

ANNEX III
PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Enbrel 25 mg/ml powder and solvent for solution for injection for paediatric use

Etanercept

Read all (both sides) of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a Patient Alert 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 or pharmacist.
- This medicine has been prescribed for a child in your care. Do not pass it on to others. It may harm them, even if their symptoms are the same as those of the child you are caring for.
- If you are concerned about any side effect, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

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. **Before you use Enbrel**
3. **How to use Enbrel**
4. **Possible side effects**
5. **How to store Enbrel**
6. **Further information**
7. **Instructions for preparing and giving an injection of Enbrel (See overleaf)**

1. WHAT ENBREL IS AND WHAT IT IS USED FOR

Etanercept, the active ingredient in Enbrel, is made from two human proteins. It blocks the activity of another protein in the body that causes inflammation. Etanercept works by reducing the inflammation associated with the disease that the child under your care has.

The child you are caring for has been prescribed Enbrel for the treatment of polyarticular juvenile idiopathic arthritis affecting many joints. Enbrel is for children and adolescents aged 4 years or over who have had an inadequate response to (or are unable to take) methotrexate.

Enbrel is not effective in the treatment of Wegener's granulomatosis, a rare inflammatory disease. If the child you are caring for has Wegener's granulomatosis talk to your doctor.

2. BEFORE YOU USE ENBREL

Do not use Enbrel

- **Allergy:** If the child you are caring for is allergic to etanercept or any of the other ingredients of Enbrel. If the child experiences allergic reactions such as chest tightness, wheezing, dizziness or rash, do not inject more Enbrel, and contact your doctor immediately.

- **Serious blood infection:** If the child has, or is at risk of developing, a serious blood infection called sepsis. If you are not sure, please contact your doctor.
- **Infections:** If the child has an infection of any kind. If you are unsure, please talk to your doctor.
- **Newborn babies:** In premature or newborn babies, because it contains benzyl alcohol.

Take special care with Enbrel

- **Infections/surgery:** If the child develops a new infection, or is about to have any major surgery, the doctor may wish to monitor the child's treatment with Enbrel.
- **Infections/diabetes:** Tell your doctor if the child has a history of recurrent infections, or suffers from diabetes or other conditions that increase the risk of infection.
- **Infections/monitoring:** Your doctor may decide to continue to monitor the child for the presence of infections after the child stops 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 Alert Card. It is very important that you tell your doctor if the child has ever had tuberculosis, or has 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:** Your doctor may decide to test for the presence of hepatitis B infection before the child begins treatment with Enbrel.
- **Hepatitis C:** Tell your doctor if the child has hepatitis C. Your doctor may wish to monitor the treatment with Enbrel in case the infection worsens.
- **Blood disorders:** Seek medical advice immediately if the child has 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 the child has 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 the child has a history of congestive heart failure, because Enbrel needs to be used with caution under these circumstances.
- **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 the child's doctor before the child receives any vaccines.
- **Chickenpox:** Tell your doctor if the child is exposed to chickenpox when using Enbrel. Your doctor will determine if preventative treatment for chickenpox is appropriate.
- **Babies and young children:** Enbrel contains the ingredient benzyl alcohol, which may cause toxic and allergic reactions in infants and children up to 3 years old. Enbrel must not be given to premature or newborn babies.

Using other medicines

Tell the doctor or pharmacist if the child is taking, or has recently taken any other medicines, even those not prescribed by the child's doctor. You or the child should not use Enbrel with medicines that contain the active ingredients anakinra or abatacept.

Taking Enbrel with food and drink

Enbrel can be taken with or without food or drink.

Pregnancy and breast-feeding

The effects of Enbrel in pregnant women are not known, and so the use of Enbrel during pregnancy is not recommended. People using Enbrel should not become pregnant. If the patient becomes pregnant, you should consult the patient's doctor.

People using Enbrel should not breast-feed, since it is not known if Enbrel passes into human breast milk.

Driving and using machines

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

Important information about some of the ingredients of Enbrel

Enbrel contains the ingredient benzyl alcohol, which may cause toxic and allergic reactions in infants and children up to 3 years old. Enbrel must not be given to premature or newborn babies.

3. HOW TO USE ENBREL

Dosing for children and adolescents (aged 4 to 17 years)

Always use Enbrel exactly as the doctor has told you. You should check with the doctor or pharmacist if you are not sure.

