

PATIENT INFORMATION LEAFLET

Serious infections, including tuberculosis (TB) may occur with ENBREL; some have resulted in death. Speak to your doctor at once if you develop any new infection while you take ENBREL. You may need to stop treatment if you develop an infection.

SCHEDULING STATUS: S4

ENBREL® 25 mg PS solution for injection in pre-filled syringe

ENBREL® 50 mg PS solution for injection in pre-filled syringe or

pre-filled MYCLIC pen

Etanercept

Contains sugar

Each 1 mL of ENBREL 25 mg PS contains 10 mg of sucrose

Each 1 mL of ENBREL 50 mg PS contains 10 mg of sucrose

Read all of this leaflet carefully before you are given ENBREL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ENBREL has been prescribed for you personally and you should not share your medicine with other people.
It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ENBREL is and what it is used for
2. What you need to know before you use ENBREL
3. How to use ENBREL
4. Possible side effects
5. How to store ENBREL
6. Contents of the pack and other information

1. What ENBREL is and what it is used for

ENBREL is a biological medicine and is a type of protein called tumour necrosis factor (TNF) blocker that blocks the action of TNF in your body's immune system. People with an auto immune disease have too much TNF in their bodies. ENBREL blocks the action of TNF, helping to treat your disease. But, in doing so, ENBREL lowers the ability of your immune system to fight infections.

ENBREL is an anti-rheumatic medicine used to treat:

- The signs and symptoms of active rheumatoid arthritis (RA) in adults and children. It is reserved for patients who have not responded to or have responded poorly to other disease-modifying medicines (DMARDS) used for rheumatoid arthritis. ENBREL can be used alone or in combination with methotrexate.
- Severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.
- Polyarticular-course juvenile idiopathic arthritis in children and adolescents from the age of 2 years, when the response to one or DMARDS has proved inadequate.
- Polyarticular-course juvenile idiopathic arthritis and extended oligoarthritis in children and adolescents from the age of 2 years when treatment with methotrexate has not worked well enough or is not suitable for them.
- Psoriatic arthritis in adolescents from the age of 12 years when treatment with methotrexate has not worked well enough or is not suitable for them.
- Enthesitis-related arthritis in adolescents from the age of 12 years when other widely used treatments have not worked well enough or are not suitable for them.
- The signs and symptoms of psoriatic arthritis (PS), and for inhibiting the progression of structural damage of active arthritis in patients. ENBREL can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.
- Adults with a type of arthritis called ankylosing spondylitis (AS), and where your doctor may or may not be able to see swelling in the sacroiliac (pelvic) joints and/or your spine using X-rays and in patients where other widely used treatments have not worked well enough or are not suitable for them.
- Adults (aged 18 and over), for treatment of chronic moderate to severe plaque psoriasis, who are candidates for systemic therapy or phototherapy.
- Chronic severe plaque psoriasis in children and adolescents, (from the age of 6 years), who have had an inadequate response to, or are unable to take phototherapies or other systemic therapies.

RA, PS and AS are inflammatory diseases that can affect the joints in your body. Psoriasis is an inflammatory disease that affects the skin and can cause raised, thick, red and scaly patches (psoriatic skin lesions) that can occur anywhere in the body. Psoriatic arthritis is usually seen in patients with psoriasis and affects both the joints and the skin.

2. What you need to know before you use ENBREL

Do not use ENBREL:

- if you are hypersensitive (allergic) to etanercept or to any of the other ingredients of ENBREL (listed in section 6)
- if you have or are at risk of sepsis (blood poisoning)
- if you have an infection of any type including tuberculosis or chronic infections and local infections (such as a leg ulcer)

Warnings and precautions

Take special care with ENBREL:

