

INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF ENBREL POWDER

Introduction

The following instructions explain how to prepare and inject Enbrel powder for injection. 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 or giving an injection to your child. Do not attempt to self-inject or give your child an injection until you are sure that you understand how to prepare and give the injection.

This injection should not be mixed with any other medicine.

Setting up for an injection

- Wash your hands thoroughly.
- Select a clean, well-lit, flat working surface.
- Before beginning the injection procedure, first examine the components of the dose tray to make sure they are complete and the packaging of individual components is not damaged. If the packaging is damaged, do not use the medicine and consult your pharmacist.
- The dose tray should contain the items listed below. (If not, do not use the medicine and consult your pharmacist.) Use only the items listed. **DO NOT** use any other syringe.

1 Enbrel vial

1 Sterile pre-filled syringe containing clear, colourless solvent (water for injections)

1 Sterile needle

1 Sterile vial adaptor

2 Alcohol swabs



- Inspect the expiry dates on both the vial label and the syringe label. They should not be used after the month and year shown.

Preparing the Enbrel dose for injection

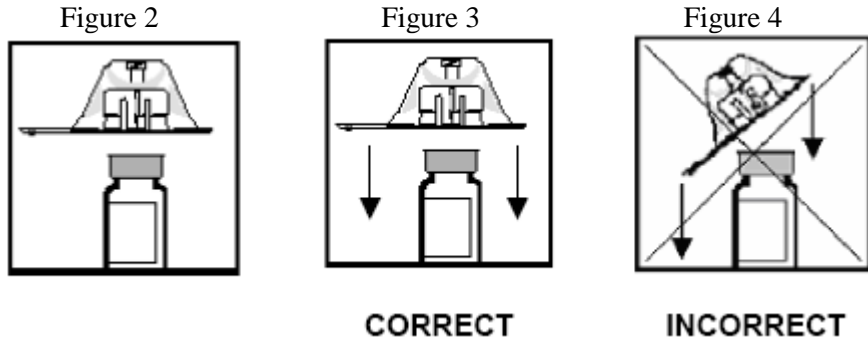
- Remove the contents of the tray.
- Remove the plastic cap from the Enbrel vial (Figure 1). **DO NOT** remove the grey stopper or aluminium ring around the top of the vial.

Figure 1

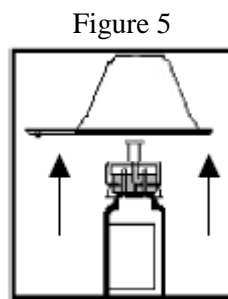


- Use a new alcohol swab to clean the grey stopper on the Enbrel vial. After cleaning, do not touch the stopper with your hands or allow it to touch any surface.
- Place the vial upright on a clean, flat surface.
- Remove the paper backing from the vial adaptor package, taking care not to touch the underside.
- While still in the plastic package, place the vial adaptor on top of the Enbrel vial so that the vial adaptor spike is centred within the raised circle on top of the vial stopper (Figure 2).
- Hold the vial firmly on a flat surface with one hand. With the other hand push **STRAIGHT DOWN FIRMLY** on the adaptor package until you feel the adaptor spike penetrate the vial stopper and **FEEL AND HEAR THE ADAPTOR RIM LOCK INTO PLACE** (Figure 3). **DO NOT** push down the

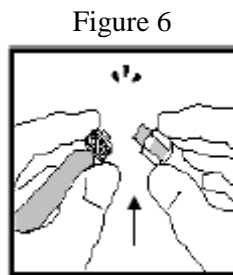
adaptor at an angle (Figure 4). It is important that the vial adaptor completely penetrates the vial stopper.



- While holding the vial in one hand, remove the plastic packaging from the vial adaptor (Figure 5).

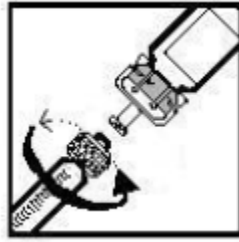


- Remove the protective rubber cover from the syringe tip by breaking the cap along the perforation. This is done by holding the barrel of the syringe while grasping the end of the white cap with the other hand and bending it down and then up until it is broken (Figure 6). **DO NOT** remove the white collar that remains on the syringe.