The appropriate dose for the child will vary depending on body weight. The doctor will provide detailed directions for preparing and measuring the appropriate dose for the child.

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

Method and route of administration

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

The powder must be dissolved before use. **Detailed instructions on how to prepare and inject Enbrel are provided in section 7, "INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF ENBREL"**. Do not mix the Enbrel solution with any other medicine.

To help you remember, it may be helpful to write in a diary which days 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 use 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

days. If you do not remember until the day that the next injection is due, do not give the child a double dose (2 doses on the same day) to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

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

Other side effects that are not listed in this leaflet may occur. If you are concerned about any side effect, or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

Allergic reactions

If any of the following happen to the child, do not give the child 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, or 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 uncommon. If the child has any of the above symptoms he/she may be having an allergic reaction to Enbrel, so you should seek immediate medical attention.

Serious side effects

If you notice any of the following, 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 child's 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 **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 child's nails or around the child's lips.

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 take the child to the casualty department at your nearest hospital.

Other side effects

The side effects and frequencies (likelihood of occurring) listed below are those that have been seen in adult patients. The side effects seen in children and adolescents are similar to those seen in adults.

- **Very common** (may occur in more than 1 in 10 patients): Infections (including colds, sinusitis, bronchitis, urinary tract infections and skin infections); injection site reactions (including bleeding,

bruising, redness, itching, pain, and swelling). Reactions at the injection site are very common but do not occur as often after the first month of treatment. Some patients have developed a reaction at an injection site that was used before.

- **Common** (may occur in less than 1 in 10, but more than 1 in 100 patients): allergic reactions; fever; itching; antibodies directed against normal tissue (autoantibody formation).
- **Uncommon** (may occur in less than 1 in 100, but more than 1 in 1,000 patients): serious infections (including pneumonia, deep skin infections, joint infections, blood infection, and infections at various sites); localized swelling of the skin (angioedema); low blood platelet count; hives (elevated patches of red or pale skin that often itch); psoriasis; rash; inflammation or scarring of the lungs.
- **Rare** (may occur in less than 1 in 1,000 patients): serious allergic reactions (including severe localized swelling of the skin and wheezing); combined low platelet, red, and white blood cell count; nervous system disorders (with signs and symptoms similar to those of multiple sclerosis or inflammation of the nerves of the eyes or spinal cord); tuberculosis; worsening congestive heart failure; seizures; lupus or lupus-like syndrome (symptoms may include persistent rash, fever, joint pain, and tiredness); inflammation of the blood vessels; low red blood cell count, low white blood cell count, low neutrophil (a type of white blood cell) count; elevated liver blood tests; skin rash which may lead to severe blistering and peeling of the skin.
- **Very rare** (may occur in less than 1 in 10,000 patients): failure of the bone marrow to produce crucial blood cells.
- **Not known:** excessive activation of white blood cells associated with inflammation (macrophage activation syndrome).

5. HOW TO STORE ENBREL

Keep out of the reach and sight of children.

Do not use Enbrel after the expiry date (EXP), which is stated on the carton.

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

After preparing the Enbrel solution, it may be stored upright in a refrigerator (2°C – 8°C) for up to 14 days.

If you are using a previously prepared Enbrel solution that has been stored in a refrigerator, wait 15 to 30 minutes to allow the Enbrel in the vial to reach room temperature before use. Do not warm Enbrel in any other way (for example, do not warm it in a microwave or in hot water).

Full instructions for storage between doses and re-use of the prepared solution are provided in subsections i and j of section 7, 'INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF ENBREL'

Do not use Enbrel if you notice the solution is not clear or contains particles. The solution should be clear, colourless or pale yellow, with no lumps or flakes or particles.

Each vial of Enbrel 25 mg/ml should be used for a maximum of 2 doses, administered to the same child. Both doses should be used within 14 days of preparing the Enbrel solution.

If there is insufficient Enbrel solution in the vial for the second dose, discard the vial and start again with a new tray.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Enbrel contains

The active ingredient in Enbrel is etanercept. Each vial of Enbrel 25 mg/ml contains 25 mg of etanercept. When reconstituted, the solution contains 25 mg/ml of etanercept.

The other ingredients are:

Powder: Mannitol, sucrose, and trometamol.

Solvent: Water for injections and benzyl alcohol.

