



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)**.

These medicines block natural substances, called cytokines, 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.

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

What benefit can you expect from your treatment?

Unlike many standard DMARDs, etanercept works relatively quickly and some relief of joint swelling, pain and stiffness may be noticed 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 may worsen. Continue with your treatment unless advised by your doctor or unless side effects develop.

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

It will also only be continued if the response is adequate. Initial response will be assessed at least 12 weeks after the start of treatment.

How is etanercept given?

Etanercept is given as an injection 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 medicine must also be kept refrigerated.

The usual dose for adults is 50mg once a week. The dose may be different in children.

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.

It should not be given with other biological DMARDs.

Are there any side effects?

Biological DMARDs have now been given to over 750,000 people worldwide since initial use in the late 1990s.

Below are side effects that you might experience with your treatment. Tell your doctor if you experience any 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.

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 below).
- 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.
- Very rarely '*drug-induced lupus*' has occurred with symptoms of rash, fever and increased joint pain. This usually disappears when etanercept treatment is stopped.
- *Cancer*: It is unclear if there is an increased risk of cancer when etanercept is used to treat rheumatic diseases. There have been cases of certain types of cancer in patients

taking TNF inhibitors. 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.

If cancer has been previously treated and cured it is unclear whether a TNF-biological DMARD 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-biological DMARDs.

For general cancer prevention, stopping smoking is recommended, so too are skin cancer prevention measures (see *Precautions* overleaf).

Talk to your doctor, if you have any concerns about issues relating to cancer risk.

What precautions are necessary?

Infections:

- Etanercept should 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 4 to 6 weeks before etanercept. The anti-TB treatment may need to be taken for up to 9 months.
- Hepatitis B infection presents a risk but you may still be able to receive treatment with etanercept. Etanercept can usually be given safely if you have Hepatitis C.
- The following tests are required before commencing treatment with etanercept:
 - blood tests for Hepatitis B and C;
 - chest x-ray and two step Tuberculin Skin Test (Mantoux) or QuantiFERON assay for tuberculosis (TB).
- HIV tests are required only for those who are at risk of this infection.
- If you have an active infection of any kind, treatment with etanercept will not be given until the infection is treated successfully.

Ongoing blood tests:

- 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.

Other diseases:

- Due to the possible effects of etanercept on the nerves, it should not be given to people with multiple sclerosis.
- It should not be given to people with moderate to severe heart failure.
- Use in systemic lupus erythematosus, (lupus/SLE) needs to be considered carefully.

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:

- Most vaccines can be given safely with etanercept. Talk with your rheumatologist before receiving any vaccines.
- Pneumovax and yearly flu vaccinations are safe and recommended to reduce your risk of those infections.

Pregnancy and breastfeeding:

- Until more is known about its effects on the unborn baby, you should not take etanercept if you are pregnant or if you plan to become pregnant.
- You should also not breastfeed when taking etanercept.

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.

Skin cancer prevention:

- When taking etanercept, it is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.

All patients taking etanercept should be seen regularly by a rheumatologist to optimise treatment and to minimise any potential side effects.

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

Your doctor's contact details:

REMEMBER – Keep all medicines out of reach of children

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.