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 herbal products
- 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
- Have been 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 painless swollen lymph nodes.
- 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 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:
- Infection site reactions, upper respiratory infections (sinus infections), and 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.

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 accompanying Medication Guide on the next page.
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:
- Risk of Infection
- Risk of Cancer

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 test you for TB if you have or had a nervous system problem such as multiple sclerosis or Guillain-Barré syndrome.
- Have symptoms of an infection such as fever, sweats or chills, cough or sore throat.
- Have or have had hepatitis B.
- People with rheumatoid arthritis or psoriasis, especially those with very active disease, may be more likely to get lymphoma.
- 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.
- TNF-blocker medicines, including Enbrel, can cause new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red patches or plaques.

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:

Refer to the following for more information:
- Have an infection (See “What is the most important information I should know about Enbrel?”)
- Are being treated for an infection.
- Have symptoms of an infection such as fever, sweats or chills, cough or sore throat.
- Have or have had a nervous system problem such as multiple sclerosis or Guillain-Barré syndrome.
- Some people using Enbrel developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red patches or plaques.

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.

Before starting Enbrel, be sure to talk to your doctor:
- Your doctor should test you for TB before starting Enbrel.
- Your doctor should test you for TB if you have or had a nervous system problem such as multiple sclerosis or Guillain-Barré syndrome.
- Have symptoms of an infection such as fever, sweats or chills, cough or sore throat.
- Have or have had hepatitis B.
- 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:

Refer to the following for more information:
- Have an infection (See “What is the most important information I should know about Enbrel?”)
- Are being treated for an infection.
- Have symptoms of an infection such as fever, sweats or chills, cough or sore throat.
- Have or have had a nervous system problem such as multiple sclerosis or Guillain-Barré syndrome.
- Some people using Enbrel developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red patches or plaques.

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).

Do not use Enbrel if you:
- Enbrel is a prescription medicine called a Tumor Necrosis Factor (TNF) blocker. Enbrel is used to treat:
  - moderating or moderate-to-severe 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 18 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 steriods, 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?”
- 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 notice 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.
- Nervous system problems. 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.
  - 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 notice 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).

What are the ingredients in Enbrel?

Enbrel is a single-use prefilled Syringe (15 mg) or Autoinjector (15 mg) that contains:

- The active ingredient is etanercept.

Inactive Ingredients:
- aspartame (saccharin sodium, sacrallose, and sodium phosphate)
- hydrochloric acid
- sodium hydroxide
- methylparaben
- propylparaben
- polysorbate 80
- sodium chloride
- water for injection

The Autoinjector also contains: Multiaxial Ejector System
- polyethylene glycol 400
- polyethylene glycol 6000
- polysorbate 80
- water for injection

The needle covers on the single-use prefilled syringes and the needle covers within the needle caps on the single-use prefilled SureClick® autoinjectors contain dry natural rubber.

How should I store Enbrel?

Store Enbrel in the refrigerator at 36°F to 46°F (2°C to 8°C). If needed, you may store the Enbrel syringe, autoinjector, or the dose tray for the single-use prefilled syringe at room temperature between 68°F and 77°F (20°C to 25°C) for up to 14 days.

- Once Enbrel has reached room temperature, do not put it back in the refrigerator.
- Store Enbrel in extreme heat or cold. For example, avoid storing Enbrel in your vehicle’s glove box or trunk.
- Do not freeze.
- Do not shake.

Keep Enbrel in the original carton to protect from light or physical damage.

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: aspartame, sodium chloride, L-arginine hydrochloride and sodium phosphate

Multiple-use Vial

Active Ingredient: etanercept

Inactive Ingredients: mannitol, sucrose, tromethamine

This Medication Guide has been approved by the U.S. Food and Drug Administration.