

Medication Guide ENBREL[®] (en-brel) (etanercept)

Read the Medication Guide that comes with ENBREL[®] before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or treatment with ENBREL[®].

What is the most important information I should know about ENBREL[®]?

ENBREL[®] is a medicine that affects your immune system. ENBREL[®] can lower the ability of your immune system to fight infections. Serious infections, including tuberculosis (TB), have happened in patients taking ENBREL[®]. Some patients have died from these serious infections.

Before starting ENBREL[®], tell your doctor if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as a fever, cough, flu-like symptoms
- have any open sores on your body
- get a lot of infections or have infections that keep coming back
- have diabetes or an immune system problem. People with these conditions have a higher chance for infections.
- have tuberculosis (TB), or if you have been in close contact with someone who has had tuberculosis
 - Your doctor should test you for TB before starting ENBREL[®]
 - Your doctor should monitor you closely for signs and symptoms of TB during treatment with ENBREL[®]
- use the medicine Kineret[®] (anakinra)
- have or have had hepatitis B

After starting ENBREL[®], if you get an infection, any sign of an infection including a fever, cough, flu-like symptoms, or have any open sores on your body, **call your doctor right away.**

ENBREL[®] can make you more likely to get infections or make any infection that you may have worse.

What is ENBREL[®]?

ENBREL[®] is a medicine called a Tumor Necrosis Factor (TNF) blocker. ENBREL[®] is used in adults to treat:

- **moderately to severely active rheumatoid arthritis (RA).** ENBREL[®] can be used alone or with a medicine called methotrexate.

- **psoriatic arthritis.** ENBREL[®] can be used with methotrexate in patients who have not responded well to methotrexate alone.
- **ankylosing spondylitis (AS)**
- **chronic, moderate to severe psoriasis**

ENBREL[®] is used in children ages 2 years and older to treat **moderately to severely active polyarticular juvenile idiopathic arthritis (JIA).**

ENBREL[®] has not been studied in children under 2 years of age.

ENBREL[®] can help reduce joint damage, and the signs and symptoms of the above mentioned diseases. People with these diseases have too much protein called tumor necrosis factor (TNF), which is made by your immune system. ENBREL[®] can reduce the amount of TNF in the body to normal levels and block the damage that too much TNF can cause, but it can also lower the ability of your immune system to fight infections. See “What is the most important information I should know about ENBREL[®]?” and “What are the possible side effects of ENBREL[®]?”

Who should not use ENBREL[®]?

Do not use ENBREL[®] if you:

- have an infection that has spread through your body (sepsis)
- have ever had an allergic reaction to ENBREL[®]

What should I tell my doctor before starting ENBREL[®]?

ENBREL[®] may not be right for you. Before starting ENBREL[®], tell your doctor about all of your health conditions, including if you:

- **have an infection.** (See “What is the most important information I should know about ENBREL[®]?”)
- **have seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis**
- **have heart failure**
- **are scheduled to have surgery**
- **are scheduled for any vaccines.** All vaccines should be brought up-to-date before starting ENBREL[®]. Patients taking ENBREL[®] should not receive live vaccines.
- **are allergic to rubber or latex.** The needle cover on the single-use prefilled syringe and the single-use prefilled SureClick[™] autoinjector contains latex.

Tell your doctor if you are pregnant, planning to become pregnant, or breastfeeding. ENBREL[®] has not been studied in pregnant women or nursing mothers.

Pregnancy Registry: Amgen has a registry for pregnant women exposed to ENBREL[®]. The purpose of this registry is to check the health of the pregnant mother and her child. Talk to your doctor if you are pregnant and contact the registry at 1-877-311-8972.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Your doctor will tell

you if it is okay to take your other medicines while taking ENBREL[®]. Especially, tell your doctor if you take:

- Kineret[®] (anakinra). You have a higher chance for serious infections when taking ENBREL[®] with Kineret[®].
- cyclophosphamide. You may have a higher chance for getting certain cancers when taking ENBREL[®] with cyclophosphamide.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist each time you get a new medicine.

How should I use ENBREL[®]?

See the Patient Instructions for Use that comes with your ENBREL[®] product for complete instructions. ENBREL[®] is available as:

- ENBREL[®] Single-use Prefilled Syringe
 - ENBREL[®] Single-use Prefilled SureClick[™] Autoinjector
 - ENBREL[®] Multiple-use Vial
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- ENBREL[®] is given by injection under the skin
 - Make sure you have been shown how to inject ENBREL[®] before you do it yourself. Someone you know can also help you with your injection.
 - Your doctor will tell you how often you should use ENBREL[®]. This is based on your condition to be treated. **Do not use ENBREL[®] more often than prescribed.**
 - Do not miss any doses of ENBREL[®]. **Call your doctor if you miss a dose of ENBREL[®]. Your doctor will tell you when to take your missed dose.**
 - Your child's weekly dose of ENBREL[®] depends on his or her weight. Your child's doctor will tell you which form of ENBREL[®] to use and how much to give your child.

What are the possible side effects of ENBREL[®]?

Serious side effects have happened in people taking ENBREL[®], including:

- **Serious Infections including tuberculosis (TB).** See “What is the most important information I should know about ENBREL[®]?”
- **Nervous system problems** such as Multiple Sclerosis, seizures, or inflammation of the nerves of the eyes have occurred in rare cases. Symptoms include numbness or tingling, problems with your vision, weakness in your arms and legs, and dizziness.
- **Blood problems.** In rare cases, your body may not make enough of the blood cells that help fight infections or help stop bleeding. This can lead to death. Symptoms include a fever that doesn't go away, bruising or bleeding very easily, or looking very pale.

- **Heart failure including new heart failure or worsening of heart failure you already have.** Symptoms include shortness of breath or swelling of your ankles and feet.
- **Allergic reactions.** Signs of an allergic reaction include a severe rash, a swollen face, or trouble breathing.
- **Immune reactions including a lupus-like syndrome.** Symptoms include a rash on your face and arms that gets worse in the sun. Symptoms may go away when you stop taking ENBREL®.
- **Lymphoma (a type of cancer).** People with rheumatoid arthritis or psoriasis may have a higher chance for getting lymphoma.

Call your doctor right away if you develop any of the above symptoms.

Common side effects of ENBREL® include:

- **Injection site reactions** such as redness, rash, swelling, itching, or bruising. These symptoms usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away or gets worse, call your doctor.
- **Upper respiratory infections** (sinus infections)
- **Headaches**

These are not all the side effects with ENBREL®. Ask your doctor or pharmacist for more information.

How should I store ENBREL®?

- Store ENBREL® in the refrigerator at 36° to 46°F (2° to 8°C).
- **Do not freeze.**
- Keep ENBREL® in the original carton to protect from light.
- **Keep ENBREL® and all medicines out of the reach of children.**

General Information about ENBREL®

Medicines are sometimes prescribed for purposes not mentioned in a Medication Guide. Do not use ENBREL® for a condition for which it was not prescribed. Do not give ENBREL® to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about ENBREL®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ENBREL® that was written for healthcare professionals. For more information call 1-888-4ENBREL (1-888-436-2735).

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What are the ingredients in ENBREL® Single-use Prefilled Syringe and the Single-use Prefilled SureClick™ Autoinjector?

Active Ingredient: etanercept

Inactive Ingredients: sucrose, sodium chloride, L-arginine hydrochloride and sodium phosphate

What are the ingredients in ENBREL® Multiple-use Vial?

Active Ingredient: etanercept

Inactive Ingredients: mannitol, sucrose, tromethamine.



Manufactured by:

Immunex Corporation,
Thousand Oaks, CA 91320-1799
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