- if you are prone to infection (i.e. if you think you have an infection, are being treated for an infection, have signs of an infection such as fever, cough, flu-like symptoms and have open sores on your body). ENBREL may lessen the body's ability to fight infections. You should be evaluated for infections, specifically for tuberculosis before, during and after treatment with ENBREL.
- if you are about to have any surgery or if you develop a new infection.
- if you have any immune system disorders, cancer, advanced or poorly controlled diabetes mellitus (sugar diabetes). ENBREL may lessen the body's ability to fight infection.
- if you have tuberculosis (TB), or if you have been in close contact with someone who has had tuberculosis
- if you have or have had hepatitis B or hepatitis C
- if you have liver disease caused by the excessive intake of alcohol
- if you have or have ever had lymphoma (a type of blood cancer) or any other cancer. Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher than average risk of developing lymphoma. There have been reports of children and adolescents developing cancers, including

lymphoma and skin cancers who have received ENBREL or other medicines that work in the same way as ENBREL. Tell your doctor if you or your child develops any change in the appearance of the skin or growths on the skin

- if you have any blood disorders (signs include persistent fever, bruising, bleeding, or paleness). ENBREL may increase the risk of blood disorders such as anaemia. There have been rare reports of serious blood disorders, some resulting in death
- do not have any vaccinations (immunisations) without your doctor's approval
- if you have any diseases of the central nervous system such as multiple sclerosis, seizures, or optic neuritis (inflammation of the nerves of the eyes). ENBREL may make these conditions worse
- if you have any heart problems. ENBREL may worsen congestive heart failure
- if you are being treated for diabetes, as ENBREL may lower your blood sugar levels. ENBREL has been tested in elderly patients (65 – 87 years of age) with similar response rates and safety profiles as seen in adult patients under 65 years of age

Other medicines and ENBREL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

ENBREL should NOT be used together with

- live attenuated vaccines, such as the oral polio vaccine
- anakinra as it may increase the risk of serious infection and blood disorders
- abatacept as it may increase the incidence of serious adverse events
- sulfasalazine as it may decrease your white blood cell count
- any other medicine in the same syringe

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

You should only be treated with ENBREL during pregnancy if clearly needed. It is important that you tell your health care provider about the use of ENBREL during pregnancy before the baby receives any vaccine.

You should only be treated with ENBREL during breastfeeding if clearly needed. Talk to your doctor if you want to breastfeed while on ENBREL treatment. It is important that you tell your baby's doctors and other health care providers about the use of ENBREL during breastfeeding before your baby receives any vaccine.

Safety in pregnancy and lactation has not been established.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed.

It is not always possible to predict to what extent ENBREL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ENBREL affects them.

ENBREL contains latex

The needle cover of the pre-filled syringe and the needle cap of the pre-filled pen contain latex (dry natural rubber) and may cause severe allergic reactions. Patients or caregivers with a known or possible hypersensitivity (allergy) to latex should contact their doctor before using ENBREL.

3. How to use ENBREL

Do not share medicines prescribed for you with any other person.

Always use ENBREL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. To help you remember, write in a diary which days of the week you should have an injection. Your doctor will prescribe the appropriate dose for you or your child according to the condition.

Your doctor will tell you how long your treatment with ENBREL will last. Do not stop treatment early. If you have

the impression that the effect of ENBREL is too strong or too weak, tell your doctor or pharmacist.

Adults

The usual adult dose of ENBREL for rheumatoid arthritis is 25 mg given twice a week (3 – 4 days apart) or 50 mg given once weekly, and can be administered as follows

- once weekly two ENBREL 25 mg pre-filled syringes administered subcutaneously at approximately the same time, or
- one ENBREL 25 mg pre-filled syringe administered twice weekly, 3 – 4 days apart (i.e. two 25 mg pre-filled syringes per week), or
- ENBREL 50 mg pre-filled syringe or pre-filled pen administered once weekly as a subcutaneous injection.

If you have psoriatic arthritis, ankylosing spondylitis or non-radiographic axial spondylarthritis, the recommended dose is 50 mg per week (given as one ENBREL 25 mg pre-filled syringe given twice weekly, 3 – 4 days apart). Doses other than 25 mg administered twice weekly have not been studied.

