



ETANERCEPT

What are the aims of this leaflet?

This leaflet has been written to help you understand more about etanercept (Enbrel). It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is etanercept and how does it work?

Etanercept is a powerful drug that has been specially designed to mimic normal human molecules, and for this reason it is classed as a biological drug. It can reduce inflammation and affect the immune system (the body's own system of defence). One of its actions in psoriasis is to reduce the activity of a chemical in the body called tumour necrosis factor alpha (TNF-alpha). This name is misleading since, apart from attacking tumours, TNF-alpha has many important functions such as fighting infections. There are, however, many diseases in which too much TNF-alpha is produced, causing unwanted inflammation. Etanercept opposes the effects of TNF-alpha.

Which skin conditions are treated with etanercept?

Etanercept is used to treat psoriasis, psoriatic arthritis, and several other inflammatory conditions such as rheumatoid arthritis.

Why have I been selected for treatment with etanercept?

Etanercept is reserved for patients with severe psoriasis who cannot take drugs such as methotrexate, ciclosporin, or use phototherapy (see separate British Association of Dermatologists leaflets on these drugs, and on severe psoriasis), or who have failed to respond to those treatments. Dermatologists are likely to use the British Association of Dermatologists Guidelines to

decide who is and who is not suitable for this treatment. Its availability will possibly be restricted by its cost - like most biological treatments it is much more expensive than regular non-biological drugs.

How long will I need to take etanercept before it has an effect?

Etanercept does not work immediately. It may be 3-12 weeks before you notice any benefit. Around 60-75% of patients achieve a good and worthwhile response.

How do I take etanercept?

Etanercept is injected under the skin twice weekly. It has to be stored in a refrigerator (at 2 to 8 °C) and reconstituted (dissolved) prior to injection. Travelling with etanercept, or transporting your treatment, requires a coolbox or coolbag with icepacks to maintain a cool temperature. Injections are made under the skin of the stomach, thighs or upper outer arms. A trained nurse or doctor will teach you how to do this. Instructions are also given in the package insert. You will be provided with sharps bins to dispose of your syringes and needles safely.

What dose should I take?

The recommended dose of etanercept for an adult patient with psoriasis is 25-50 mg, taken twice a week (3 or 4 days apart), and given for the first three months. After 3 months it may be stopped and then restarted if you have a relapse. Some patients may need to continue treatment, particularly if their psoriasis comes back quickly.

What are the possible side effects of etanercept?

All medicines have side effects. Those, like etanercept, that affect your immune system can rarely cause serious ones. These may include:

- **Serious infections**. Etanercept may decrease your ability to fight infection and increase the risk that you will get a serious or life-threatening one. You should avoid close contact with anyone with a bad cold, flu or pneumonia, and wash your hands often while you are taking this medication. Tell your doctor if you have any current infection, or if you are prone to infections such as cold sores or cystitis. Also tell your doctor if you have or have ever had any disease that affects your immune system, such as cancer, a human

immunodeficiency virus (HIV) infection, acquired immunodeficiency syndrome (AIDS), or viral hepatitis.

- **Nervous system diseases.** There have been rare cases of disorders affecting the nervous system of people taking etanercept or other TNF-alpha blockers. Signs of this include: numbness or tingling throughout your body; problems with your vision; weakness in your arms and/or legs; and dizziness. Tell your doctor if you have ever had a disease that affected your nervous system, such as multiple sclerosis; Guillain-Barré syndrome; numbness, burning or tingling in any part of your body; or seizures.
- **Blood problems.** Some patients may fail to produce enough of the blood cells that help to fight infections or to stop bleeding. If you develop a fever that doesn't go away, bruise or bleed very easily, or look very pale, call your doctor right away. Your doctor may decide to stop your treatment. Some people have also had symptoms that resemble lupus erythematosus (a rash on your face and arms that gets worse in the sun) and these may go away when you stop taking etanercept.
- **Heart problems.** You should also tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on etanercept, or may want to monitor you more closely.
- **Allergic reactions.** Some patients have had allergic reactions to etanercept. If you develop a severe rash, a swollen face, or difficulty with breathing while taking etanercept, visit your local hospital A & E department and make sure that your dermatologist is informed.
- There have been rare reports of lymphoma in patients taking etanercept, or other TNF blockers, for arthritis. The role of etanercept in the development of cancer is not known. However there is, in theory at least, an increased risk of developing certain cancers, though this remains unproven.

