Package leaflet: Information for the user

Enbrel 25 mg solution for injection in pre-filled syringe
Enbrel 50 mg solution for injection in pre-filled syringe
etanercept

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a Patient Card, which contains important safety information that you need to be aware of before and during treatment with Enbrel.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you or a child in your care. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or those of the child you are caring for.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

Information in this leaflet is organised under the following 7 sections:

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
7. Instructions for use

1. What Enbrel is and what it is used for

Enbrel is a medicine that is made from two human proteins. It blocks the activity of another protein in the body that causes inflammation. Enbrel works by reducing the inflammation associated with certain diseases.

In adults (aged 18 and over), Enbrel can be used for moderate or severe **rheumatoid arthritis**, **psoriatic arthritis**, severe **axial spondyloarthritis** including **ankylosing spondylitis,** and moderate or severe **psoriasis** – in each case usually when other widely used treatments have not worked well enough or are not suitable for you.

For rheumatoid arthritis, Enbrel is usually used in combination with methotrexate, although it may also be used alone if treatment with methotrexate is unsuitable for you. Whether used alone or in combination with methotrexate, Enbrel can slow down the damage to your joints caused by the rheumatoid arthritis and improve your ability to do normal daily activities.

For psoriatic arthritis patients with multiple joint involvement, Enbrel can improve your ability to do normal daily activities. For patients with multiple symmetrical painful or swollen joints (e.g., hands, wrists and feet), Enbrel can slow down the structural damage to those joints caused by the disease.

Enbrel is also prescribed for the treatment of the following diseases in children and adolescents

- For the following types of juvenile idiopathic arthritis when treatment with methotrexate has not worked well enough or is not suitable for them:
    - Polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in patients from the age of 2 years
    - Psoriatic arthritis in patients from the age of 12 years
- For enthesitis-related arthritis in patients from the age of 12 years when other widely used treatments have not worked well enough or are not suitable for them
- Severe psoriasis in patients from the age of 6 years who have had an inadequate response to (or are unable to take) phototherapies or other systemic therapies.

2. What you need to know before you use Enbrel

Do not use Enbrel

- if you, or the child you are caring for, are allergic to etanercept or any of the other ingredients of Enbrel (listed in section 6). If you or the child experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more Enbrel, and contact your doctor immediately.
- if you or the child have, or are at risk of developing a serious blood infection called sepsis. If you are not sure, please contact your doctor.
- if you or the child have an infection of any kind. If you are not sure, please talk to your doctor.

Warning and precautions

Talk to your doctor before taking Enbrel.

- **Allergic reactions**: If you or the child experience allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more Enbrel, and contact your doctor immediately.
- **Infections/surgery**: If you or the child develop a new infection, or are about to have any major surgery, your doctor may wish to monitor the treatment with Enbrel.
- **Infections/diabetes:** Tell your doctor if you or the child have a history of recurrent infections or suffer from diabetes or other conditions that increase the risk of infection.
- **Infections/monitoring:** Tell your doctor of any recent travel outside the European region. If you or the child develop symptoms of an infection such as fever, chills or cough, notify your doctor immediately. Your doctor may decide to continue to monitor you or the child for the presence of infections after you or the child stop using Enbrel.
- **Tuberculosis:** As cases of tuberculosis have been reported in patients treated with Enbrel, your doctor will check for signs and symptoms of tuberculosis before starting Enbrel. This may include a thorough medical history, a chest X-ray and a tuberculin test. The conduct of these tests should be recorded on the Patient Card. It is very important that you tell your doctor if you or the child have ever had tuberculosis, or have been in close contact with someone who has had tuberculosis. If symptoms of tuberculosis (such as persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy, tell your doctor immediately.
- **Hepatitis B:** Tell your doctor if you or the child have or have ever had hepatitis B. Your doctor should test for the presence of hepatitis B infection before you or the child begin treatment with Enbrel. Treatment with Enbrel may result in reactivation of hepatitis B in patients who have previously been infected with the hepatitis B virus. If this occurs, you should stop using Enbrel.

