

IMPORTANT SAFETY INFORMATION

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 have happened in patients taking ENBREL. These infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients have died from these infections. Your doctor should test you for TB before you take ENBREL and monitor you closely for TB before, during, and after ENBREL treatment, even if you have tested negative for TB.

There have been some cases of unusual cancers reported in children and teenage patients who started using tumor necrosis factor (TNF) blockers before 18 years of age. Also, for children, teenagers, and adults taking TNF blockers, including ENBREL, the chances of getting lymphoma or other cancers may increase. Patients with RA or psoriasis may be more likely to get lymphoma.

Before starting ENBREL, tell your doctor if you:

- Have any existing medical conditions
- Are taking any medicines, including herbals
- Think you have, are being treated for, have signs of, or are prone to infection. You should not start taking ENBREL if you have any kind of infection, unless your doctor says it is okay
- Have any open cuts or sores
- Have diabetes, HIV, or a weak immune system
- Have TB or have been in close contact with someone who has had TB
- Were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure
- Live, have lived in, or traveled to certain parts of the country (such as, the Ohio and Mississippi River valleys, or the Southwest) where there is a greater risk for certain kinds of fungal infections, such as histoplasmosis. These infections may develop or become more severe if you take ENBREL. If you don't know if these infections are common in the areas you've been to, ask your doctor
- Have or have had hepatitis B
- Have or have had heart failure
- Develop symptoms such as persistent fever, bruising, bleeding, or paleness while taking ENBREL
- Use the medicine Kineret® (anakinra), Orencia® (abatacept), or Cytoxan® (cyclophosphamide)
- Are taking anti-diabetic medicines
- Have, have had, or develop a serious nervous disorder, seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis or Guillain-Barré syndrome
- Are scheduled to have surgery
- Have recently received or 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
- Are pregnant, planning to become pregnant, or breastfeeding
- Have been around someone with chicken pox

What are the possible side effects of ENBREL?

ENBREL can cause serious side effects including: New **infections** or worsening of infections you already have; **hepatitis B** can become active if you already have had it; **nervous system problems**, such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes; **blood problems** (some fatal); new or worsening **heart failure**; new or worsening **psoriasis**; **allergic reactions**; **autoimmune reactions**, including a lupus-like syndrome and autoimmune hepatitis.

Common side effects include: Injection site reactions, upper respiratory infections (sinus infections), and headache.

In a medical study of patients with JIA, infection, headache, abdominal pain, vomiting, and nausea occurred more frequently than in adults. The kinds of infections reported were generally mild and similar to those usually seen in children. Other serious adverse reactions were reported, including serious infection and depression/personality disorder.

These are not all the side effects with ENBREL. Tell your doctor about any side effect that bothers you or does not go away.

If you have any questions about this information, be sure to discuss them with your doctor. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see **Prescribing Information** and **Medication Guide**.



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. It is important to remain under your doctor's care while using Enbrel.

Enbrel is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker that affects your immune system.

What is the most important information I should know about Enbrel?

Enbrel may cause serious side effects, including:

1. Risk of infection

Enbrel can lower the ability of your immune system to fight infections. Some people have serious infections while taking Enbrel. These infections include tuberculosis (TB), and infections caused by viruses, fungi, or bacteria that spread throughout their body. Some people have died from these infections.

- Your doctor should test you for TB before starting Enbrel.
- Your doctor should monitor you closely for symptoms of TB during treatment with Enbrel even if you tested negative for TB.
- Your doctor should check you for symptoms of any type of infection before, during, and after your treatment with Enbrel.

You should not start taking Enbrel if you have any kind of infection unless your doctor says it is okay.

2. Risk of cancer

- There have been cases of unusual cancers in children and teenage patients who started using TNF-blocking agents at less than 18 years of age.
- For children, teenagers, and adults taking TNF-blocker medicines, including Enbrel, the chances of getting lymphoma or other cancers may increase.
- People with rheumatoid arthritis or psoriasis, especially those with very active disease, may be more likely to get lymphoma.

Before starting Enbrel, be sure to talk to your doctor:

Enbrel may not be right for you. Before starting Enbrel, tell your doctor about all of your medical conditions, including:

Infections – tell your doctor if you:

- have an infection. (See “**What is the most important information I should know about Enbrel?**”)
- are being treated for an infection.
- think you have an infection.
- have symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms, shortness of breath, blood in your phlegm, weight loss, muscle aches, warm, red, or painful areas on your skin, sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than normal, and feel very tired.
- have any open cuts on your body.
- get a lot of infections or have infections that keep coming back.
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- were born in, lived in, or traveled to countries where there is a risk for getting TB. Ask your doctor if you are not sure.
- live, have lived in, or traveled to certain parts of the country (such as the Ohio and Mississippi River valleys, or the Southwest) where there is a greater risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may happen or become more severe if you use Enbrel. Ask your doctor if you do not know if you live or have lived in an area where these infections are common.
- have or have had hepatitis B.

Also, BEFORE starting Enbrel, tell your doctor:

- **About all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements including:**
 - ✓ **Orencia[®] (abatacept) or Kineret[®] (anakinra).** You have a higher chance for serious infections when taking Enbrel with Orencia[®] or Kineret[®].
 - ✓ **Cyclophosphamide (Cytoxan[®]).** You may have a higher chance for getting certain cancers when taking Enbrel with cyclophosphamide.
 - ✓ **Anti-diabetic Medicines.** If you have diabetes and are taking medication to control your diabetes, your doctor may decide you need less anti-diabetic medicine while taking Enbrel.

