ETANERCEPT

What are the aims of this leaflet?

This leaflet has been written to help you understand more about etanercept. 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 one of the first of a group of modern drugs called 'biologics' or 'biologicals.' Unlike ordinary drugs which can usually be made from chemicals in a test tube, biologics are complex molecules made by living cells. They are designed to mimic or change processes in the human body and are used to treat a range of diseases from cancer to arthritis.

Etanercept blocks the effect of tumour necrosis factor alpha (TNF-alpha) so it is called an 'anti-TNF' drug. TNF-alpha helps the body fight infection and cancer, but when over produced it can have harmful effects. Over-production of TNF occurs in several diseases including Crohn's disease, psoriasis and inflammatory arthritis, so anti-TNF drugs have been as treatment.

What skin conditions are treated with etanercept?

Etanercept is used to treat chronic plaque psoriasis, psoriatic arthritis and other forms of arthritis such as ankylosing spondylitis and rheumatoid arthritis.

Are there different types of etanercept?

Yes; the first version of etanercept is called Enbrel® and another newer version is called Benepali®. Most biologics are very expensive because of their complicated manufacturing and regulatory processes.

Why have I been offered treatment with etanercept?

Etanercept is used to treat moderate to severe chronic plaque psoriasis when other drugs (including ciclosporin and methotrexate - see patient information leaflets) or ultraviolet phototherapy have failed to work or cannot be safely used. Enbrel is approved for children over six, and Benepali is approved for adults over 18.

The National Institute of Clinical Excellence (NICE) specifies that these drugs should only be prescribed through the NHS for severe psoriasis which is defined by a Psoriasis Area Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) score of more than 10. The PASI is a visual measure of how widespread, and active someone's psoriasis is, and the DLQI is a questionnaire to find out how much it is affecting their daily life.

How do I take etanercept?

Etanercept is given by injection under the skin (subcutaneous injection) once or twice a week. The medication comes in vials as a powder which needs to be dissolved in water before injection, or as a pre-filled injection 'pen' or syringe. These must be kept cool in a refrigerator (at 2-8^{0}C).

A trained nurse or doctor will teach you how inject yourself or your child. The usual places for injection are the abdomen, thighs or outer arms. A sharps bin will be provided for safe disposal of syringes / needles.

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

Etanercept works over several weeks and it may take up to three months before someone's psoriasis really improves. If there has not been a considerable improvement after 3 months the medication is stopped. The effectiveness of psoriasis treatment is assessed by comparing the PASI score and DLQI before and after 3 months' treatment. Further assessments are made every 3 months throughout treatment to check that is still working. A reduction in the PASI score of 75% from baseline (PASI 75) is considered a good response.

About two thirds of patients will get a 75% improvement in their psoriasis score with etanercept. In a smaller number, it may almost clear. If treatment is stopped, psoriasis usually comes back over several weeks.

What dose should I take?

The standard dose of etanercept for treatment of psoriasis in adults is 25mg twice a week, three or four days apart or 50mg once a week. Lower doses are used for children. It is usually given on its own for treatment of psoriasis, but psoriatic arthritis sufferers may also be given methotrexate.

What are the possible side effects of etanercept?

All medicines can cause side effects. Detailed information about side effects is found in the package insert leaflet. Please read this carefully before starting treatment.

Most side effects from Etanercept are mild and harmless, but because it affects the immune system there is a small chance of serious side effects.

Mild side effects include:

- **Soreness, redness, swelling and irritation of the skin** at the site of the injection (injection site reactions). These affect about 15% of people and should settle within a few days. If the skin does not clear and the swelling or pain gets worse, seek medical attention.
- **Upper respiratory infections** such as sinusitis and cold symptoms
- **Headache, muscular aches, and fatigue**
- **Mild allergic reactions** and irritation of the skin

Major side effects include:

- **Serious infections, especially tuberculosis.** Etanercept reduces the body's ability to fight certain infections and if you have dormant /inactive tuberculosis (Tb) or catch Tb while taking Etanercept, it can cause severe illness. Tell your doctor if you have ever had Tb or if you come into contact with a person with Tb. Etanercept may also make other infections such as chest infection, urine infection or cold sores worse. Seek urgent medical advice if you become unwell with a fever and weight loss or develop 'flu' symptoms while taking etanercept.
- **Nervous system diseases** have been reported very rarely. Symptoms include numbness or tingling, disturbed vision, weakness in the limbs and dizziness. Tell your doctor if you or a family member have ever had these symptoms or a disease that affects the nervous system such as multiple sclerosis or Guillain-Barre syndrome.
- **Heart failure** may be made worse by etanercept so it is not usually given to people who have had this problem. Inform your doctor if you

develop swelling of the ankles, difficulty breathing / shortness of breath as these can indicate heart failure.

- **Severe allergic reactions** with swelling of the face, widespread hives and difficulty breathing are very rare. If affected, seek urgent medical attention (call the emergency services on 999).
- **Blood disorders** due to failure of new blood cell production. Symptoms include easy bruising, bleeding and fever. If affected, seek urgent medical advice.

Possible side effects include:

Lymphoma (cancer of the lymph glands) has been reported in a very small number of patients taking etanercept. It is not yet clear if there is a genuine increased risk of cancers in patients taking etanercept. There is a theoretical increased risk because the medication reduces the body's immune response to cancer cells. Women should stay up to date with regular cancer screening tests (cervical smear, mammograms).

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

Before treatment is started, routine blood tests are carried and additional tests done for HIV and hepatitis virus infection in people who are at risk of these infections. A chest x ray is usually done. If you have ever had tuberculosis, further tests or treatment may be needed to make sure the infection has cleared.

Blood tests are usually checked after 3 months' treatment then every 3-6 months. Your PASI score and DLQI are usually measured every three months. Advise your doctor or nurse about any new symptoms or problems with your general health during etanercept as these may need further investigation.

The BAD Biologic Interventions Register (BADBIR)

You may be asked to take part in a national register if you are prescribed a biologic medication. This register will collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use biologic drugs. No information will be passed to the register without your informed consent.

Can I have immunisations (vaccinations) whilst taking etanercept?

Live vaccines such as rubella (German measles), yellow fever and oral polio should not be given to people taking etanercept. Inactivated vaccines are safe. Pneumovax and the 'flu' jab are safe, but the new nasal 'flu' vaccine is live so it should not be given to people on etanercept.

Does etanercept affect pregnancy?

Use of etanercept during pregnancy is not recommended. Consult your doctor if you are planning to have a baby or get pregnant during treatment with etanercept. Tell your health care team if you have taken etanercept during pregnancy as it may increase your baby's chances of catching an infection.

May I drink alcohol while taking etanercept?

Yes, as there is no known interaction between alcohol and Etanercept. Always aim to keep your drinking within the recommended limits.

Can I take other medicines if I take etanercept?

Most medicines are safe to take with etanercept. Tell your doctors and pharmacist if you take any mew medication including over-the-counter treatment, herbal medicine and supplements.

What will happen if I need an operation or dental surgery?

Etanercept can increase your risk of getting an infection after a surgical or dental procedure. Advise your dermatologist if you are going to have planned major surgery as they may recommend stopping etanercept temporarily.

Can I sunbathe?

Etanercept can increase the chance of getting skin cancer so you should not sunbathe or use sun-beds. Protect your skin from sunburn with clothing and sunscreens.

Where can I get more information about etanercept?

This leaflet does not list all 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 further details, look at the drug information sheet which comes as an insert with your prescription for etanercept.

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: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

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

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