- **Hepatitis C:** Tell your doctor if you or the child have hepatitis C. Your doctor may wish to monitor the treatment with Enbrel in case the infection worsens.
- **Blood disorders:** Seek medical advice immediately if you or the child have any signs or symptoms such as persistent fever, sore throat, bruising, bleeding or paleness. Such symptoms may point to the existence of potentially life-threatening blood disorders, which may require discontinuation of Enbrel.
- **Nervous system and eye disorders:** Tell your doctor if you or the child have multiple sclerosis, optic neuritis (inflammation of the nerves of the eyes) or transverse myelitis (inflammation of the spinal cord). Your doctor will determine if Enbrel is an appropriate treatment.
- **Congestive heart failure:** Tell your doctor if you or the child have a history of congestive heart failure, because Enbrel needs to be used with caution under these circumstances.
- **Cancer:** Tell your doctor if you have or have ever had lymphoma (a type of blood cancer) or any other cancer before you are given Enbrel.
  Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher than average risk of developing lymphoma.
  Children and adults taking Enbrel may have an increased risk of developing lymphoma or another cancer.
  Some children and teenage patients who have received Enbrel or other medicines that work the same way as Enbrel have developed cancers, including unusual types, which sometimes resulted in death.
  Some patients receiving Enbrel have developed skin cancers. Tell your doctor if you or the child develop any change in the appearance of the skin or growths on the skin.
- **Chickenpox:** Tell your doctor if you or the child are exposed to chickenpox when using Enbrel. Your doctor will determine if preventive treatment for chickenpox is appropriate.
- **Latex:** The needle cover is made from latex (dry natural rubber). Contact your doctor before using Enbrel if the needle cover will be handled by, or Enbrel will be given to, someone with a known or possible hypersensitivity (allergy) to latex.
- **Alcohol abuse**: Enbrel should not be used for the treatment of hepatitis related to alcohol abuse. Please tell your doctor if you or the child in your care have a history of alcohol abuse.
- **Wegener's granulomatosis**: Enbrel is not recommended for the treatment of Wegener's granulomatosis, a rare inflammatory disease. If you or the child in your care have Wegener's granulomatosis, talk to your doctor.
- **Anti-diabetic medicines**: Tell your doctor if you or the child have diabetes or are taking medicines to treat diabetes. Your doctor may decide if you or the child need less anti-diabetic medicine while taking Enbrel.

Children and adolescents

Vaccinations: If possible, children should be up to date with all vaccinations before using Enbrel. Some vaccines, such as oral polio vaccine, should not be given while using Enbrel. Please consult your doctor before you or the child receive any vaccines.

Enbrel should not normally be used in children with polyarthritis or extended oligoarthritis below the age of 2 years, or in children with enthesitis-related arthritis or psoriatic arthritis below the age of 12 years, or in children with psoriasis below the age of 6 years.

Other medicines and Enbrel

Tell your doctor or pharmacist if you or the child are taking, have recently taken or might take any other medicines (including anakinra, abatacept or sulfasalazine), even those not prescribed by the doctor. You or the child should not use Enbrel with medicines that contain the active substance anakinra or abatacept.

Pregnancy and breast-feeding

Enbrel should only be used during pregnancy if clearly needed. You should consult your doctor if you become pregnant, think you may be pregnant, or are planning to have a baby.

If you received Enbrel during pregnancy, your baby may have a higher risk of getting an infection. In addition, one study found more birth defects when the mother had received Enbrel in pregnancy, compared with mothers who had not received Enbrel or other similar medicines (TNF-antagonists), but there was no particular kind of birth defect reported. Another study found no increased risk of birth defects when the mother had received Enbrel in pregnancy. Your doctor will help you to decide whether the benefits of treatment outweigh the potential risk to your baby.

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 healthcare professionals about the use of Enbrel during pregnancy and breastfeeding before your baby receives any vaccine.

Driving and using machines

The use of Enbrel is not expected to affect the ability to drive or use machines.

Enbrel contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to use Enbrel

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

If you feel that the effect of Enbrel is too strong or too weak, talk to your doctor or pharmacist.

The pre-filled syringe is available in dose strengths of 25 mg and 50 mg.

Dosing for adult patients (aged 18 years or over)

Rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis including ankylosing spondylitis

The usual dose is 25 mg given twice a week or 50 mg once a week as an injection under the skin. However, your doctor may determine an alternative frequency at which to inject Enbrel.

Plaque psoriasis

The usual dose is 25 mg twice a week or 50 mg once a week.

Alternatively, 50 mg may be given twice a week for up to 12 weeks, followed by 25 mg twice a week or 50 mg once a week.

Your doctor will decide how long you should take Enbrel and whether retreatment is needed based on your response. If Enbrel has no effect on your condition after 12 weeks, your doctor may tell you to stop taking this medicine.

Use in children and adolescents

The appropriate dose and frequency of dosing for the child or adolescent will depend on body weight and disease. Your doctor will determine the correct dose for the child and will prescribe an appropriate strength of Enbrel (10 mg, 25 mg or 50 mg).

For polyarthritis or extended oligoarthritis in patients from the age of 2 years, or enthesitis-related arthritis or psoriatic arthritis in patients from the age of 12 years, the usual dose is 0.4 mg of Enbrel per kg bodyweight (up to a maximum of 25 mg) given twice weekly, or 0.8 mg of Enbrel per kg of bodyweight (up to a maximum of 50 mg) given once weekly.