If you have plaque psoriasis, the recommended starting dose of ENBREL for adult patients is 50 mg per week as one ENBREL 25 mg pre-filled syringe administered twice weekly, 3 – 4 days apart or ENBREL 50 mg pre-filled syringe or pre-filled pen administered once weekly. After three months your doctor will tell you whether to reduce your dose.

Children

The recommended dose of ENBREL for children with juvenile rheumatoid arthritis, idiopathic arthritis and psoriasis is based upon the child's body weight. Your child's doctor will tell you the amount of ENBREL your child should use.

See your doctor at regular visits. It is important that your doctor checks your progress to make sure that this medicine is working properly.

Route of administration

ENBREL is injected under the skin. Your doctor will show you how and where to give the injection. Follow the detailed instructions on ENBREL injection preparation and injection procedure as provided below.

ENBREL 25 mg PS and ENBREL 50 mg PS pre-filled syringes or pre-filled pen are ready for use.

Instructions for preparing and giving an ENBREL injection

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 technique of self-injection. Do not attempt to self-inject an injection until you are sure that you understand how to prepare and give the injection.

This injection should not be mixed in the same syringe with any other medicine.

ENBREL 25 mg PS and ENBREL 50 mg PS solution for injection in pre-filled syringe

Step 1: Setting up for an injection

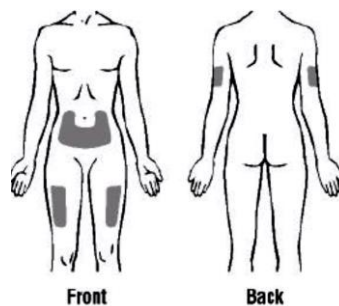
1. Select a clean well-lit, flat working surface.
2. Take the ENBREL carton containing the pre-filled syringes out of the refrigerator and place it on the flat work surface. Starting from one of the top corners, pull back the paper cover from the top and sides of the tray. Remove one pre-filled syringe 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 health care provider 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 in a microwave or in hot water).

4. Assemble the additional supplies you will need for your injection. These include an alcohol swab and a cotton ball or gauze.
5. Wash your hands thoroughly with warm water and soap.
6. **Inspect the solution in the pre-filled syringe. It should be clear colourless, yellow or pale brown. The liquid may contain trace levels of translucent to white amorphous particles. This appearance is normal for ENBREL. Do not inject 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, contact your pharmacist for assistance.**

Step 2: Choosing an injection site

- The three recommended injection sites for ENBREL 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.

Diagram 1

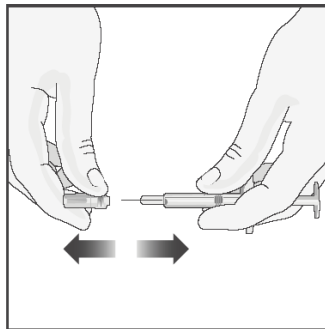


- A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site. DO NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks. (It may be helpful to keep notes on the location of the previous injections.)
- If you or the child has 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

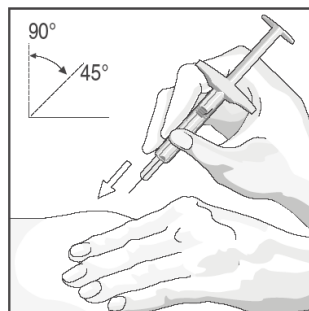
- Wipe the injection site where ENBREL is to be injected with an alcohol swab, using a circular motion. DO NOT touch this area again before giving the injection.
- Pick up the pre-filled syringe from the flat work surface. Remove the needle cover by firmly pulling it straight off the syringe (Diagram 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



- 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.
- 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.