Before you start taking etanercept, your dermatologist may ask you about the following:

- **Any kind of infection:** including an infection that is in only one place in your body (such as an open sore); infections that affect your whole body; a history of infections that keep coming back; or other conditions, like diabetes, that might increase your risk of getting an infection.
- **Tuberculosis** or close contact with someone who has had it. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. You will need to be examined for tuberculosis and have a skin test.

- Hepatitis or an HIV infection, or if you think you are at risk of having these.
- Numbness or tingling or a disease that affects your nervous system like multiple sclerosis.
- A recent diagnosis of congestive heart failure, or if you are already being treated for it.
- If you are scheduled to have major surgery.
- If you are scheduled to have any type of vaccination.
- Latex allergy.

If you are not sure, or have questions about any of this information, arrange to discuss with your doctor before taking etanercept.

What are the more common, side effects of etanercept?

- Reactions where the injection was given. These are usually mild and include redness, a rash, swelling, itching, or bruising. They 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 (e.g. sinus infections).
- Headaches

I am planning to have an operation / dental surgery - what should I do?

Etanercept may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking etanercept.

How will I be monitored for the side effects of etanercept treatment?

You should have had a recent chest X-ray, blood checks and examinations before treatment starts; and blood checks need only be done 3 months after starting treatment, at 6 months, and then every 6 months. Regular visits for monitoring are essential, to assess your response and to look out for side effects.

The BAD Biologic Interventions Register (BADBIR)

Because etanercept treatment for psoriasis is relatively new, you will be asked to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and benefits and will inform doctors on how best to use etanercept and similar drugs. No information will

be passed to the register without your informed consent.

Can I have immunizations (vaccinations) whilst on etanercept?

You should not be immunized using any of the 'live' vaccines such as those for polio, rubella (German measles) and yellow fever. An 'inactivated' polio vaccine can be given instead of the 'live' one, and the 'inactivated' version should also be given to people you are in close contact with, such as members of your household.

If you are on etanercept you should avoid contact with children who have been given the 'live' polio vaccine, for 4-6 weeks after the vaccination.

Does etanercept affect pregnancy?

Etanercept has not been studied in pregnant women or nursing mothers, so it is not known what its effects are on pregnant women or babies who are being breast fed. You should tell your doctor if you are pregnant, become pregnant, or are thinking about becoming pregnant.

May I drink alcohol while I am taking etanercept?

There is no known interaction between alcohol and etanercept - but too much alcohol can make psoriasis worse, and so should be avoided.

Can I take other medicines at the same time as etanercept?

Most medicines are safe to take with etanercept. However it is important that your GP and other doctors are aware that you are taking it if any new drug is prescribed. Your GP and dermatologist should be aware of all your medications, including over-the-counter ones, and supplements, including herbal medicines. Methotrexate can be taken along with etanercept. However you should not take other immunosuppressives (medicines which suppress the immune system) while you are on etanercept.

Can I sunbathe?

Sunbeds and sunbathing should be avoided to reduce the risk of skin cancer.

Where can I find out more about etanercept?

This information sheet does not list all of the side effects of etanercept. If you want to know more about etanercept, or if you have any concerns about your treatment, you should speak to your doctor, specialist nurse or pharmacist. For fuller details, look at the drug information sheet which comes as an insert with your prescription for etanercept.

The British Association of Dermatologists' guidelines for use of biological interventions in psoriasis is available in the guidelines section of the BAD website.

Or visit the website <http://www.enbrel.com/>

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: its contents, however, may occasionally differ from the advice given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

**BRITISH ASSOCIATION OF DERMATOLOGISTS
PATIENT INFORMATION LEAFLET
PRODUCED JUNE 2005
UPDATED SEPTEMBER 2009
REVIEW DATE SEPTEMBER 2012**