

**PIL Title:** ENBREL

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# ENBREL SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE

Etanercept (25 mg, 50 mg)

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## What Enbrel is used for

Enbrel is a biological medicine which is made by living organisms. The medicine mimics substances produced by your body.

Enbrel is used to treat:

- Moderately to severely active rheumatoid arthritis (RA). It is a long lasting inflammation of the joints. Enbrel can be used alone or with a medicine called methotrexate.
- Active polyarticular juvenile idiopathic arthritis in children aged 2 years and older who have got inadequate response or not tolerant to methotrexate. Polyarticular juvenile idiopathic arthritis is inflammation of many joints of unknown cause seen in children.
- Active psoriatic arthritis. Psoriatic arthritis is mainly inflammation of joints associated with a skin disease called psoriasis which presents as scales or flakes. Enbrel can be used alone or with methotrexate.
- Active axial spondyloarthritis which includes ankylosing spondylitis and non-radiographic axial spondyloarthritis who have had an inadequate response to nonsteroidal anti-inflammatory

drugs (NSAIDs). It is a long lasting inflammation of joints involving the spine and other joints which connects it to the hip bone.

- Moderate to severe plaque psoriasis in adults or long lasting severe plaque psoriasis in children 6 years and older who were not able to tolerate or have not benefited from taking other treatments such as cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).

## How Enbrel works

Enbrel is a human fusion protein that blocks the activity of another protein in the body that causes inflammation, which in turn reduces inflammation and damage to your joints.

## Before you use Enbrel

### - When you must not use it

- Do not take Enbrel if you are allergic to etanercept or to any other ingredients in Enbrel.
- Do not take Enbrel if you have sepsis (a life threatening condition as a response to any infection, causing injury to its own tissue and organs) or at risk of developing sepsis.
- Do not take Enbrel if you have serious active infection or long lasting or localized infection.
- Do not take Enbrel if you have blood vessel disorder called Wegener's granulomatosis.

### Pregnancy and lactation

The safe use of Enbrel during pregnancy has not been established. Do not take Enbrel if you are pregnant, trying to get pregnant or think you may be pregnant.

You must use an effective method of birth control during treatment and for 3 weeks after you stop treatment with Enbrel. Tell your doctor right away if you become pregnant or think you are pregnant while taking Enbrel.

The safe use of Enbrel during breastfeeding has not been established. Enbrel passes into breast milk. Do not take Enbrel if you are breastfeeding. You and your doctor should decide if you will take Enbrel or breastfeed. You should not do both. Ask your doctor or pharmacist for advice before taking this medicine.

### - Before you start to use it

Before taking Enbrel, tell your doctor if you:

- Had recurring infections, chronic infections, or underlying conditions which may predispose you to infections, including serious infections such as sepsis and tuberculosis (TB) or if you have signs and symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms. Before starting treatment with Enbrel, your doctor should evaluate and treat you for any infections and tuberculosis (active/latent). If you have latent TB infection, preventive treatment should be given prior to treatment with Enbrel.
- Have or have had liver problems including previous or current infection with hepatitis B virus and hepatitis C virus and moderate to severe alcoholic hepatitis (inflammation of the liver)
- Have risk of lymphoma or other types of cancer or skin cancers

- Have diabetes, your doctor may reduce the dosage of your diabetic medicines
- Have reduced number of any type of blood cells in your body
- Have recently been vaccinated. Children should be brought up to date with their immunization before starting treatment with Enbrel.
- Have or have had any neurological disorders including multiple sclerosis and/or Guillain-Barré syndrome (a disease where in the insulation covers of nerve cells are damaged). Your doctor should perform a neurological assessment if you have, have had or are at increased risk of developing demyelinating disease.
- Have a reduced pumping activity of the heart known as congestive heart failure. Enbrel may worsen your heart failure.

#### - Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Using Enbrel with certain medicines may affect each other causing serious side effects. Enbrel may affect the way other medicines work, and other medicines may affect how Enbrel works.

Especially tell your doctor if you take:

- Anakinra or Abatacept (other medicines used to treat RA). You have a higher chance for serious infections or adverse events when taking Enbrel with these medicines.
- Sulfasalazine (another medicine used to treat RA). You have a higher chance of reduction in white blood cells when concurrently used with this medicine.
- Other immunosuppressants
- Diabetic medicines

### **How to use Enbrel**

#### - How much to use

Enbrel treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of diseases listed below.

Adults (18-64 years)  
*Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondyloarthritis and Non-radiographic Axial Spondyloarthritis*  
25 mg twice weekly, or 50 mg once weekly.

*Plaque Psoriasis*  
25 mg twice weekly, or 50 mg once weekly. Alternatively, 50 mg given twice weekly may be used for up to 12 weeks followed, if necessary, by a dose of 25 mg twice weekly or 50 mg once weekly. Treatment with Enbrel should continue until remission is achieved, for up to 24 weeks.

However, treatment beyond 24 weeks may be required for some adults. Treatment is usually halted if there is still no response after 12 weeks of treatment.