Diagram 3



- 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



- 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. It should NEVER be reused. NEVER re-cap a needle. Dispose of the needles and syringe as instructed by your doctor, nurse or pharmacist.
- **All questions should be answered by a doctor, nurse or pharmacist familiar with ENBREL.**

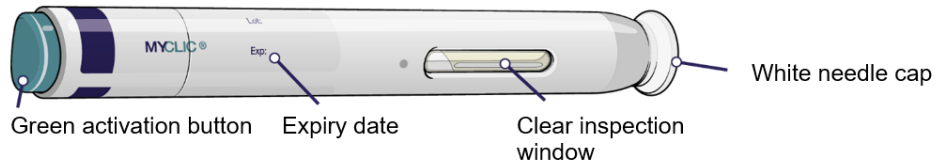
ENBREL 50 mg solution for injection in pre-filled pen

Introduction

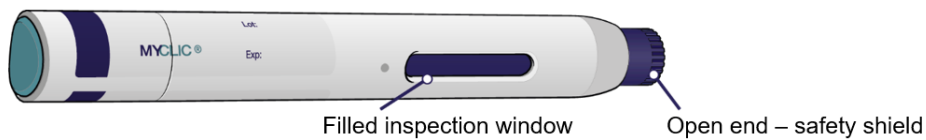
- The instructions below explain how to use the MYCLIC pen to inject ENBREL.
- Please read the instructions carefully, and follow them step by step.
- Your health care provider will tell you how to inject ENBREL. Do not attempt to administer an injection until you are sure that you understand how to use the MYCLIC pen properly.
- If you have questions about how to inject, please ask your health care provider for help.

The MYCLIC pre-filled pen

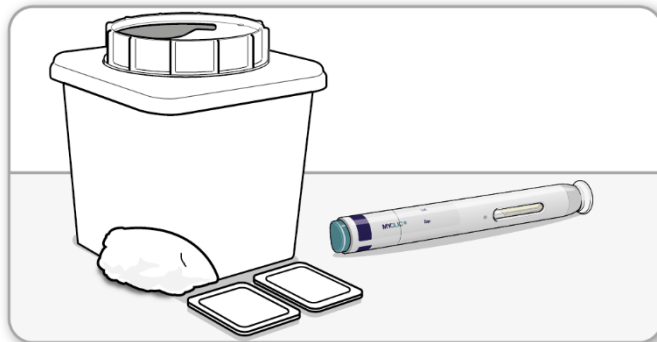
Before injection



After injection

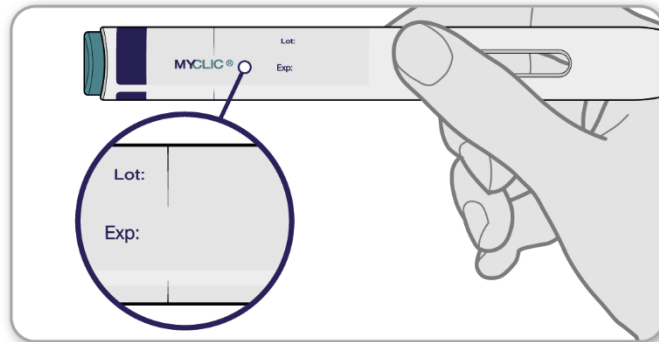


Step 1: Preparing for an ENBREL injection



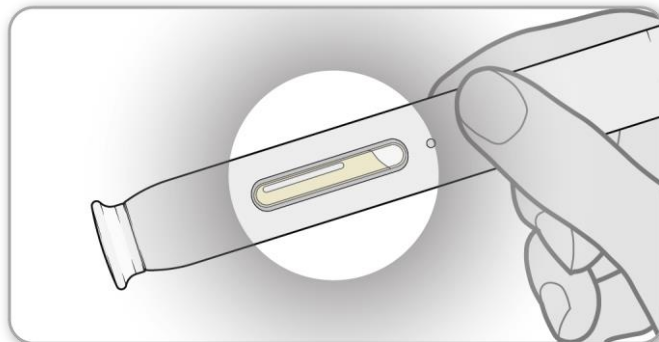
- Gather the following items for each injection on a clean, well-lit flat surface:
 - One MYCLIC pre-filled pen
 - One alcohol swab
 - A suitable sharps container (not included)
 - Clean cotton balls or gauze pads (not included)
- Do not shake the pen.
- Do not remove the white cap until instructed to do so.
- For a more comfortable injection, leave your pen at room temperature for 15 to 30 minutes with the white cap in place.
- Do not warm the pen in any other way.