For psoriasis in patients from the age of 6 years, the usual dose is 0.8 mg of Enbrel per kg bodyweight (up to a maximum of 50 mg), and should be given once weekly. If Enbrel has no effect on the child's condition after 12 weeks, your doctor may tell you to stop using this medicine.

The doctor will provide you with detailed directions for preparing and measuring the appropriate dose.

Method and route of administration

Enbrel is administered by an injection under the skin (by subcutaneous injection).

Enbrel can be taken with or without food or drink.

Detailed instructions on how to inject Enbrel are provided in section 7, "Instructions for use."
Do not mix the Enbrel solution with any other medicine.

To help you remember, it may be helpful to write in a diary which day(s) of the week Enbrel should be used.

If you use more Enbrel than you should

If you have used more Enbrel than you should (either by injecting too much on a single occasion or by using it too frequently), talk to a doctor or pharmacist immediately. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to inject Enbrel

If you forget a dose, you should inject it as soon as you remember, unless the next scheduled dose is the next day; in which case you should skip the missed dose. Then continue to inject the medicine on the usual day(s). If you do not remember until the day that the next injection is due, do not take a double dose (two doses on the same day) to make up for a forgotten dose.

If you stop using Enbrel

Your symptoms may return upon discontinuation.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Allergic reactions

If any of the following happen, do not inject more Enbrel. Tell your doctor immediately, or go to the casualty department at your nearest hospital.

- Trouble swallowing or breathing
- Swelling of the face, throat, hands, or feet
- Feeling nervous or anxious, throbbing sensations, sudden reddening of the skin and/or a warm feeling
- Severe rash, itching, or hives (elevated patches of red or pale skin that often itch)

Serious allergic reactions are rare. However, any of the above symptoms may indicate an allergic reaction to Enbrel, so you should seek immediate medical attention.

Serious side effects

If you notice any of the following, you or the child may need urgent medical attention.

- Signs of **serious infections**, such as high fever that may be accompanied by cough, shortness of breath, chills, weakness, or a hot, red, tender, sore area on the skin or joints
- Signs of **blood disorders**, such as bleeding, bruising, or paleness
- Signs of **nerve disorders**, such as numbness or tingling, changes in vision, eye pain, or onset of weakness in an arm or leg
- Signs of **heart failure** or **worsening heart failure**, such as fatigue or shortness of breath with activity, swelling in the ankles, a feeling of fullness in the neck or abdomen, night-time shortness of breath or coughing, bluish colour of the nails or the lips
- **Signs of cancers:** Cancers may affect any part of the body including the skin and blood, and possible signs will depend on the type and location of the cancer. These signs may include weight loss, fever, swelling (with or without pain), persistent cough, presence of lumps or growths on the skin
- Signs of **autoimmune reactions** (where antibodies are made that may harm normal tissues in the body) such as pain, itching, weakness, and abnormal breathing, thinking, sensation, or vision
- Signs of lupus or lupus-like syndrome, such as weight changes, persistent rash, fever, joint or muscle pain, or fatigue
- Signs of **inflammation of the blood vessels** such as pain, fever, redness or warmth of the skin, or itching.

These are rare or uncommon side effects, but are serious conditions (some of which may rarely be fatal). If these signs occur, tell your doctor immediately, or visit the casualty department at your nearest hospital.

The known side effects of Enbrel include the following in groups of decreasing frequency:

- **Very common** (may affect more than 1 in 10 people):
  Infections (including colds, sinusitis, bronchitis, urinary tract infections and skin infections); injection site reactions (including bleeding, bruising, redness, itching, pain, and swelling) (these do not occur as often after the first month of treatment; some patients have developed a reaction at an injection site that was recently used); and headache.

- **Common** (may affect up to 1 in 10 people):
  Allergic reactions; fever; rash; itching; antibodies directed against normal tissue (autoantibody formation).

- **Uncommon** (may affect up to 1 in 100 people):

Serious infections (including pneumonia, deep skin infections, joint infections, blood infection, and infections at various sites); worsening of congestive heart failure; low red blood cell count, low white blood cell count, low neutrophil (a type of white blood cell) count; low blood platelet count; skin cancer (excluding melanoma); localised swelling of the skin (angioedema); hives (elevated patches of red or pale skin that often itch); eye inflammation; psoriasis (new or worsening); inflammation of the blood vessels affecting multiple organs; elevated liver blood tests (in patients also receiving methotrexate treatment, the frequency of elevated liver blood tests is common); abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems).

