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Enbrel

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Generic Name: etanercept (ee TAN er sept) Brand Names: *Enbrel, Enbrel Prefilled Syringe, Enbrel SureClick, Erelzi Prefilled Syringe, Erelzi Sensoready Pen*

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What is Enbrel?

Enbrel (etanercept) is a tumor necrosis factor (TNF) blocker. It works by decreasing TNF, a protein produced by the immune system to helps the body fight infections. In people with autoimmune disorders, the immune system produces too much TNF and mistakenly attacks healthy cells.

Enbrel is used to treat rheumatoid arthritis, psoriatic arthritis, or

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ankylosing spondylitis, and to prevent joint damage caused by these conditions.

Enbrel is also used to treat polyarticular juvenile idiopathic arthritis in children who are at least 2 years old.

Enbrel is also used to treat plaque psoriasis in adults and children who are at least 4 years old.

Important information

Using Enbrel may increase your risk of developing certain types of cancer, including a rare type of lymphoma. Ask your doctor about your specific risk. This has occurred mainly in teenagers and young adults using Enbrel or similar medicines to treat Crohn's disease or ulcerative colitis. Call your doctor at once if you have any of the following symptoms: fever, night sweats, itching, loss of appetite, weight loss, tiredness, feeling full after eating only a small amount, pain in your upper stomach that may spread to your shoulder, nausea, easy bruising or bleeding, pale skin, feeling light-headed or short of breath, rapid heart rate, dark urine, clay-colored stools, or jaundice (yellowing of the skin or eyes).

Enbrel can weaken your immune system. Serious and sometimes fatal infections may occur. Call your doctor right away if you have signs of infection such as: fever, chills, cough, sweating, body aches, skin sores or redness, diarrhea, burning when you urinate, or feeling very tired or short of breath.



21 Arthritis Facts: It's A Game Changer

Before taking this medicine

You should not use Enbrel if you are allergic to etanercept, or if you have a severe infection such as sepsis (infection of the blood).

To make sure Enbrel is safe for you, tell your doctor if you have:

- a weak immune system, HIV or AIDS, tuberculosis, or any type of recurring infection;
- symptoms of an active infection such as fever, flu symptoms, diarrhea, or painful urination;
- an open cut or skin sores;
- diabetes;
- congestive heart failure;
- a history of nerve disorders such as multiple sclerosis, Guillain-Barré syndrome, myelitis, or optic neuritis;
- epilepsy or other seizure disorder;
- asthma or other breathing disorder;
- if you have ever had hepatitis B;
- if you are allergic to latex rubber; or

• if you are scheduled to receive any vaccines, or if you have recently been vaccinated with BCG (Bacille Calmette-Guerin).

Tell your doctor if you have ever had tuberculosis, if anyone in your household has tuberculosis, or if you have recently traveled to an area where certain infections are common (Ohio River Valley, Mississippi River Valley, and the Southwest).

Children using this medication should be current on all childhood immunizations before starting treatment with Enbrel.

Using Enbrel may increase your risk of developing certain types of cancer, including a fast-growing lymphoma that can be fatal. This rare lymphoma has occurred in male teenagers and young men using a combination of immunosuppressant medicines to treat Crohn's disease or ulcerative colitis. However, people with autoimmune disorders (including rheumatoid arthritis, Crohn's disease, ankylosing spondylitis, and psoriasis) may have a higher risk of lymphoma. Talk to your doctor about your individual risk.

Tell your doctor if you are pregnant or plan to become pregnant while using this medicine. If you are pregnant, your name may be listed on a pregnancy registry. This is to track the outcome of the pregnancy and to evaluate any effects of Enbrel on the baby.

Etanercept can pass into breast milk and may harm a nursing baby. You should not breast-feed while using this medicine.



How should I use Enbrel?

Before you start treatment with Enbrel, your doctor may perform tests to make sure you do not have an infection.

Enbrel is injected under the skin. You may be shown how to use injections at home. Do not give yourself this medicine if you do not understand how to use the injection and properly dispose of used needles and syringes.

You may need to mix Enbrel with a liquid (diluent) before using it. If you are using the injections at home, be sure you understand how to properly mix and store the medication.

A child who weighs less than 138 pounds may not be able to use certain forms of Enbrel. If a child is using this medicine, tell your doctor if the child has any changes in weight.

Your care provider will show you the best places on your body to inject Enbrel. Do not inject into the same place two times in a row. Avoid injecting into skin that is bruised, tender, red, or hard.