- Do not use the syringe if this perforation is already broken. Start again with another dose tray.
- Holding the glass barrel of the syringe (not the white collar) in one hand and the vial adaptor (not the vial) in the other, connect the syringe to the vial adaptor by inserting the tip into the opening and turn clockwise until completely secured (Figure 7).

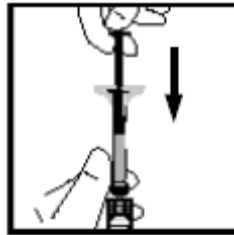
Figure 7



Adding solvent

- While holding the vial upright on the flat surface, push the plunger **VERY SLOWLY** until all the solvent is in the vial. This will help to reduce foaming (lots of bubbles) (Figure 8).

Figure 8



- Once the solvent is added to the Enbrel, the plunger may move up by itself. This is due to air pressure and should not be of concern.
- With the syringe still attached, gently move the vial in circles a few times (Figure 9), to dissolve the powder. **DO NOT** shake the vial. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear to slightly milky and colourless to slightly yellow or pale brown. 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. If you are concerned with the appearance of the solution, contact your doctor, nurse or pharmacist for assistance.

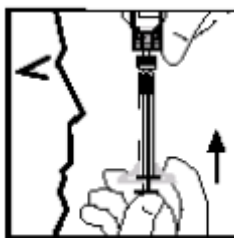
Figure 9



Withdrawing the Enbrel solution from the vial

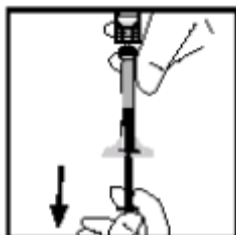
- With the syringe still attached to the vial and vial adaptor, hold the vial upside down at eye level. Push the plunger all the way into the syringe (Figure 10).

Figure 10



- Then, slowly pull the plunger back to draw the liquid into the syringe (Figure 11). For adult patients, unless directed otherwise by your doctor, withdraw the entire volume. For children, remove only the portion of liquid as directed by your child's doctor.

Figure 11



After you have withdrawn the Enbrel solution from the vial, you may have some air in the syringe. Do not be concerned as you will remove the air in a later step.

If you are giving Enbrel to a child (age 2 to 17 years), the amount of Enbrel solution given is based on the child's weight. After emptying the pre-filled syringe into the vial of Enbrel, draw up the correct amount of Enbrel solution. The dosing table below tells you how much Enbrel solution to draw up and inject, using a 25 mg vial of Enbrel. The syringe is clearly graduated to ensure the correct volume is withdrawn from the vial. For doses above 1 mL, a second vial of Enbrel will need to be used, and so 2 injections will be given at the same time.

Child's weight	Volume of Enbrel to inject (25 mg vial)	
	Once weekly dosing	
15 kg	0.48 mL	
20 kg	0.64 mL	
30 kg	0.96 mL	
40 kg	1.28 mL	1 mL from first vial and 0.28 mL from second vial
50 kg	1.6 mL	1 mL from first vial and 0.6 mL from second vial
60 kg	1.92 mL	1 mL from first vial and 0.92 mL from second vial

- With the vial held upside down, unscrew the syringe from the vial adaptor by turning it anti-clockwise (Figure 12).

Figure 12



- Place the filled syringe on the clean, flat surface. Make sure the tip does not touch anything. Be careful not to push down on the plunger.

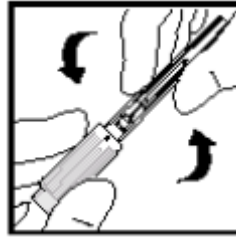
(Note: After you have completed these steps, a small amount of liquid may remain in the vial. This is normal.)

Placing the needle on the syringe

- 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 larger end down and then up until broken (Figure 13).

