Country: Singapore

Reference document: CDS version 43 Effective date 13 April 2018

Reason for change: to align with LPD update due to CMC change in CDS version 43

INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF ENBREL (POWDER AND SOLVENT FOR INJECTION)

This section is divided into the following subsections:

- a. Introduction
- b. Setting up for an injection
- c. Preparing the ENBREL dose for injection
- d. Adding solvent
- e. Withdrawing the ENBREL solution from the vial
- f. Placing the needle on the syringe
- g. Choosing an injection site
- h. Injecting the ENBREL solution
- i. 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 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.

This injection should not be mixed with any other medicine.

b. Setting Up For An Injection

- Wash your hands thoroughly.
- Select a clean well-lit, flat working surface.
- The dose tray should contain the items listed below. (If not, don't use the dose tray and consult your pharmacist). Use only the items listed. DO NOT use any other syringe.
 - 1 ENBREL vial
 - 1 Pre-filled syringe containing clear, colorless solvent (water for injections)
 - 1 Needle
 - 1 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.

c. Preparing the ENBREL Dose For Injection

- Remove the contents of the tray
- Remove the plastic cap from the ENBREL vial (see <u>Diagram 1</u>). DO NOT remove the gray stopper or aluminum ring around the top of the vial.

Diagram 1.



ENB-SIN-0918/PIL/0

Country: Singapore

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- Use a new alcohol swab to clean the gray 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.
- While still in the plastic package, place the vial adaptor on top of the ENBREL vial so that the vial adaptor spike is centered within the raised circle on top of the vial stopper (see Diagram 2).
- Hold the vial firmly on the 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 (see <u>Diagram 3</u>). DO NOT push down the adaptor at an angle (see <u>Diagram 4</u>). It is important that the vial adaptor spike completely penetrates the vial stopper.

Diagram 2.

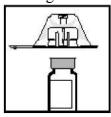


Diagram 3.

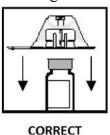
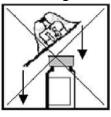


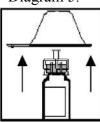
Diagram 4.



INCORRECT

• While still holding the vial in one hand, remove the plastic packaging from the vial adaptor (see <u>Diagram 5</u>).

Diagram 5.



• Remove the protective rubber cover from the syringe tip by breaking the white 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 (see Diagram 6). DO NOT remove the white collar that remains on the syringe.

Diagram 6.



• Do not use the syringe if this perforation is already broken. Start again with another dose tray.

Country: Singapore

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• 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 (see <u>Diagram 7</u>).

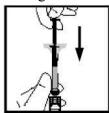
Diagram 7.



d. 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) (see Diagram 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.

Diagram 8.



• With the syringe still attached, gently move the vial in circles a few times, to dissolve the powder (see <u>Diagram 9</u>). DO NOT shake the vial. Wait until all the powder dissolves (usually less than 10 minutes). The solution should be clear to slightly opalescent and colorless to slightly yellow or pale brown. DO NOT use ENBREL if all the powder in the vial is not dissolved within 10 minutes. Start again with another dose tray.

Diagram 9.



Country: Singapore

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e. 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 (see Diagram 10).

Diagram 10.



• Then, slowly pull the plunger back to draw the liquid into the syringe (see <u>Diagram 11</u>). Unless otherwise instructed by your physician, withdraw the entire volume. For children, remove only the portion of liquid as directed by your child's doctor. After you have withdrawn the ENBREL 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.

Diagram 11.



• With the vial held upside down, unscrew the syringe from the vial adaptor by turning it anti-clockwise (see <u>Diagram 12</u>).

Diagram 12.



• Place the filled syringe on the clean, flat surface. Make sure that 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.)

f. Placing the Needle on the Syringe

• The needle has been placed in a plastic container to keep it sterile.

ENB-SIN-0918/PIL/0

Country: Singapore

Reference document: CDS version 43 Effective date 13 April 2018

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- 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 (see Diagram 13).

Diagram 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 (see <u>Diagram 14</u>).

Diagram 14.



• Remove the needle cover by firmly pulling it straight off the syringe (see <u>Diagram 15</u>). Be careful not to bend or twist the cover during removal to avoid damage to the needle.

Diagram 15.



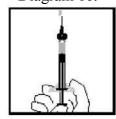
• While holding the syringe upright, remove any air bubbles by slowly pushing on the plunger until the air is removed (see <u>Diagram 16</u>).

Country: Singapore

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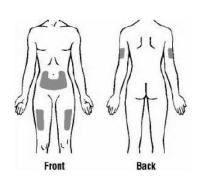
Diagram 16.



g. 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 (see <u>Diagram 17</u>). If you are self injecting, you should not use the outer area of the upper arms.

Diagram 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 notes on 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").

h. 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, gently pinch the sides of the cleaned area of skin with one hand and hold firmly. With the other hand, hold the syringe like a pencil. Be careful not to touch the cleaned area. (see Diagram 18).

Diagram 18.

Country: Singapore

Reference document: CDS version 43 Effective date 13 April 2018

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- With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (see <u>Diagram 18</u>). With experience, you will find the angle that is most comfortable for you. Be careful not to push the needle into the skin too slowly, or with great force.
- 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 stabilize it. Then push the plunger to inject all of the solution at a slow, steady rate (see <u>Diagram 19</u>).

Diagram 19.



• 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.

i. 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.
- If you have any questions, please talk to a doctor, nurse or pharmacist who is familiar with ENBREL.

ENB-SIN-0918/PIL/0

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