

## 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**

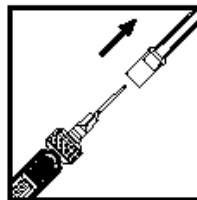
- Remove one of the needles from the tray. The needle has been placed in a plastic container to keep it sterile. To open the plastic container, hold the short, wide end in one hand. Place your other hand on the longer portion of the container.
- To break the seal, bend the longer end down and then up 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.

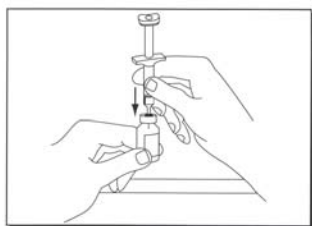


Diagram 5.

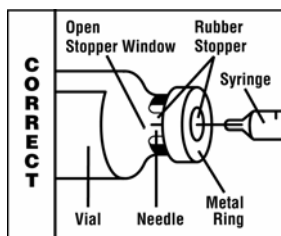
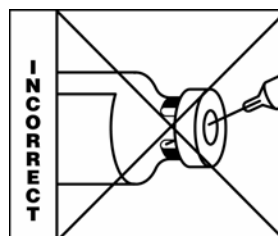
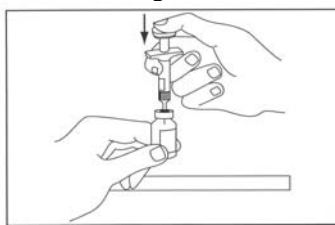


Diagram 6.



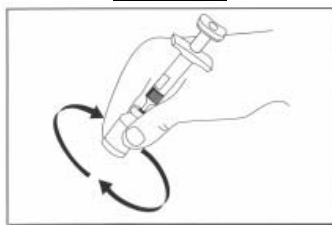
- Push the plunger in **VERY SLOWLY** until all the solvent is in the vial. This will help reduce foaming (lots of bubbles) (see Diagram 7).

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.

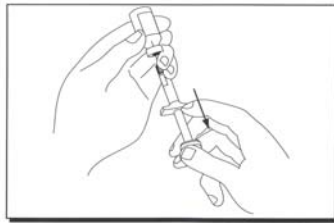


- Remove the solvent syringe and needle from the vial and discard them.

**f. Withdrawing the Enbrel solution from the vial**

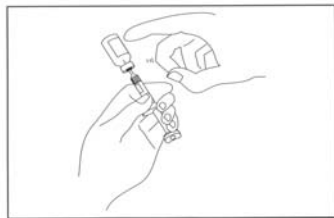
- The doctor or his/her assistant should have instructed you on the proper amount of solution to be withdrawn from the vial. If the doctor has not given this instruction, please contact him/her.
- Take one of the empty syringes from the tray and remove the plastic wrap. Take care not to let anything 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.

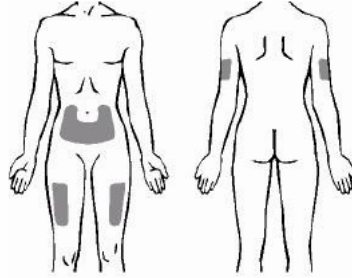


- Slide the needle out of the vial. If you notice that you have withdrawn too much solution, do not re-insert the needle once it has been removed from the vial. If there is too much solution in the syringe, hold the syringe with the needle pointing upwards at eye level and push the plunger in gently 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.

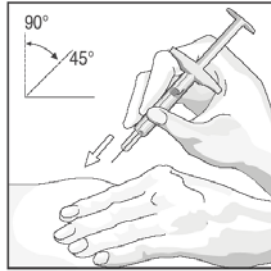


- A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site. Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks. (It may be helpful to keep notes on the location of the previous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

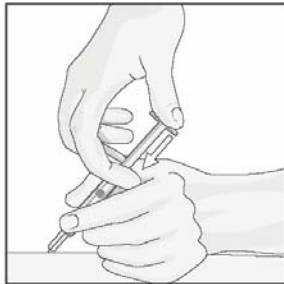
- Wipe the site where Enbrel is to be injected with an alcohol swab, using a circular motion. **DO NOT** touch this area again before giving the injection.
- When the cleaned area of skin has dried, pinch and hold it firmly with one hand. With the other hand, hold the syringe like a pencil.
- With a 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.**