Figure 13



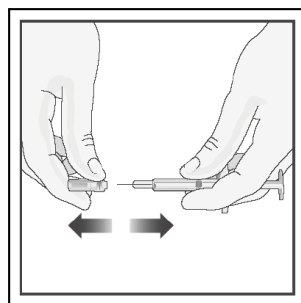
- Once the seal has been broken, remove the short, wide end of the plastic container. The needle will remain in the long part of the package.
- While holding the needle and container in one hand, pick up the syringe and insert the syringe tip into the needle opening.
- Attach the syringe to the needle by turning it clockwise until completely secured (Figure 14).

Figure 14



- Remove the needle cover by firmly pulling it straight off the syringe. (Figure 15). The needle cap should be pulled off using a single, straight motion. If the needle cap is twisted or snapped off, the cap may damage the needle tip. This may blunt or bend the needle and can also damage the surface lubrication, which may contribute to pain on insertion.

Figure 15



- While holding the syringe upright, remove any air bubbles by slowly pushing on the plunger until the air is removed (Figure 16).

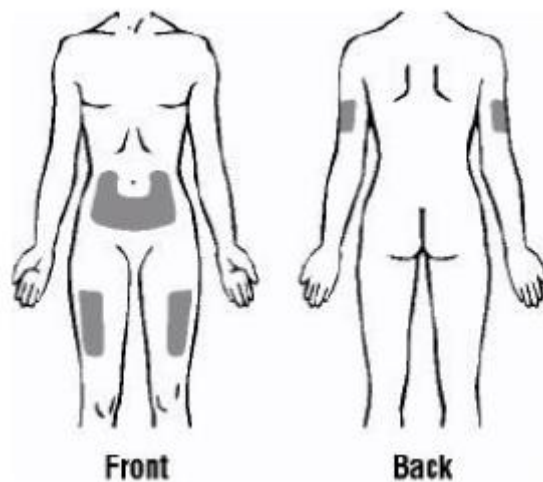
Figure 16



Choosing an injection site

- 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. If you are self-injecting, you should not use the outer area of the upper arms (Figure 17).

Figure 17

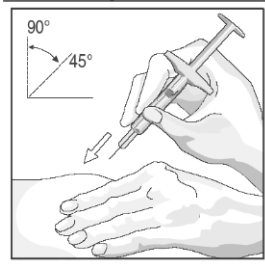


- A different site should be used for each new injection. Each new injection should be given at least 3 cm from an old site. **DO NOT** inject into areas where the skin is tender, bruised, red, or hard. (It may be helpful to keep a note of the location of the previous injections.)
- If you or the child have psoriasis, you should try not to inject directly into any raised, thick, red, or scaly skin patches (“psoriasis skin lesions”).

Preparing the injection site and injecting the Enbrel solution

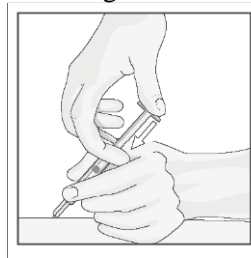
- Wipe the site where Enbrel is to be injected with an alcohol swab, using a circular motion. **DO NOT** touch this area before giving the injection.
- When the cleaned area of skin has dried, gently pinch the sides of the cleaned area of skin with one hand and hold it firmly. With the other hand, hold the syringe like a pencil at an angle between 45 and 90 degrees with the bevel of the needle facing away from the skin. A 90-degree angle may minimise discomfort unless you have little fat beneath the skin. Be careful not to touch the cleaned area (Figure 18).

Figure 18



- With a quick, short motion, push the needle all the way into the skin.
- With your free hand, slowly push the plunger to inject solution (Figure 19). After the needle is completely inserted into the skin, let go of the skin. With your free hand, hold the syringe near its base to stabilise it. Then slowly push the plunger at a steady rate to inject all of the solution.

Figure 19



- 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.
- 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.

Disposing of supplies

The syringe and needles should **NEVER** be reused. Dispose of the needles and syringe as instructed by your doctor, nurse or pharmacist.

Any questions you may have should be handled by a doctor, nurse or pharmacist familiar with Enbrel.