Step 2 : Check label for expiry and dose

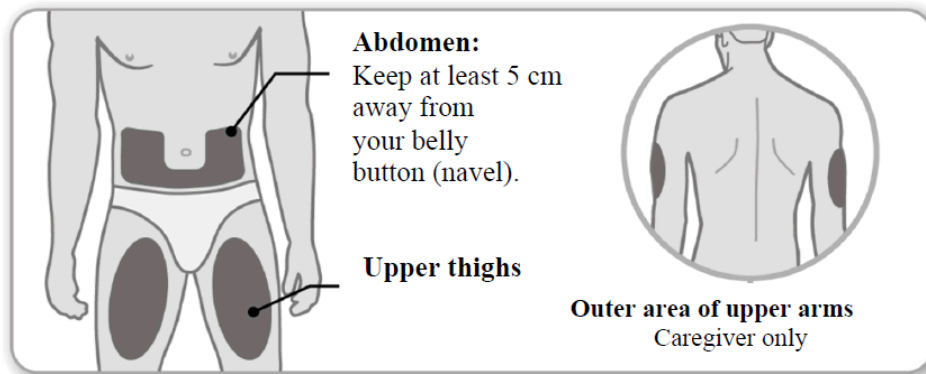


- Check the expiry date (month/year) on the pen label.
- Make sure the correct dose strength is shown on the pen label.
- If the expiry date has passed or it is not your prescribed dose, do not use the pen and contact your health care provider for assistance.

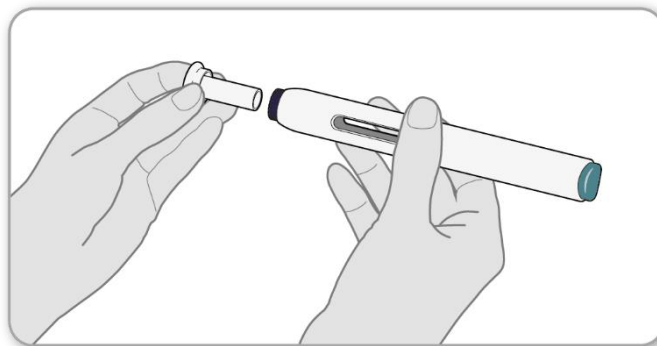
Step 3 Inspect the medicine



- **Inspect the medicine in the pen by looking through the clear inspection window. The solution should be clear colourless, yellow or pale brown, and may contain small white or almost transparent particles of protein. This appearance is normal for ENBREL.**
- **Do not use ENBREL if the medicine is discoloured, cloudy, or if particles other than those described above are present. If you are concerned with the appearance of the medicine, then contact your pharmacist for assistance.**
- Note: You may see an air bubble in the window. This is normal.

Step 4 Choose and clean injection site

- Choose an injection site in the middle of the front of your upper thighs or stomach area 5 cm away from the belly button (navel). The outer area of the back of the upper arms may also be used by a caregiver.
- Each injection should be given at least 3 cm from where you last injected. Do not inject into tender, bruised or hard skin. Avoid scars or stretch marks. If you have psoriasis, do not inject directly into any raised, thick, red or scaly skin.
- Clean the injection site with soap and water, or an alcohol swab if convenient.
- Allow the site to dry. Do not touch, fan or blow on the cleaned injection site.