- **Rare** (may affect up to 1 in 1,000 people):
  Serious allergic reactions (including severe localised swelling of the skin and wheezing); lymphoma (a type of blood cancer); leukaemia (cancer affecting the blood and bone marrow); melanoma (a type of skin cancer); combined low platelet, red, and white blood cell count; 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); tuberculosis; new onset congestive heart failure; seizures; lupus or lupus-like syndrome (symptoms may include persistent rash, fever, joint pain, and tiredness); skin rash, which may lead to severe blistering and peeling of the skin; lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes); inflammation of the liver caused by the body's own immune system (autoimmune hepatitis; in patients also receiving methotrexate treatment, the frequency is uncommon); immune disorder that can affect the lungs, skin and lymph nodes (sarcoidosis); inflammation or scarring of the lungs (in patients also receiving methotrexate treatment, the frequency of inflammation or scarring of the lungs is uncommon); damage to the tiny filters inside your kidneys leading to poor kidney function (glomerulonephritis).

- **Very rare** (may affect up to 1 in 10,000 people): failure of the bone marrow to produce crucial blood cells.

- **Not known** (frequency cannot be estimated from the available data): Merkel cell carcinoma (a type of skin cancer); Kaposi’s sarcoma (a rare cancer related to infection with human herpes virus 8. Kaposi’s sarcoma most commonly appear as purple lesions on the skin); excessive activation of white blood cells associated with inflammation (macrophage activation syndrome); recurrence of hepatitis B (a liver infection); worsening of a condition called dermatomyositis (muscle inflammation and weakness with an accompanying skin rash).

Additional side effects in children and adolescents

The side effects and their frequencies seen in children and adolescents are similar to those described above.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Enbrel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pre-filled syringe after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2° – 8°C). Do not freeze.

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

After taking a syringe from the refrigerator, **wait approximately 15-30 minutes to allow the Enbrel solution in the syringe to reach room temperature**. Do not warm in any other way. Immediate use is then recommended.

Enbrel may be stored outside of the refrigerator at temperatures up to a maximum of 25°C for a single period of up to four weeks; after which, it should not be refrigerated again. Enbrel should be discarded if not used within four weeks after removal from the refrigerator. It is recommended that you record the date that Enbrel is removed from the refrigerator and the date after which Enbrel should be discarded (no more than 4 weeks following the removal from the refrigerator).

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Enbrel contains

Enbrel 25 mg solution for injection in pre-filled syringe
The active substance in Enbrel is etanercept. Each pre-filled syringe contains 0.5 ml of solution, providing 25 mg of etanercept.

Enbrel 50 mg solution for injection in pre-filled syringe
The active substance in Enbrel is etanercept. Each pre-filled syringe contains 1.0 ml of solution, providing 50 mg of etanercept.

The other ingredients are sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic dihydrate and sodium phosphate dibasic dihydrate, and water for injections.

What Enbrel looks like and contents of the pack

Enbrel 25 mg solution for injection in pre-filled syringe
Enbrel is supplied as a pre-filled syringe containing a clear, colourless to pale yellow or pale brown solution for injection (solution for injection). Each pack contains 4, 8, 12 or 24 pre-filled syringes and 4, 8, 12 or 24 alcohol swabs. Not all pack sizes may be marketed.

Enbrel 50 mg solution for injection in pre-filled syringe
Enbrel is supplied as a pre-filled syringe containing a clear, colourless to pale yellow or pale brown solution for injection (solution for injection). Each pack contains 2, 4 or 12 pre-filled syringes and 2, 4 or 12 alcohol swabs. Not all pack sizes may be marketed.

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7. Instructions for use

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.

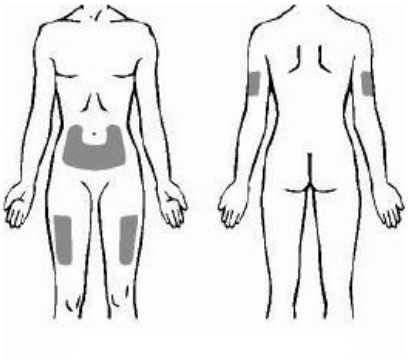
5. Wash your hands with soap and warm water.

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.

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").

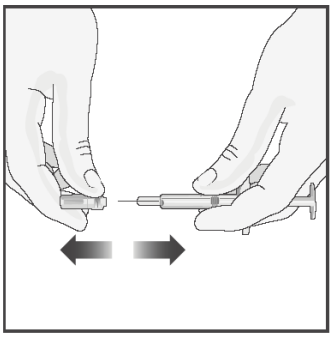
Step 3: Injecting the Enbrel solution

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.**

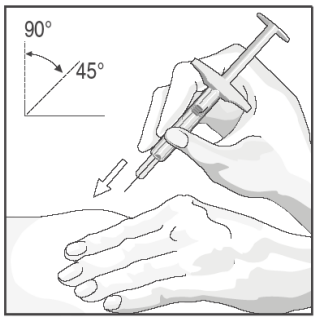
   When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. Do not touch the needle or allow it to touch any surface. Do not touch or bump the plunger. Doing so could cause the liquid to leak out.

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.

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.