What Enbrel looks like and contents of the pack

Enbrel is supplied as a white powder and solvent for solution for injection for paediatric use. Each pack contains 4 vials, 4 pre-filled syringes of solvent, 8 empty syringes, 20 needles and 24 alcohol swabs.

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This leaflet was last approved on {date}

Detailed information on this product is available on the website of the European Medicines Agency (EMA) <http://www.emea.europa.eu>

7. INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF ENBREL

This section is divided into the following sub-sections:

- a. **Introduction**
- b. **Setting up for an injection**
- c. **Preparing the Enbrel dose for injection**
- d. **Placing the needle on the syringe**
- e. **Adding solvent to the powder**
- f. **Withdrawing the Enbrel solution from the vial**
- g. **Choosing an injection site**
- h. **Preparing the injection site and injecting the Enbrel solution**
- i. **Storing the Enbrel solution between doses**
- j. **Withdrawing a second dose of Enbrel from a vial that was previously prepared**
- k. **Disposing of supplies**

a. **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 the child's doctor or his/her assistant on the technique of giving an injection and the amount to be given to the child. Do not attempt to give the child 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 or vial with any other medicine. . See section 5 for instructions on how to store Enbrel.

b. **Setting up for an injection**

- Wash your hands thoroughly.
- Select a clean, well-lit, flat working surface.
- Remove one Enbrel dosing tray from the refrigerator. Replace the other trays in the refrigerator.
- The dose tray should contain all the items needed for one dose. The contents of the tray are listed below. Use only the items listed. **DO NOT** use any other syringe.

1 Vial containing Enbrel powder

1 pre-filled syringe containing clear, colourless solvent

2 Empty syringes

5 Needles

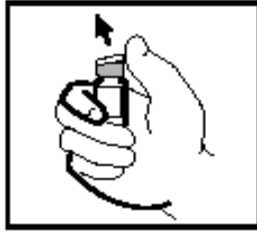
6 Alcohol swabs

- If any of the items listed above are missing, do not use the dose tray, but consult your pharmacist.
- Inspect the expiry dates on both the vial label and the syringe label. They should not be used after the month and year shown.

c. **Preparing the Enbrel dose for injection**

- Remove the Enbrel vial from the tray
- Remove the pink plastic cap from the Enbrel vial. **Do NOT** remove the grey stopper or aluminium ring around the top of the vial (see Diagram 1).

Diagram 1.

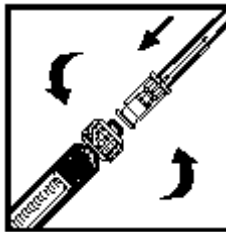


- Use a new alcohol swab to clean the grey stopper on the Enbrel vial. After cleaning, do not touch the stopper with your hands or allow it to touch any surface.
- Place the vial upright on a clean, flat surface.
- Unscrew the cap from the syringe containing the solvent taking care not to touch the tip of the syringe or allowing it to touch any surface.

d. Placing the needle on the syringe

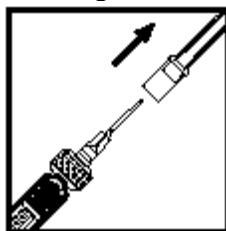
- Remove one of the needles from the tray. The needle has been placed in a plastic container to keep it sterile. To open the plastic container, hold the short, wide end in one hand. Place your other hand on the longer portion of the container.
- To break the seal, bend the longer end down and then up until broken.
- Once the seal is broken, remove the short, wide end of the plastic container.
- The needle will remain in the long part of the package.
- While holding the needle and container in one hand, pick up the syringe and insert the syringe tip into the needle.
- Attach the syringe to the needle by turning the syringe clockwise until completely secured (see Diagram 2).

Diagram 2.



- . Remove the needle cover by firmly pulling it straight off the syringe taking care not to touch the needle or allow the needle to touch any surfaces (see Diagram 3). Be careful not to bend or twist the cover during removal to avoid damage to the needle.

Diagram 3.



e. **Adding solvent to the powder**

- With the vial upright on a flat surface, such as a table, insert the syringe needle straight down through the centre ring of the grey stopper on the vial (see Diagram 4). If the needle is correctly lined up, you should feel a slight resistance and then a "pop" as the needle goes through the centre of the stopper. Look for the needle tip inside the stopper window (see Diagram 5). If the needle is not correctly lined up, you will feel constant resistance as it goes through the stopper and no "pop". **DO NOT** insert the needle at an angle, this may cause the needle to bend and/or prevent proper addition of the solvent into the vial (see Diagram 6).