You may have pain, redness, swelling, or warmth where the medicine was injected. Call your doctor if these symptoms continue for longer than 5 days.

Use a disposable needle and syringe only once. Follow any state or local laws about throwing away used needles and syringes. Use a puncture-proof "sharps" disposal container (ask your pharmacist where to get one and how to throw it away). Keep this container out of the reach of children and pets.

A single-use prefilled syringe or injection pen is for one use only. Throw away after one use, even if there is still some medicine left in it after injecting your dose.

Do not shake this medicine. Prepare your dose only when you are ready to give an injection. Do not use the medicine if it looks cloudy or has changed colors. Call your pharmacist for new medicine.

Enbrel can weaken your immune system. Your blood may need to be tested often.

If you have ever had hepatitis B, Enbrel can cause this condition to come back or get worse. You will need frequent blood tests to check your liver function during treatment and for several months after you stop using this medicine.

If you need surgery, tell the surgeon ahead of time that you are using Enbrel.

Store Enbrel in its original carton in the refrigerator. Do not freeze. Do not use after the expiration date on the label has passed. After mixing Enbrel with a diluent, store in the refrigerator and use within 14 days.

If you need to store Enbrel at room temperature, protect the medicine from light and from extreme hot or cold temperatures. Once the medicine has reached room temperature, you should not put it back into the refrigerator.

Throw away any Enbrel not used within 14 days. Throw away any Erelzi not used within 28 days.

Enbrel dosing information

Usual Adult Dose of Enbrel for Ankylosing Spondylitis:

50 mg subcutaneously once a week

Comments:

-Methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs (NSAIDs), or analgesics may be continued during treatment with this drug.

-Doses higher than 50 mg per week are not recommended.

Uses:

-Rheumatoid Arthritis: To reduce symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). This drug can be used alone or in combination with methotrexate (MTX).

-Ankylosing Spondylitis: To reduce symptoms in patients with active ankylosing spondylitis (AS).

-Psoriatic Arthritis: To reduce symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). This drug can be used alone or in combination with methotrexate (MTX).

Usual Adult Dose of Enbrel for Rheumatoid Arthritis:

50 mg subcutaneously once a week

Comments:

-Methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs (NSAIDs), or analgesics may be continued during treatment with this drug.

-Doses higher than 50 mg per week are not recommended.

Uses:

-Rheumatoid Arthritis: To reduce symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). This drug can be used alone or in combination with methotrexate (MTX).

-Ankylosing Spondylitis: To reduce symptoms in patients with active ankylosing spondylitis (AS).

-Psoriatic Arthritis: To reduce symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). This drug can be used alone or in combination with methotrexate (MTX).

Usual Adult Dose for Psoriatic Arthritis:

50 mg subcutaneously once a week

Comments:

-Methotrexate, glucocorticoids, salicylates, nonsteroidal anti-inflammatory drugs (NSAIDs), or analgesics may be continued during treatment with this drug.

-Doses higher than 50 mg per week are not recommended.

Uses:

-Rheumatoid Arthritis: To reduce symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). This drug can be used alone or in combination with methotrexate (MTX).

-Ankylosing Spondylitis: To reduce symptoms in patients with active ankylosing spondylitis (AS).

-Psoriatic Arthritis: To reduce symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis (PsA). This drug can be used alone or in combination with methotrexate (MTX).

Usual Adult Dose of Enbrel for Plaque Psoriasis:

Initial dose: 50 mg subcutaneously 2 times a week (administered 3 to 4 days apart) for 3 months; alternatively, starting doses of 25 to 50 mg once a week have been shown to be effective Maintenance dose: 50 mg subcutaneously once a week

Use: For the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

Usual Pediatric Dose for Juvenile Idiopathic Arthritis:

2 years and older:

-Less than 63 kg: 0.8 mg/kg subcutaneously once a week

-Greater than or equal to 63 kg: 50 mg subcutaneously once a week

-Maximum dose: 50 mg subcutaneously once a week

Comments:

-Glucocorticoids, nonsteroidal anti-inflammatory drugs (NSAIDs), or analgesics may be continued during treatment with this drug.

Use:

-For reducing symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients 2 years and older

Usual Pediatric Dose for Plaque Psoriasis:

4 years and older:

-Less than 63 kg: 0.8 mg/kg subcutaneously once a week

-Greater than or equal to 63 kg: 50 mg subcutaneously once a week

-Maximum: 50 mg subcutaneously once a week

Comments:

-Glucocorticoids, nonsteroidal anti-inflammatory drugs (NSAIDs), or analgesics may be continued during treatment with this drug.