Keep a list of all your medications with you to show your doctor and pharmacist each time you get a new medicine. Ask your doctor if you are not sure if your medicine is one listed above.

Other important medical information you should tell your doctor BEFORE starting Enbrel, includes if you:

- have or had a nervous system problem such as multiple sclerosis or Guillain-Barré syndrome.
- have or had heart failure.

- are scheduled to have surgery.
- have recently received or are scheduled to receive a vaccine.
 - ✓ all vaccines should be brought up-to-date before starting Enbrel.
 - ✓ people taking Enbrel should not receive live vaccines.
 - ✓ ask your doctor if you are not sure if you received a live vaccine.
- are allergic to rubber or latex.
 - ✓ the needle covers on the single-use prefilled syringes and the single-use prefilled SureClick[®] autoinjectors contains dry natural rubber.
- have been around someone with varicella zoster (chicken pox).
- are pregnant or plan to become pregnant. It is not known if Enbrel will harm your unborn baby.
 - ✓ **Pregnancy Registry:** Amgen has a registry for pregnant women who take 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.
- are breastfeeding or plan to breastfeed. It is not known if Enbrel passes into your breast milk. You and your doctor should decide if you will take Enbrel or breast feed. You should not do both.

See the section “What are the possible side effects of Enbrel?” below for more information.

What is Enbrel?

Enbrel is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker.

Enbrel is used 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 alone or with methotrexate.
- **ankylosing spondylitis (AS).**
- **chronic moderate to severe plaque psoriasis in adults ages 18 years and older.**
- **moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in children ages 2 years and older.**

You may continue to use other medicines that help treat your condition while taking Enbrel, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

Enbrel can help reduce joint damage and the signs and symptoms of the above mentioned diseases. People with these diseases have too much of a protein called tumor necrosis factor (TNF), which is made by your immune system. Enbrel can reduce the effect of TNF in the body 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).

How should I use Enbrel?

- Enbrel is given as an injection under the skin (subcutaneous or SC).
- If your doctor decides that you or a caregiver can give the injections of Enbrel at home, you or your caregiver should receive training on the right way to prepare and inject Enbrel. Do not try to inject Enbrel until you have been shown the right way by your doctor or nurse.
- Enbrel is available in the forms listed below. Your doctor will prescribe the type that is best for you.
 - Single-use Prefilled Syringe
 - Single-use Prefilled SureClick Autoinjector
 - Multiple-use Vial
- See the detailed “Patient Instructions for Use” with this Medication Guide for instructions about the right way to store, prepare, and give your Enbrel injections at home.
- Your doctor will tell you how often you should use Enbrel. Do not miss any doses of Enbrel. If you forget to use Enbrel, inject your dose as soon as you remember. Then, take your next dose at your regular(ly) scheduled time. In case you are not sure when to inject Enbrel, call your doctor or pharmacist. **Do not use Enbrel more often than as directed by your doctor.**
- Your child’s 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?

Enbrel can cause serious side effects, including:

See “What is the most important information I should know about Enbrel?”

- **Infections.** Enbrel can make you more likely to get infections or make any infection that you have worse. Call your doctor right away if you have any symptoms of an infection. See “**Before starting Enbrel, be sure to talk to your doctor**” for a list of symptoms of infection.
- **Hepatitis B infection** in people who carry the virus in their blood. If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus can become active while you use Enbrel. Your doctor may do a blood test before you start treatment with Enbrel and while you use Enbrel.
- **Nervous system problems.** Rarely, people who use TNF-blocker medicines have developed nervous system problems such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Tell your doctor right away if you get any of these symptoms: numbness or tingling in any part of your body, vision changes, weakness in your arms and legs, and dizziness.
- **Blood problems.** Low blood counts have been seen with other TNF-blocker medicines. Your body may not make enough of the blood cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding very easily, or looking pale.

- **Heart failure** including new heart failure or worsening of heart failure you already have. New or worse heart failure can happen in people who use TNF- blocker medicines like Enbrel. If you have heart failure your condition should be watched closely while you take Enbrel. Call your doctor right away if you get new or worsening symptoms of heart failure while taking Enbrel, such as shortness of breath or swelling of your lower legs or feet.
- **Psoriasis.** Some people using Enbrel developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps that may be filled with pus. Your doctor may decide to stop your treatment with Enbrel.
- **Allergic reactions.** Allergic reactions can happen to people who use TNF-blocker medicines. Call your doctor right away if you have any symptoms of an allergic reaction. Symptoms of an allergic reaction include a severe rash, a swollen face, or trouble breathing.
- **Autoimmune reactions, including:**
 - ✓ **Lupus-like syndrome.** Symptoms include a rash on your face and arms that gets worse in the sun. Tell your doctor if you have this symptom. Symptoms may go away when you stop using Enbrel.
 - ✓ **Autoimmune hepatitis.** Liver problems can happen in people who use TNF-blocker medicines, including Enbrel. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of your stomach (abdomen).

Common side effects of Enbrel include:

- **Injection site reactions** such as redness, swelling, itching, or pain. 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).
- **Headache.**

These are not all the side effects with Enbrel. Tell your doctor about any side effect that bothers you or does not go away.

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

How should I store Enbrel?

- Store Enbrel in the refrigerator at 36° to 46°F (2° to 8°C).
- **Do not freeze.**
- **Do not shake.**
- 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.

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).

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

Multiple-use Vial:

Active Ingredient: etanercept

Inactive Ingredients: mannitol, sucrose, tromethamine

AMGEN[®]



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