Country: Singapore

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

INSTRUCTIONS FOR USING THE MYCLIC PRE-FILLED PEN TO INJECT ENBREL

This section is divided into the following subsections:

Introduction

Step 1: Preparing for an Enbrel injection

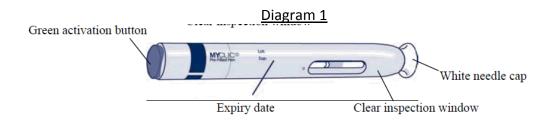
Step 2: Choosing an injection site

Step 3: Injecting the Enbrel solution

Step 4: Disposing of the used MYCLIC pen

Introduction

The instructions below explain how to use the MYCLIC pen to inject Enbrel. Please read the instructions carefully, and follow them step by step. Your doctor or nurse will tell you how to inject Enbrel. Do not attempt to administer an injection until you are sure that you understand how to use the MYCLIC pen properly. If you have questions about how to inject, please ask your doctor or nurse for help.



Step 1: Preparing for an Enbrel injection

- 1. Select a clean, well-lit, flat surface.
- 2. Gather the items that you will need for your injection, and place them on the chosen surface:
 - a. **One MYCLIC pre-filled pen and one alcohol swab** (take these from the carton of pens you keep in your refrigerator). Do not shake the pen.
 - b. One cotton ball or gauze
- 3. Check the expiry date (month/year) on the pen. If the date has passed, do not use the pen and contact your pharmacist for assistance.
- 4. Inspect the solution in the pen by looking through the clear inspection window. Only inject the solution in the pen if it is clear to opalescent, colourless to yellow or pale brown, and free from easily visible particles. If it is not, use a different syringe, then contact your pharmacist for assistance.
- 5. Leave the white needle cap in place and wait approximately 15-30 minutes to allow the Enbrel solution in the pen to reach room temperature. Waiting until the solution reaches room temperature may make the injection more comfortable for you. Do not warm in any other way. Always leave the pen out of sight and reach of children.

Whilst waiting for the solution in the pen to reach room temperature, read Step 2 (below), and choose an injection site.

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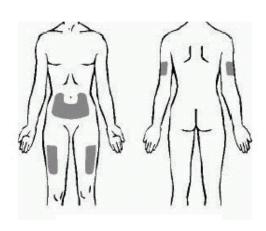
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Step 2: Choosing an injection site (see Diagram 2)

1. The recommended injection site is the middle of the front of the thighs. If you prefer, you may alternatively use the stomach area, but make sure you choose a site at least 5 cm away from the belly button (navel). If someone else is giving you the injection, the outer area of the upper arms may also be used.

Diagram 2



- 2. Each injection should be given at least 3 cm from where you last injected. Do not inject into tender, bruised or hard skin. Avoid scars or stretch marks. (It may be helpful to keep notes on the location of the previous injections.)
- 3. If you have psoriasis, you should try not to inject directly into any raised, thick, red, or scaly skin.

Step 3: Injecting the Enbrel solution

- 1. After waiting approximately 15-30 minutes for the solution in the pen to warm to room temperature, wash your hands with soap and water.
- 2. Clean the injection site with the alcohol swab using a circular motion, and allow it to dry. Do not touch this area again before injecting.
- 3. Pick up the pen, and remove the white needle cap by pulling it straight off (see Diagram 3). To avoid damaging the needle inside the pen, do not bend the white needle cap while you are removing it, and do not re-attach it once it has been removed. After removal of the needle cap, you will see a purple needle safety shield extending slightly from the end of the pen. The needle will remain protected inside the pen until the pen is activated. Do not use the pen if it is dropped with the needle cap off.

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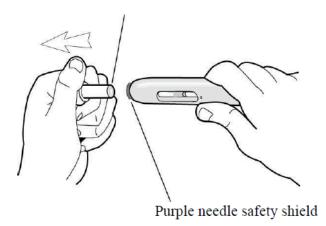
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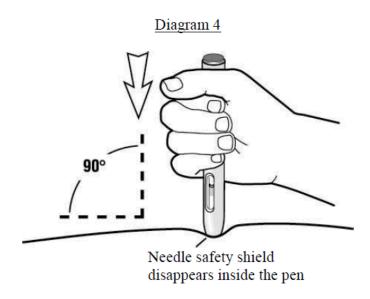
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Diagram 3

White needle cap



- 4. Lightly pinching the skin around the injection site between the thumb and index finger of your free hand may make the injection easier and more comfortable.
- 5. Hold the pen at a right angle (90°) to the injection site. Push the open end of the pen firmly against the skin, so that the needle safety shield is pushed completely inside of the pen. A slight depression in the skin will be seen (see Diagram 4). The pen can only be activated when the needle shield is completely pushed inside the pen.



6. Whilst pushing the pen firmly against the skin to ensure that the needle safety shield is fully depressed inside the pen, press **the centre of the green button** on top of the pen with your thumb to start the injection (see Diagram 5). On pressing the centre of the button, you will hear a click.

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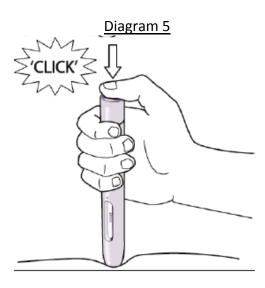
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Continue to hold the pen firmly against your skin until you hear a second click, or until 10 seconds after the first click (whichever happens first).

Note – If you are unable to start the injection as described, press the pen more firmly against your skin, then press the green button again.



7. On hearing the second 'click' (or, if you do not hear a second 'click', after 10 seconds have passed), your injection will be complete (see Diagram 6). You may now lift the pen from your skin (see Diagram 7). As you lift the pen, the purple needle safety shield will automatically extend to cover the needle.

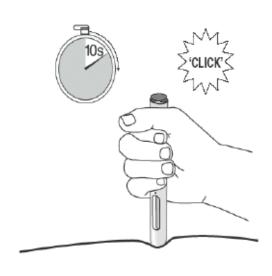
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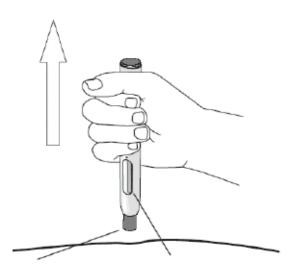
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Diagram 6

Diagram 7

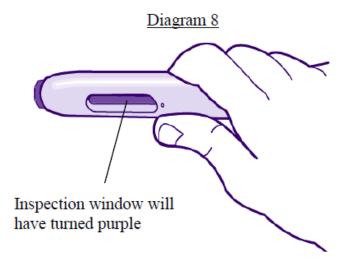




Purple needle safety shield extends to cover needle

Inspection window will have turned purple

8. The pen's inspection window should now be completely purple, confirming that the dose has been injected correctly (see Diagram 8). If the window is not completely purple, contact your nurse or pharmacist for assistance, since the pen may not have injected the Enbrel solution completely. Do not try to use the pen again, and do not try to use another pen without agreement from your nurse or pharmacist.



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9. If you notice a spot of blood at the injection site, you should press the cotton ball or gauze over the injection site for 10 seconds. Do not rub the injection site.

Step 4: Disposing of the used MYCLIC pen

• The pen should be used once only - it should never be re-used. Dispose of the used pen as instructed by your doctor, nurse or pharmacist. Do not attempt to recap the pen.

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

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