Diagram 4.

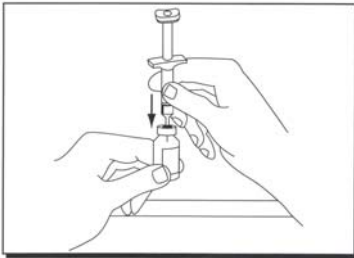


Diagram 5.

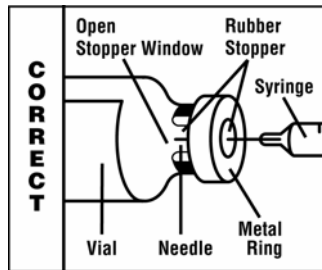
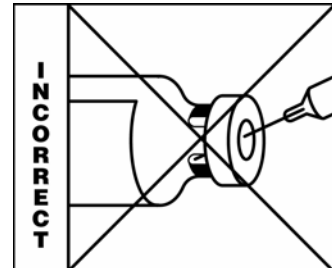
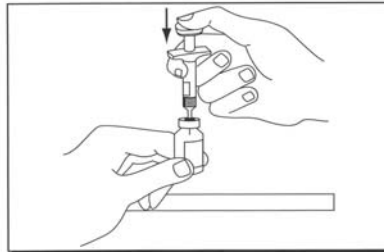


Diagram 6.



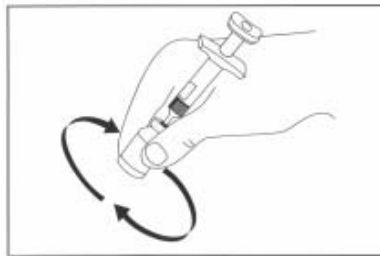
- Push the plunger in **VERY SLOWLY** until all the solvent is in the vial. This will help reduce foaming (lots of bubbles) (see Diagram 7).

Diagram 7.



- Leave the syringe in place. Gently move the vial in circles a few times, to dissolve the powder. **DO NOT** shake the vial (see Diagram 8). Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear and colourless to pale yellow, with no lumps, flakes, or particles. Some white foam may remain in the vial – this is normal. **DO NOT** use Enbrel if all the powder in the vial is not dissolved within 10 minutes. Start again with another dose tray.

Diagram 8.

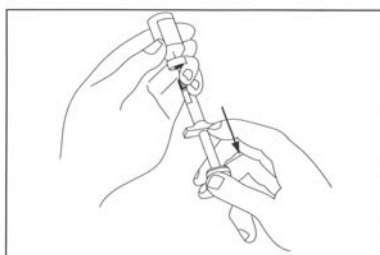


- Remove the solvent syringe and needle from the vial and discard them.

f. Withdrawing the Enbrel solution from the vial

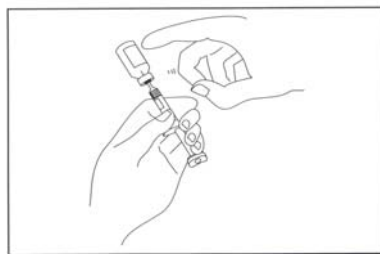
- The doctor or his/her assistant should have instructed you on the proper amount of solution to be withdrawn from the vial. If the doctor has not given this instruction, please contact him/her.
- Take one of the empty syringes from the tray and remove the plastic wrap. Take care not to let anything touch the tip of the syringe.
- Take a new needle from the tray and attach it to the empty syringe in the same way as for the solvent syringe (see **d. Placing the needle on the syringe**).
- With the Enbrel vial on a flat surface, insert the syringe needle straight down through the centre ring of the grey stopper. If the needle is correctly lined up, you should feel a slight resistance and then a "pop" as the needle goes through the centre of the stopper. Look for the needle tip inside the stopper window. If the needle is not correctly lined up, you will feel constant resistance as it goes through the stopper and no "pop". Do not insert the needle at an angle, this may cause the needle to bend and/or prevent proper withdrawal of the solution from the vial.
- With the needle still in the vial, hold the vial upside down at eye level. Slowly pull the plunger back to draw the liquid into the syringe (see Diagram 9).

Diagram 9.