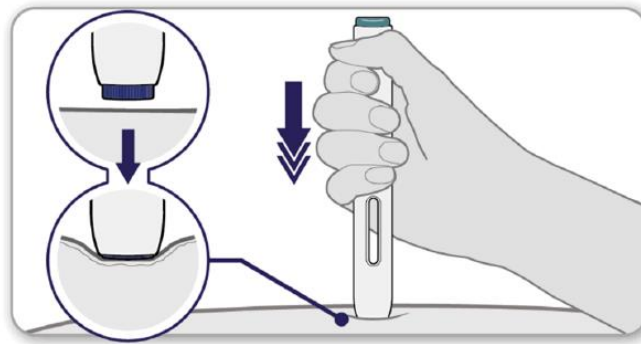
Step 5 Remove needle cap

- Remove the white needle cap by pulling it straight off. Do not bend the white needle cap while you are removing it.
- Do not re-attach the cap once it has been removed.
- After removal of the cap, you will see a purple needle safety shield extending slightly from the end of the pen. Do not push on the end safety shield with your fingers or thumbs.

- Do not use the pen if it is dropped with the needle cap off.

Note: You may notice a drop of liquid at the needle tip. This is normal.

Step 6 Push pen firmly against skin

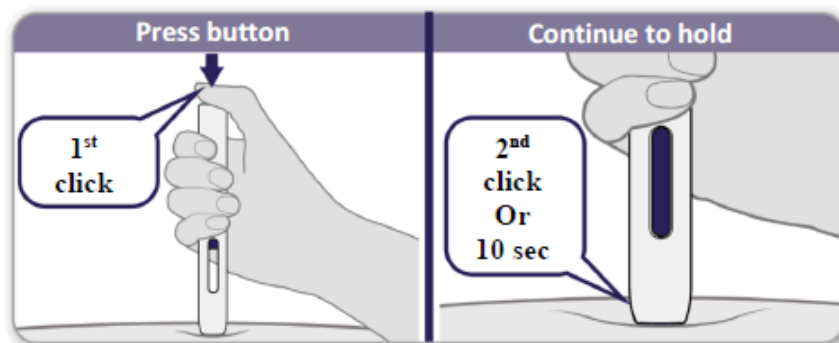


- Push the open end of your pen firmly against the skin at 90 degrees so the purple needle safety shield is pushed completely inside the pen.

Note: You will only be able to press the green button when the needle shield is completely pushed inside the pen.

- Pinching or stretching the skin before injection may make the injection site firmer, making it easier to press the injection button.

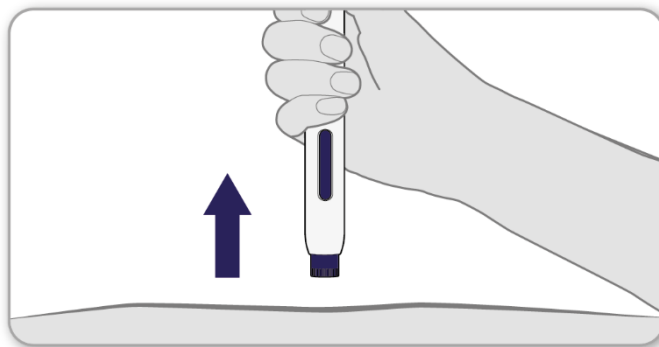
Step 7 Start your injection



- Press the green button all the way down and you will hear a “click”. The click means the start of the injection.
- Continue to hold your pen firmly against the skin until you hear a 2nd “click”, or until 10 seconds after the first click (whichever happens first).
- Note: If you are unable to start the injection as described, press the pen more firmly against your skin, then

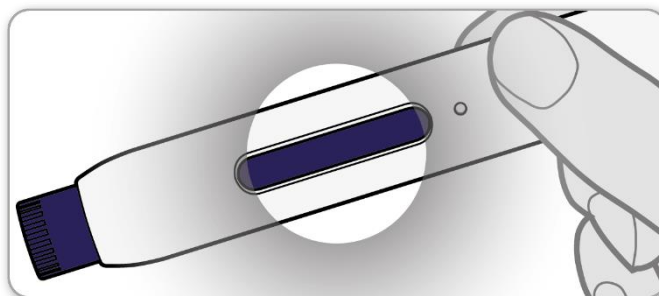
press the green button again.

