



Australian
Rheumatology
Association

PATIENT INFORMATION ON ETANERCEPT

(Brand name: Enbrel)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about:

- **How you should take your medicine;**
- **What are the possible side effects;**
- **What tests you must have to monitor your condition and to detect unwanted effects; and**
- **Other precautions you should take.**

Please read it carefully and discuss with your doctor.

What is etanercept?

Etanercept (brand name Enbrel) belongs to a new class of medicines called **biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs)**.

bDMARDs have now been given to over a million people worldwide since initial use in the late 1990s.

These medicines block natural substances, called cytokines. These are substances found in excessive amounts in the blood and joints of people with rheumatoid arthritis, psoriatic arthritis, juvenile arthritis and ankylosing spondylitis.

The increased levels of cytokines cause inflammation which results in symptoms of pain, joint swelling and stiffness, and can lead to joint damage.

By blocking the cytokine called Tumour Necrosis Factor (TNF), etanercept reduces inflammation, lessens the symptoms and helps stop further joint damage.

Important things to remember

- While taking etanercept you must see your rheumatologist regularly to make sure the treatment is working as it should and to minimise any possible side effects.
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you have had cancer or if you develop cancer while you are taking etanercept.
- If you are taking etanercept and plan to become pregnant you must discuss the timing with your doctor.

What benefit can you expect from your treatment and how is it monitored?

Unlike many standard DMARDs, etanercept works relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first 4 weeks of treatment.

If etanercept treatment is stopped for more than a few weeks there is a risk that your condition will get worse again. Continue with your treatment unless advised by your doctor or unless side effects develop (see *Side effects*).

Current prescribing restrictions for all bDMARDs mean that etanercept will only be given if your disease is active and if standard treatments have been unsuccessful.

It will also not be continued unless it helps your condition. This will be assessed at least 12 weeks after the start of treatment.

Blood tests will be required during your treatment to monitor your condition and to determine the effectiveness of treatment.

The frequency of blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will determine the frequency of tests required.

How is etanercept taken?

Etanercept is injected under the skin of the abdomen or thighs.

It can be injected by your doctor, nurse, carer or by you. If injecting yourself, be sure to follow the detailed instructions carefully to ensure the best response. It is particularly important to **change the injection site each time**.

The usual dose for adults with arthritis is **50mg once a week**. In children the dose is usually less and may be twice a week.

Can other medicines be taken with etanercept?

Etanercept may be used with other arthritis medicines including:

- other DMARDs such as methotrexate;
- steroid medicines such as prednisolone or cortisone injections into the joint;
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen, Nurofen); and/or
- simple pain medicines such as paracetamol.

Etanercept cannot be used with other bDMARDs.

Are there any possible side effects?

You might experience side effects with your treatment. Contact your doctor if you have any concerns about possible side effects.

Most common possible side effects:

- *Mild pain, swelling or itching* at the site of the injection are very common (up to 20% of patients) but can be reduced by applying ice and antihistamine/steroid creams to the injection site.
- *Headaches, cough and stomach and bowel discomfort* may also occur.
- As etanercept affects the immune system, *mild infections*, particularly of the upper respiratory tract (e.g. colds, sinusitis) may occur more frequently than usual. Treatment may need to be temporarily stopped but please contact your doctor for advice.

Tell your doctor if you experience any possible side effects.

Less common or rare possible side effects:

- Serious *infections* such as Tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins (see *Precautions*).
- Rarely etanercept may cause an *allergic reaction* with itchy, red skin or a rash or a feeling of tightness in the chest and difficulty breathing.
- Side effects involving the *nerves, such as inflammation* of the nerve to the eye, may also occur rarely, causing changes in vision or sensation.
- Very rarely '*drug-induced lupus*' has occurred with symptoms of rash, fever and increased joint pain.
- If you have concerns about any of these possible side effects contact your rheumatologist.
- Many disappear when etanercept treatment is stopped.