- As the liquid level drops in the vial, you may need to withdraw the needle partially to keep the tip of the needle in the liquid.
- With the needle still inserted in the vial, check the syringe for air bubbles. Gently tap the syringe to make any bubbles rise to the top of the syringe, near the needle (see Diagram 10). Slowly press the plunger to push bubbles out of the syringe and into the vial. When you do this, if you accidentally push liquid back into the vial, slowly pull the plunger to draw the liquid back into the syringe.

Diagram 10.

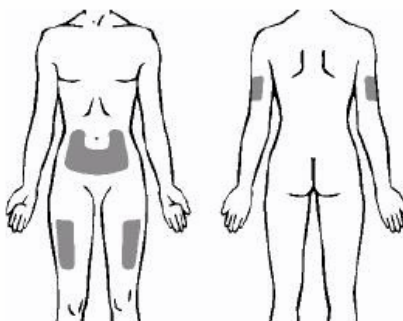


- Slide the needle out of the vial. If you notice that you have withdrawn too much solution, do not re-insert the needle once it has been removed from the vial. If there is too much solution in the syringe, hold the syringe with the needle pointing upwards at eye level and push the plunger in gently until the syringe contains the proper amount of liquid. Remove and discard the needle.
- Take a new needle from the tray and attach it to the syringe as described above (see **d. Placing the needle on the syringe**). This will be the needle you use to inject Enbrel.

g. Choosing an injection site

- 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 11). If the child is self injecting, the outer area of the upper arms should not be used.

Diagram 11.

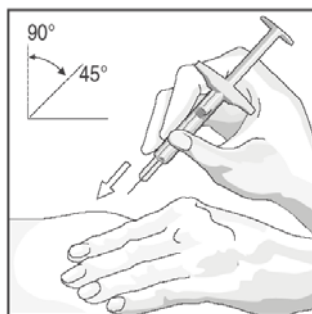


- A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site. Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks. (It may be helpful to keep notes on the location of the previous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

h. Preparing the injection site and injecting the Enbrel solution

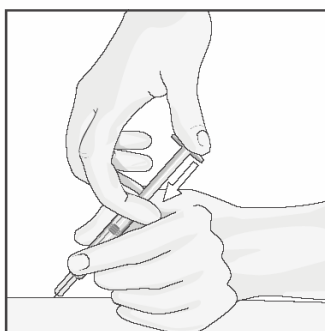
- Wipe the site where Enbrel is to be injected with an alcohol swab, using a circular motion. **DO NOT** touch this area again before giving the injection.
- When the cleaned area of skin has dried, pinch and hold it firmly with one hand. With the other hand, hold the syringe like a pencil.
- With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (see Diagram 12). With experience, you will find the angle that is most comfortable for the child. Be careful not to push the needle into the skin too slowly, or with great force.

Diagram 12



- 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 13).

Diagram 13.



- When the syringe is empty, remove the needle from the skin; being careful to keep it at the same angle it was when it was inserted.
 - Press a cotton ball over the injection site for 10 seconds. Slight bleeding may occur. **Do NOT** rub the injection site. A bandage is optional.
- i. Storing the Enbrel solution between doses**
- If the doctor has told you that you can withdraw two doses from one vial of Enbrel, you must store the solution in a refrigerator (2°C – 8°C) between the first and second doses. The vial should be stored upright in the refrigerator between doses.
 - Each vial of Enbrel 25 mg/ml should be used for a maximum of 2 doses, administered to the same child.
- j. Withdrawing a second dose of Enbrel from a vial that was previously prepared**
- Remove the Enbrel solution from the refrigerator. Wait 15 to 30 minutes to allow the Enbrel in the vial to reach room temperature. Do not warm Enbrel in any other way (for example, do not warm it in a microwave or in hot water).
 - Use a new alcohol swab to clean the grey stopper on the Enbrel vial. After cleaning, do not touch the stopper with your hands or allow it to touch any surface.
 - To prepare the second dose of Enbrel from the vial, start with the instructions under **f. ‘Withdrawing the Enbrel solution from the vial’** using the other empty syringe, needles and swabs from the tray.

- If there is insufficient Enbrel solution in the vial for your next dose, discard the vial and start again with a new tray.
- After you have withdrawn the second dose of Enbrel from the vial, discard the vial (even if some liquid remains).

k. Disposing of supplies

- The syringe and needle should **NEVER** be re-used. **Never** recap 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.