PATIENT INFORMATION ON ETANERCEPT

[ee-TAN-er-sept]

Brand name: Enbrel Biosimilar name: Brenzys

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

- how you should take your medication •
- what are the possible side effects •
- what tests you will have to monitor your condition
- other precautions you should take while • you are taking etanercept.

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as • suggested by your rheumatologist.
- It is important to tell your rheumatologist if you have a new serious illness such as a serious infection, cancer or heart failure.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop etanercept for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- If you plan to become pregnant, you must • discuss the timing with your rheumatologist

For more information about inflammatory conditions associated with arthritis, see Arthritis Australia's website: www.arthritisaustralia.com.au

What is etanercept?

Etanercept belongs to a class of medications called biological disease modifying antirheumatic drugs (biological DMARDs or bDMARDs). Specifically, it is a TNF inhibitor.

bDMARDs have now been given to over a million people worldwide since their first use in the late 1990s. These medications block substances, produced by arthritic tissues, called cytokines. These cytokines are found in excessive amounts in the blood and joints of people with rheumatoid arthritis, psoriatic arthritis, juvenile arthritis and ankylosing spondylitis.

They 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 lessens inflammation, pain symptoms and helps stop further joint damage.

What benefit can you expect from your treatment?

You may notice lessening of joint swelling, pain and stiffness, often within the first 8 weeks of starting.

Brands of etanercept

The biosimilar version of etanercept (brand name Brenzys) has been in use in Australia since early 2017. A biosimilar is a version of etanercept shown to have similar safety and benefit as the original brand. Make sure you are given the same brand each time. If you need to change brands, your rheumatologist will advise vou to and will monitor for side effects.

Stopping etanercept

If you stop or delay your etanercept treatment, you may worsen again. Keep on your treatment, unless told by your rheumatologist to stop or unless side effects occur (see Side effects).

If you stop etanercept for any reason, you must contact your rheumatologist. Failure to do so

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may mean that your treatment may no longer be funded.

How will you be checked while on etanercept?

- Medications like etanercept are very expensive and highly funded by Medicare. Certain conditions must be met to receive it.
- Etanercept will only be given if your disease is active and if standard treatments have not worked.
- It will only be kept going if it helps your condition. This must be checked between 12 and 16 weeks after the start of treatment.
- Blood tests are needed during your treatment to watch for side effects and decide if the treatment is working.
- How often you have blood tests will depend on what other medications you are taking and what other illnesses you might have. Your rheumatologist will advise on this.

How is etanercept taken?

Etanercept is injected under the skin of the abdomen or thigh. It comes in a pen or a syringe injection.

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 where you inject each time.

What is the dosage?

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

Can other medications be taken with etanercept?

Etanercept may be used with other arthritis medications including:

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

Etanercept cannot be used with other bDMARDs.

There are separate information sheets for the medications mentioned above.

Are there any side effects?

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

Many side effects disappear when etanercept treatment is stopped.

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 and/or leaving the medication out of the refrigerator for 15-30 minutes before injecting.
- Headaches, cough, stomach and bowel discomfort may also occur.
- As etanercept affects the immune system, mild infections, mainly the upper respiratory tract (e.g. colds, sinusitis) may occur more often. Treatment with etanercept may need to be briefly stopped for a serious infection so contact your rheumatologist for advice.

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.
- Rarely, etanercept may cause an *allergic reaction* with itchy, red skin or a rash or a feeling of tightness in the chest and trouble 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.
- Annual skin checks are suggested with any medications that can suppress the immune system as there is a slight increase in risk in skin cancers. To date research and use over 20 years, have not shown an increase in risk of other cancers.

What precautions are necessary? *Infections*

- If you have a current infection of any kind treatment with etanercept should not be given until the infection is treated.
- You will need some blood tests and a chest X-Ray to exclude some chronic infections before your first bDMARD.

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Precautions with other medical conditions

Worsening may occur of the following conditions:

- multiple sclerosis
- moderate to severe heart failure.
- systemic lupus erythematosus (lupus/SLE) People with SLE are not often given etanercept but each case will be assessed whether safe by your rheumatologist

Use with other medications

Etanercept can interact with other medications. You should tell all your doctors about all medications you are taking or plan to take. This includes over the counter or herbal/naturopathic medications.

Vaccines

- If you are taking etanercept you should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), Varicella vaccine (Chicken pox/shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin), Japanese Encephalitis or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumococcal vaccines and the yearly seasonal flu vaccinations are safe and encouraged.
- For more information on vaccination including the COVID-19 vaccination go to the ARA website; <u>https://rheumatology.org.au/</u> patients, medication information, vaccinations.

Surgery

 If you need surgery for any reason, etanercept should be stopped before surgery. It can start again after the operation at a time decided by your surgeon and rheumatologist, (often once the wound has healed as long as there is no infection).

Use with alcohol

 You may drink alcohol while taking etanercept. If you are also taking methotrexate you should be cautious about how much alcohol you drink.

Use in pregnancy and when breastfeeding

- It is important to discuss with you doctor if you are planning a pregnancy while on etanercept.
- It may be used in pregnancy and in men trying to father a child.

- If etanercept is kept going beyond 4 months of pregnancy it may increase the risk of infection in the newborn when live vaccines may be due.
- The rotavirus vaccine should be given within the first six months of life. MMR may be given at 6 months.
- There is only limited information regarding etanercept in breast milk and while small amounts may occur, it does not seem to be harmful.

More detailed information is available at: <u>https://rheumatology.org.au/For-</u> <u>Patients/Pregnancy-Information</u>

How to store etanercept

- Etanercept should normally be kept refrigerated. However, if needed, for example when travelling, it may be stored below 25°C for up to four weeks and then used or discarded.
- Keep all medications out of reach of children.

Questions?

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

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working 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 medications 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 medication. 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.

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