

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.
- 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.
- have serious active infection or long lasting or localized infection.
- have blood vessel disorder called Wegener's granulomatosis.

Pregnancy and lactation

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. Your doctor will advise you the possible risks to your unborn baby.

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 any 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.

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- 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 any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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

Kindly refer to the step-by-step instructions in appendix 1.

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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- 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 bleeding, bruising, redness, itching, pain, and swelling)

Common side effects with Enbrel include:

- Allergic reactions
- Autoantibody formation
- Itching, Rash
- Fever

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: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Enbrel

- Storage

Enbrel should be stored in a refrigerator at 2°C to 8°C (36°F to 46°F). 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.

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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 or pale brown, and liquid may contain trace levels of translucent to white amorphous particles, with a pH of 6.3 ± 0.2 .

- Ingredients

Active ingredient
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 Manufacturing Belgium NV
Rijksweg 12,
2870 Puurs-Sint Amands,
Belgium

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11,
Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

Date of Revision

03/01/2025

Serial Number:

NPRA (R3/01)17092019/0059

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Appendix 1

Instructions for use

Instructions for preparing and giving an injection of Enbrel

This section is divided into the following subsections:

Introduction

Step 1: Setting up for an injection

Step 2: Choosing an injection site

Step 3: Injecting the Enbrel solution

Step 4: Disposing of supplies

Introduction

The following instructions explain how to prepare and inject Enbrel. Please read the instructions carefully and follow them step by step. You will be instructed by your doctor or his/her assistant on the techniques of self-injection or on giving an injection to a child. Do not attempt to administer an injection until you are sure that you understand how to prepare and give the injection.

The Enbrel solution should not be mixed with any other medicine before use.

Step 1: Setting up for an injection

1. Select a clean, well-lit, flat working surface.
2. Take the Enbrel carton containing the pre-filled syringes out of the refrigerator and place it on the flat work surface. Starting from one of the top corners, pull back the paper cover from the top and sides of the tray. Remove one pre-filled syringe and one alcohol swab and place them on the work surface. Do not shake the pre-filled syringe of Enbrel. Fold the paper cover back over the tray and place the carton containing any remaining pre-filled syringes back into the refrigerator. Please see section 5 for instructions on how to store Enbrel. If you have any questions about storage, contact your doctor, nurse, or pharmacist for further instructions.
3. **You should allow 15 to 30 minutes for the Enbrel solution in the syringe to reach room temperature. Do NOT** remove the needle cover while allowing it to reach room temperature. Waiting until the solution reaches room temperature may make the injection more comfortable for you. Do not warm Enbrel in any other way (for example, do not warm it in a microwave or in hot water).
4. Assemble the additional supplies you will need for your injection. These include the alcohol swab from the Enbrel carton and a cotton ball or gauze.
5. Wash your hands with soap and warm water.
6. Inspect the solution in the syringe. It should be clear or slightly opalescent, colourless to pale yellow or pale brown, and may contain small white or almost transparent particles of protein. This appearance is normal for Enbrel. Do not use the solution if it is discoloured, cloudy, or if particles other than those described above are present. If you are concerned with the appearance of the solution, then contact your pharmacist for assistance.

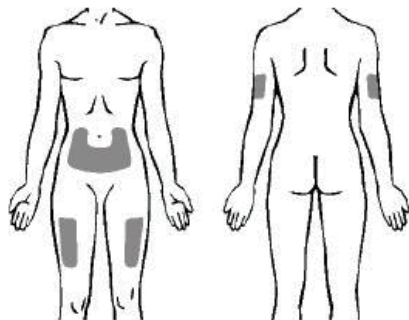
Step 2: Choosing an injection site

1. The three recommended injection sites for Enbrel using a pre-filled syringe include: (1) the front of the middle thighs; (2) the abdomen, except for the 5 cm area right around the navel; and (3) the outer area of the upper arms (see Diagram 1). If you are self injecting, you should not use the outer area of the upper arms.

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Diagram 1



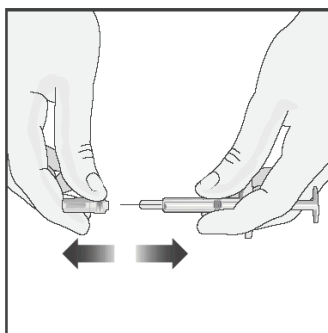
2. A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site. Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks. (It may be helpful to keep notes on the location of the previous injections.)
3. If you or the child have psoriasis, you should try not to inject directly into any raised, thick, red, or scaly skin patches ("psoriasis skin lesions").

Step 3: Injecting the Enbrel solution

1. Wipe the site where Enbrel is to be injected with the alcohol swab, using a circular motion. **Do NOT** touch this area again before giving the injection.
2. Pick up the pre-filled syringe from the flat work surface. Remove the needle cover by firmly pulling it straight off the syringe (see Diagram 2). **Be careful not to bend or twist the cover during removal to avoid damage to the needle.**

When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. Do not touch the needle or allow it to touch any surface. Do not touch or bump the plunger. Doing so could cause the liquid to leak out.

Diagram 2

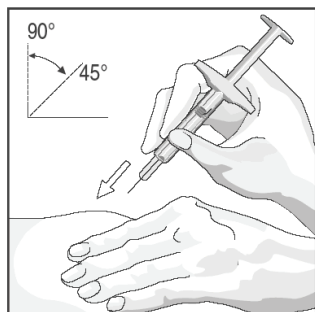


3. When the cleaned area of skin has dried, pinch and hold it firmly with one hand. With the other hand, hold the syringe like a pencil.
4. With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (see Diagram 3). With experience, you will find the angle that is most comfortable for you or the child. Be careful not to push the needle into the skin too slowly, or with great force.

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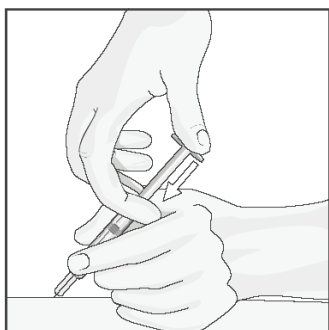
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Diagram 3



5. When the needle is completely inserted into the skin, release the skin that you are holding. With your free hand, hold the syringe near its base to stabilise it. Then push the plunger to inject all of the solution at a **slow**, steady rate (see Diagram 4).

Diagram 4



6. When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as inserted. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds. Do not rub the injection site. If needed, you may cover the injection site with a bandage.

Step 4: Disposing of supplies

- The pre-filled syringe is for single-use administration only. The syringe and needle should **NEVER** be re-used. **NEVER** re-cap a needle. Dispose of the needle and syringe as instructed by your doctor, nurse or pharmacist.

If you have any questions, please talk to a doctor, nurse or pharmacist who is familiar with Enbrel.

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