nerve that sends messages from the eye to the brain); bleeding problems ; liver disease, or heart failure.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using etanercept, call your doctor. If you use etanercept injection during your pregnancy, be sure to talk to your baby's doctor about this after your baby is born. Your baby may need to receive certain vaccinations later than usual.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are using etanercept.
- do not have any vaccinations during your treatment with etanercept without talking to your doctor. If your child will be treated with etanercept injection, talk to his or her doctor about vaccinations that should be given before the start of treatment. If possible, your child should be given all vaccinations needed for children of his or her age before beginning treatment.
- if you are exposed to chickenpox while using etanercept, call your doctor immediately.

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?

Inject the missed dose as soon as you remember it. If it is almost time for the next dose, skip the missed dose and continue your usual dosing schedule. Do not inject a double dose to make up for a missed one.

What side effects can this medication cause?

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

- redness, itching, pain, or swelling at the site of injection
- headache
- nausea
- vomiting
- heartburn
- stomach pain
- weakness
- cough

Some side effects can be serious. If you experience any of the following side effects or those mentioned in the IMPORTANT WARNING SECTION, call your doctor immediately or get emergency medical help:

- seizures
- bruising
- bleeding
- pale skin
- blistering skin
- rash
- hives
- itching
- swelling of the eyes, face, lips, tongue, throat, arms, hands, feet, ankles, or lower legs
- difficulty breathing or swallowing
- rash on the face and arms that worsens in the sun
- numbness or tingling
- vision problems
- weakness in the arms or legs
- dizziness
- red, scaly patches or pus-filled bumps on the skin

Adults who receive etanercept injection maybe at greater risk of developing lymphoma, leukemia (cancer that begins in the white blood cells), skin cancer, and other types of cancer than adults who do not receive this medication. Talk to your doctor about the risks of receiving etanercept injection.

Etanercept 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 container it came in, tightly closed, and out of reach of children. Store etanercept injection in the refrigerator but do not freeze. Keep the vials, prefilled syringes, or injection devices in their original cartons to protect them from light. If you have mixed a vial of etanercept powder with the provided liquid, you may store the solution in the refrigerator for up to 14 days.

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.

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>]

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 may order certain lab tests to check your body's response to etanercept.

Before having any laboratory test, tell your doctor and the laboratory personnel that you are using etanercept.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

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

- Enbrel[®]

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