Step 8 Lift off skin



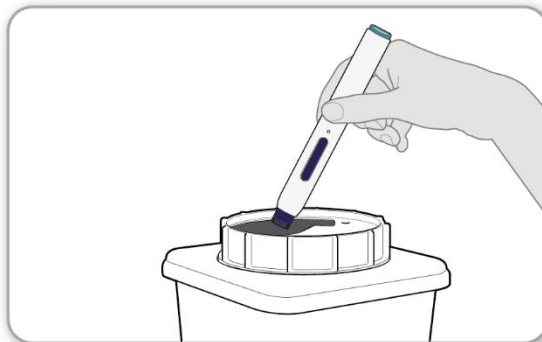
- Remove your pen from your skin by lifting it straight off the injection site.
- The purple needle safety shield will automatically extend to cover the needle.

Step 9 Check inspection window



- Check the pen's inspection window. It should be completely purple.
- If the window is not purple, you may not have received a full dose. Contact your health care provider for assistance. Do not try to use the pen again. Do not try to use another pen.
- If you notice a spot of blood at the injection site, you should press the cotton ball or gauze over the injection site for 10 seconds. Do not rub the injection site.
- Note: The injection button may stay pressed in. This is normal.

Step 10 Dispose



- Dispose of the used pen as instructed by your doctor, nurse or pharmacist. Do not attempt to recap the pen.
- Do not press on the end of the needle safety shield.
- **All questions should be answered by a doctor, nurse or pharmacist familiar with ENBREL.**

If you inject more ENBREL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to inject ENBREL

If you forget to give yourself an injection, inject the next dose as soon as you remember. Then go back to your normal dosing schedule. However, if it is nearly time for your next dose, skip the missed dose and carry on using the medicine as before. Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

ENBREL can have side effects.

Not all side effects reported for ENBREL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ENBREL, please consult your health care provider for advice.

If any of the following happens, stop using ENBREL and tell your doctor immediately or go to the casualty department at your nearest hospital

- Serious allergic reactions such as a tight chest, wheezing, dizziness, fast heartbeat, difficulty swallowing,

swelling of the face, eyelids or around the eyes, lips or tongue and skin rash

- Signs of blood disorders such as unusual bleeding, bruising or paleness especially if fever and sore throat are also present
- Signs of serious infections, such as high fever that may be accompanied by a cough, shortness of breath, chills, weakness, or a hot, red, tender, sore area on the skin or joints

These are all very serious side effects. If you have them, you may have had a serious reaction to ENBREL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following

Frequent side effects

- infections such as respiratory infections (cough, fever, chills, sneezing, congestion, sore throat), kidney infections (frequent or painful urination) or skin infections (skin rash, redness, swelling or itching of skin). You should be evaluated for infections before, during and after treatment
- autoimmune reactions where antibodies are made that may harm the normal tissues in the body
- general itching of the skin, rash
- reactions at the injection site including redness, bleeding, bruising, itching, swelling or pain at the place of injection or previously used site
- fever or chills

Less frequent side effects

- serious infections (including pneumonia, deep skin infections, joint infections, blood infection, infections at various sites and infections caused by parasites)
- tuberculosis, opportunistic infections, (including fungal, bacterial and viral infections)
- melanoma and non-melanoma skin cancers
- low blood platelet count, low red blood cell count, low white blood cell count, low neutrophil (a type of white blood cell) count, failure of the bone marrow to produce crucial blood cells
- inflammation of the blood vessels affecting multiple organs

