

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 or an immune system problem
- 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 or have lived in 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 histoplasmosis or other fungal infections are common in the areas where you live or have lived, ask your doctor
- Have or have had hepatitis B
- Have 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 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: **Infections**, including serious infections like TB; **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.

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**.

