What Is ENBREL?

ENBREL is a prescription medicine that can be self-injected. It is used to treat five long-term inflammatory diseases: moderate to severe rheumatoid arthritis (RA), moderate to severe plaque psoriasis, psoriatic arthritis, moderate to severe juvenile idiopathic arthritis (JIA), and ankylosing spondylitis (AS).

ENBREL is grouped within a class of medications called biologic response modifiers, or biologics. By working on the immune system, biologics block proteins that contribute to the disease process. Because ENBREL suppresses the immune system, patients are at a greater risk for getting serious infections.

The science behind ENBREL

Tumor necrosis factor (TNF) is a substance made by your body's immune system. People with inflammatory diseases such as rheumatoid arthritis, plaque psoriasis, psoriatic arthritis, juvenile idiopathic arthritis, and ankylosing spondylitis have too much TNF in their bodies. ENBREL reduces levels of the active form of TNF.

The clinical history of ENBREL

ENBREL was the first biologic approved for moderate to severe rheumatoid arthritis

ENBREL has an established safety profile

ENBREL has over 10 years of continuous safety data in patients with rheumatoid arthritis

How ENBREL is taken

Taking ENBREL can be simple and convenient. ENBREL is injected (by you or a trained caregiver) just under the skin in the comfort of your own home. ENBREL is available in multiple injection options. And with the design of the Enbrel® (etanercept) SureClick® autoinjector, you'll never even have to see the needle. Schedule a training session with your doctor's office to learn the proper way to self-inject.

Click here to learn more about injecting ENBREL and to view step-by-step injection videos.

Injection site reactions such as redness, rash, swelling, itching, or bruising may occur. These symptoms usually go away within 3 to 5 days. If you experience these reactions and they don't go away or get worse, call your doctor.

If you ever have questions about injecting ENBREL, you can speak to a registered nurse at no cost to you. Just call 1-888-4ENBREL (1-888-436-2735) from 8 AM to 11 PM Eastern time, 7 days a week. This is just one of the many benefits of our ENBREL Support™ program.

Please see Full Prescribing Information, Important Safety Information, and Medication Guide for complete details about ENBREL.
Talk with Your Doctor

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 start taking 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 16 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 medical conditions
- Are taking any medicines, including herbas
- 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 painless while taking ENBREL
- Use medicines for diabetes (such as(Byetta, Exenatide), 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:

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 of 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.

INDICATIONS

Moderate to Severe Rheumatoid Arthritis (RA)
ENBREL is indicated for reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in patients with moderate to severe rheumatoid arthritis. ENBREL can be taken with methotrexate or used alone.

Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis (JIA)
ENBREL is indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in children ages 2 years and older.
What is Enbrel® (etanercept)?

ENBREL is indicated for reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in patients with psoriatic arthritis. ENBREL can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.

**Ankylosing Spondylitis (AS)**
ENBREL is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

**Moderate to Severe Plaque Psoriasis**
ENBREL is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

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**Supportive data**

**Moderate to Severe Rheumatoid Arthritis (RA):**
- In medical studies, ENBREL was shown to be clinically effective in about 2 out of 3 adults with moderate to severe RA. ENBREL has been shown to begin working in as few as 2 weeks, and most patients who benefit will do so within 3 months. In another medical study, 55% of patients who were evaluated 5 years after beginning ENBREL therapy had no further progression of joint damage.

**Moderately to Severely Active Polyarticular Juvenile Idiopathic Arthritis (JIA):**
- In a medical study, ENBREL was shown to be effective in about 3 out of 4 children with JIA who used it. For these JIA patients, ENBREL was shown to begin working in approximately 2 to 4 weeks.

**Psoriatic Arthritis:**
- In a medical study, ENBREL was shown to be effective in about 50% of psoriatic arthritis patients who used it. Clinical responses were apparent at the time of the first visit (4 weeks) and were maintained through 6 months of therapy.

**Ankylosing Spondylitis (AS):**
- In a medical study, ENBREL was shown to be effective in about 3 out of 5 adults with AS who used it. Clinical responses were seen at 2 weeks in 46% of patients, with 59% of patients receiving benefit within 8 weeks.

**Moderate to Severe Plaque Psoriasis:**
- In medical studies, nearly half of patients saw a significant improvement in their plaque psoriasis within 3 months of using ENBREL. Overall, 3 out of 4 patients saw improvement. ENBREL can work fast; many patients saw improvement within 2 months.