- serious allergic reactions (including severe localised swelling of the skin, wheezing)
- an immune disorder that can affect the lungs, skin and lymph nodes (sarcoidosis)
- nervous system disorders (with severe muscle weakness and signs and symptoms similar to those of multiple sclerosis or inflammation of the nerves of the eyes or spinal cord)
- seizure (fit)
- inflammation of the eye
- new onset or worsening of existing congestive heart failure including shortness of breath or troubled breathing, chest pain, numbness on one side of the face or body
- inflammation or scarring of the lungs
- elevated liver blood tests, inflammation of the liver caused by the body's own immune system (autoimmune hepatitis)
- localised swelling of the skin (angioedema);
- psoriasis (new or worsening);
- hives (elevated patches of red or pale skin that often itch)
- extreme sensitivity reaction resulting in inflammation and damage to the blood vessels mainly in the skin.
- lupus-like syndrome (symptoms may include persistent rash, fever, pain or back pain, joint or muscle pain or stiffness, loss of energy and tiredness)

Side effects where the frequency is unknown

- recurrence of hepatitis B (a liver infection)
- *Listeria* (infections caused by certain types of bacteria)
- lymphoma (a type of blood cancer)
- leukaemia (cancer affecting the blood and bone marrow)
- Merkel cell carcinoma (a type of skin cancer)
- a condition where your body stops producing new blood cells (aplastic anaemia)
- histiocytosis haematophagic (excessive activation of white blood cells associated with inflammation)
- headache
- a condition where the immune system attacks the nerves (Guillain-Barré syndrome)
- inflammation of the nerves which can result in loss in sensation, tingling and pain, difficulty walking and

weakness, numbness

- pain from nerve damage which can cause muscle weakening and wasting to be experienced
- abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems)
- painful red or purplish rash that can cause blistering or peeling of the skin. These may be signs of lupus erythematosus or Stevens-Johnson Syndrome, or toxic epidermal necrolysis (TEN)
- damage to the tiny filters inside your kidneys leading to poor kidney function (glomerulonephritis)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ENBREL.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store ENBREL

ENBREL 25 mg and 50 mg PS solution for injection in pre-filled syringe or pre-filled pen

- Store all medicines out of the reach of children
- Store ENBREL PS pre-filled syringes and ENBREL PS pre-filled pens in the refrigerator (2 – 8 °C). DO NOT FREEZE
- Before injection, ENBREL PS pre-filled syringes and pre-filled pens should be taken out the refrigerator and allowed to reach room temperature (approximately 15 to 30 minutes). The needle cover or cap should not be removed while allowing the pre-filled syringe or pre-filled pen to reach room temperature
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What ENBREL contains

ENBREL 25 mg and 50 mg PS solution for injection in pre-filled syringe or pre-filled pen

- ENBREL 25 mg PS is supplied as a pre-filled syringe and ENBREL 50 mg PS is supplied as a pre-filled syringe or pre-filled pen and contains 1 mL.
- The active substance is etanercept 25 mg or 50 mg.
- The other ingredients are L-arginine HCl, sodium chloride and sucrose.

What ENBREL looks like and contents of the pack

ENBREL PS

The liquid is a clear colourless, yellow or pale brown solution. The liquid may contain trace levels of translucent to white amorphous particles.

ENBREL solution for injection in pre-filled syringe

ENBREL 25 mg PS is supplied in cartons containing four or eight clear glass pre-filled syringes with eight or sixteen alcohol swabs.

ENBREL 50 mg PS is supplied in cartons containing four or twelve clear glass pre-filled syringes with eight or twenty-four alcohol swabs.

ENBREL solution for injection in pre-filled pen (MYCLIC)

ENBREL 50 mg PS is supplied in cartons containing four pre-filled pens with alcohol swabs.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Enbrel 25 mg PS solution for injection in pre-filled syringe

Enbrel 50 mg PS solution for injection in pre-filled syringe or pre-filled MYCLIC pen

Final Approved PIL – 12 November 2025

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