- It is still unclear from research if there is an increased risk of *cancer* due to etanercept treatment (see *Precautions*).

What precautions are necessary?

Infections:

- If you have an active infection of any kind, treatment with etanercept will not be given until the infection is treated successfully.
- Etanercept will not be given if you have active untreated tuberculosis (TB) or HIV (AIDS) infection, as it is likely to make these conditions worse.
- If you have latent (inactive) TB, preventative anti-TB treatment will be started at least 4 weeks before etanercept. The anti-TB treatment will need to be taken for 9 months.
- Hepatitis B or C infection may not necessarily exclude treatment.
- Because of the risks associated with infection, the following tests will be conducted **before commencing treatment** with etanercept:
 - blood tests for Hepatitis B and C;
 - chest x-ray and two step Tuberculin Skin Test (Mantoux) or QuantiFERON blood test for tuberculosis (TB).
 - HIV tests are required for those who are at risk of this infection.

Precautions with other diseases:

- People with multiple sclerosis should not be treated with etanercept due to the possible effects on the nerves.
- People with moderate to severe heart failure may not be treated with etanercept as the medicine can make heart failure worse.
- People with systemic lupus erythematosus, (lupus/SLE) may still be able to take etanercept.

Use with other medicines:

- Etanercept can interact with other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.
- You should also mention your treatment when you see other health professionals.
- The risk of side effects from the low doses of aspirin used to prevent heart attack and strokes is not increased when taken with etanercept.
- Combined pain medicines such as Panadeine and Panadeine Forte, can be used while you are receiving etanercept treatment provided you take them as directed.

Surgery:

- If you require surgery for any reason, treatment with etanercept will be stopped before surgery. It will be restarted again after the operation, at a time determined by your surgeon and rheumatologist. Treatment will be restarted once the wound is healed and if there is no infection present.

Vaccines:

- You can have most vaccines safely with etanercept. Talk with your rheumatologist before receiving any vaccines.
- Pneumovax and the combined yearly seasonal flu /swine flu vaccinations are safe and recommended to reduce your risk of those infections.

Pregnancy and breastfeeding:

- It has previously been recommended that etanercept be avoided in pregnancy as not enough is known about its effects on the unborn baby. However if you plan to become pregnant it is important to discuss this with your doctor as each case is different.
- You should not breastfeed when taking etanercept.

Use with alcohol:

- You may drink alcohol while taking etanercept. However, since you are likely to be also taking methotrexate, you should be cautious about your alcohol intake. It is not known precisely what level of drinking is safe when on methotrexate, however there is general agreement that 1 to 2 standard drinks taken once or twice a week is unlikely to cause a problem.
- Drinking more than 4 standard drinks on one occasion, even if infrequently, is strongly discouraged.

Cancer risk:

- Lymphoma, a cancer of lymph glands, is found more commonly in patients with severe active rheumatoid arthritis than in the general population. Studies are in progress to see if treatment with etanercept changes this, but currently there is no evidence to suggest that this medicine increases lymphoma.
- If cancer has been previously treated and cured it is unclear whether a TNF-bDMARD such as etanercept can be used safely. At present an interval of at least 5 years is recommended between cure of a cancer and starting TNF-bDMARDs.

- For general cancer prevention, stopping smoking and skin cancer prevention measures are recommended. It is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.
- Talk to your doctor, if you have any concerns about issues relating to cancer risk.

How to store etanercept

- Keep the medicine **refrigerated**, even when travelling.
- Keep all medicines out of reach of children.

Stopping etanercept

- If you stop etanercept for any reason you must contact your doctor. Failure to do so may put your ability to continue on subsidised treatment at risk.

For more information about RHEUMATOID ARTHRITIS see the Arthritis Australia website
www.arthritisaustralia.com.au/index.php/arthritisminformation/information-sheets.html

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details:

If you are taking etanercept you should see your rheumatologist regularly to make sure the treatment is working as it should and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA.

The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.