Use: For the treatment of patients 4 years and older with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.

See also: Dosage Information (in more detail)

What happens if I miss a dose?

Call your doctor for instructions if you miss a dose of Enbrel.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while using Enbrel?

Avoid being near people who are sick or have infections. Call your doctor for preventive treatment if you are exposed to chicken pox.

Do not receive a "live" vaccine while using Enbrel. The vaccine may not work as well during this time, and may not fully protect you from disease. Live vaccines include measles, mumps, rubella (MMR), polio, rotavirus, typhoid, yellow fever, varicella (chickenpox), zoster (shingles), and nasal flu (influenza) vaccine.

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Enbrel side effects

Get emergency medical help if you have signs of an allergic reaction to Enbrel: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Serious and sometimes fatal infections may occur. Call your doctor right away if you have signs of infection such as: fever, chills, cough, sweating, body aches, skin sores or redness, diarrhea, weight loss, burning when you urinate, coughing up blood, or feeling very tired or short of breath.

Also call your doctor at once if you have:

- blood problems fever, pale skin, easy bruising or bleeding;
- liver problems upper stomach pain, vomiting, tiredness, loss of appetite, jaundice (yellowing of the skin or eyes);
- lupus-like syndrome joint pain or swelling, chest discomfort, feeling short of breath, skin rash on your cheeks or arms (worsens in sunlight);
- nerve problems numbness or tingling, problems with vision, or weak feeling in your arms or legs;
- new or worsening psoriasis skin redness or scaly patches, raised bumps filled with pus;
- signs of heart failure shortness of breath with swelling of your ankles or feet, rapid weight gain;

signs of lymphoma - fever, night sweats, weight loss, stomach pain or swelling, chest pain, cough, trouble breathing, swollen glands (in your neck, armpits, or groin); or

• signs of tuberculosis - fever, cough, night sweats, loss of appetite, weight loss, feeling constantly tired.

Common Enbrel side effects may include:

- pain, swelling, itching, or redness where the medicine was injected;
- headache; or
- cold symptoms such as stuffy nose, sneezing, sore throat.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See also: Side effects (in more detail)

What other drugs will affect Enbrel?

Tell your doctor about all your current medicines and any you start or stop using, especially:

- abatacept (Orencia);
- anakinra (Kineret);
- cyclophosphamide (Cytoxan); or
- insulin or oral diabetes medicine.

This list is not complete. Other drugs may interact with etanercept, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible interactions are listed in this medication guide.

Next → <u>Side Effects</u>



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- 206 Reviews Add your own review/rating
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Consumer resources

- Enbrel
- Enbrel Multiple-Use Vials
- Enbrel prefilled syringes
- Enbrel vials
- Enbrel (Advanced Reading)

Other brands: Erelzi

- Professional resources
- Enbrel (AHFS Monograph)
- Enbrel (FDA)
- □ Related treatment guides
- Psoriatic Arthritis
- Ankylosing Spondylitis
- Plaque Psoriasis
- Rheumatoid Arthritis
- Juvenile Idiopathic Arthritis
- Juvenile Rheumatoid Arthritis

Where can I get more information?

- Your doctor or pharmacist can provide more information about Enbrel.
- Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Enbrel only for the indication prescribed.
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DRUG STATUS



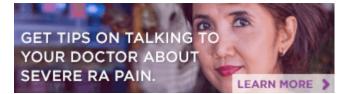
Availability Prescription only



Pregnancy Category No proven risk in humans

CSA Schedule Not a controlled drug

Approval History FDA approved 1998



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Drug Class Antirheumatics TNF alfa inhibitors

Related Drugs

Ankylosing Spondylitis prednisone, naproxen, Humira, aspirin, diclofenac, triamcinolone, More...

Rheumatoid Arthritis Humira, Plaquenil, hydroxychloroquine, Remicade, sulfasalazine, Rituxan, More...

Psoriatic Arthritis prednisone, Humira, methotrexate, triamcinolone, dexamethasone, Decadron, More...

Plaque Psoriasis Humira, dexamethasone, betamethasone topical, methylprednisolone, Remicade, Otezla, More... 2 more conditions...

Enbrel Rating 206 User Reviews

8.0/10

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