#### *Polyarticular Juvenile Idiopathic Arthritis*

In children, dosage of Enbrel should be based on body weight (mg/kg) for children weighing less than 62.5 kg. The recommended dose is 0.4 mg/kg (up to a maximum of 25 mg per dose) twice weekly as a subcutaneous injection with an interval of 3-4 days between doses. Treatment may be stopped if no response is seen after 4 months.

#### *Pediatric Plaque Psoriasis*

For children age 6 years and above, the recommended dose is 0.8 mg/kg (up to a maximum of 50 mg per dose) once weekly for up to 24 weeks. Treatment should be discontinued in patients who show no response after 12 weeks.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will tell you how much Enbrel to take and when to take it. Do not change your dose of Enbrel unless your doctor tells you to.

#### - When to use it

Use as directed by your doctor or pharmacist.

The first injection will be given by a qualified health care professional to show how it should be taken. You have to follow the same method for injecting Enbrel under the skin.

#### - How long to use it

Continue taking Enbrel for as long as your doctor recommends.

#### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

#### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

### **While you are using it**

#### - Things you must do

Tell your doctor if you:

- Experience any signs and symptoms of an infection (fever, chills)
- Develop any cancer throughout treatment with Enbrel.

Enbrel is a subcutaneous injection. This means that it is injected under your skin. You should inject Enbrel at areas such as your thigh, abdomen or upper arm. Give each new injection at least 3 cm from the previous site of injection.

Tell all the doctors, dentists and pharmacists treating you that you are taking Enbrel.

The needle cover of the pre-filled syringe contain latex (dry natural rubber). Individuals or caregivers should contact their doctor before using Enbrel if the needle cover will be handled by or if Enbrel will be given to someone with a known or possible hypersensitivity (allergy) to latex.

Tell your doctor immediately if you become pregnant while taking this medication. Tell your doctor if you wish to breastfeed

Avoid receiving live vaccines while taking Enbrel. Some vaccines may not work as well while you are taking Enbrel.

Use of live vaccines to infants for 16 weeks after the mother's last dose of Enbrel is generally not recommended.

Limit your time in sunlight and UV light. Cover your skin with clothing and use a sunscreen with a high protection factor because of the increased risk for skin cancer with Enbrel.

**- Things you must not do**

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Enbrel to anyone else, even if they have the same symptoms or condition as you.

**- Things to be careful of**

**Driving and using machines**

No formal studies have been carried out to study the effects of Enbrel on the ability to drive and use machines.

**Side Effects**

Like all medicines, Enbrel can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you experience any side effects after taking Enbrel.

**Very common side effects with Enbrel include:**

- Infections (upper respiratory tract infections, inflammation of tubes of lungs, inflammation of urinary bladder and skin infections)
- Injection site reactions (including redness, itching, pain, and swelling

**Common side effects with Enbrel include:**

- Allergic reactions
- Autoantibody formation
- Itching
- Fever

**Uncommon side effects with Enbrel include:**

- Serious infections like pneumonia, cellulitis, septic arthritis, sepsis and parasitic infection
- Skin cancers affecting the non-pigmented cells
- Thrombocytopenia (reduction in the number of platelets)
- Inflammation of the vessels affecting the whole body
- Uveitis (inflammation of the middle layer of the eyes), scleritis (inflammation of white part of the eye)
- Interstitial lung disease (inflammation of the tissue of lungs)

- Rash, hives, angioedema (characterized by swelling beneath the skin)
- Psoriasis (new onset or flaring of existing psoriasis)

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Enbrel. For more information ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems/Side Effects/AEFI/Vaccine Safety).

**Storage and Disposal of Enbrel**

**- Storage**

Enbrel should be stored in a refrigerator at 2°C to 8°C (36°F to 46°F) before reconstitution. Do not freeze.

Keep the pre-filled syringes in the outer carton in order to protect from light.

Keep out of reach of children.

**- Disposal**

Enbrel pre-filled syringe and needle should not be reused.

Unused Enbrel, syringes, or waste materials should be disposed of according to local requirements. Ask your pharmacist for information on disposal of these waste materials.

**Product Description**

**- What it looks like**

Enbrel solution for injection are available as pre-filled syringes.

Physical appearance: The solution for injection in the pre-filled syringe is clear to opalescent, colorless to yellow, and liquid may contain small translucent to white protein particles.

- Ingredients

- Active ingredient(s)

Etanercept

- Inactive ingredients

Sucrose, sodium chloride, L arginine hydrochloride, sodium phosphate monobasic dihydrate, sodium phosphate dibasic dihydrate, and water.

- MAL number:

Pre-filled syringe 25 mg-

MAL20071720ARZ

Pre-filled syringe 50 mg-

MAL20071721ARZ

**Manufacturer**

Manufactured by:

Pfizer Ireland Pharmaceuticals  
Grange Castle Business Park,  
Clondalkin,  
Dublin 22,  
Ireland

Packed by:

Wyeth Pharmaceuticals  
New Lane, Havant  
UK

**Product Registration Holder**

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